Raad voor Accreditatie (Dutch Accreditation Council RvA)

Implementation of ISO/IEC 17021-1:2015

Document code:	**RvA-T032-UK**
	Version 5, 13 februari 2017

A 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 en 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

On 15 June 2015 the standard ISO/IEC 17021-1:2015 “Conformity assessment – requirements for bodies providing audit and certification of management systems” has been published. This standard replaces the standard ISO/IEC 17021:2011 with the identical title.

The International Accreditation Forum (IAF) has set a 2-year transition term for the transition from the ISO/IEC 17021:2011 to the ISO/IEC 17021-1:2015, in other words up to 15 June 2017.

The changes include new requirements, changes of texts of ISO/IEC 17021:2011 to otherwise formulated requirements as well as exclude (remove) requirements from ISO/IEC 17021:2011 in the ISO/IEC 17021-1:2015.

This explanatory document describes the RvA policy and practices concerning the assessments against the ISO/IEC 17021-1:2015, taking decisions for accreditation against this new standard and the replacement of the declaration of accreditation and the scope of accreditation.

This explanatory document applies to all accreditations for all schemes previously accredited against ISO/IEC 17021:2011.

2. Transition to ISO/IEC 17021-1:2015

2.1 General

The RvA assessments against the new standard will be performed as much as possible during the regular assessments. The RvA has defined the transitional provisions for the implementation of ISO/IEC 17021-1:2015 as follows:

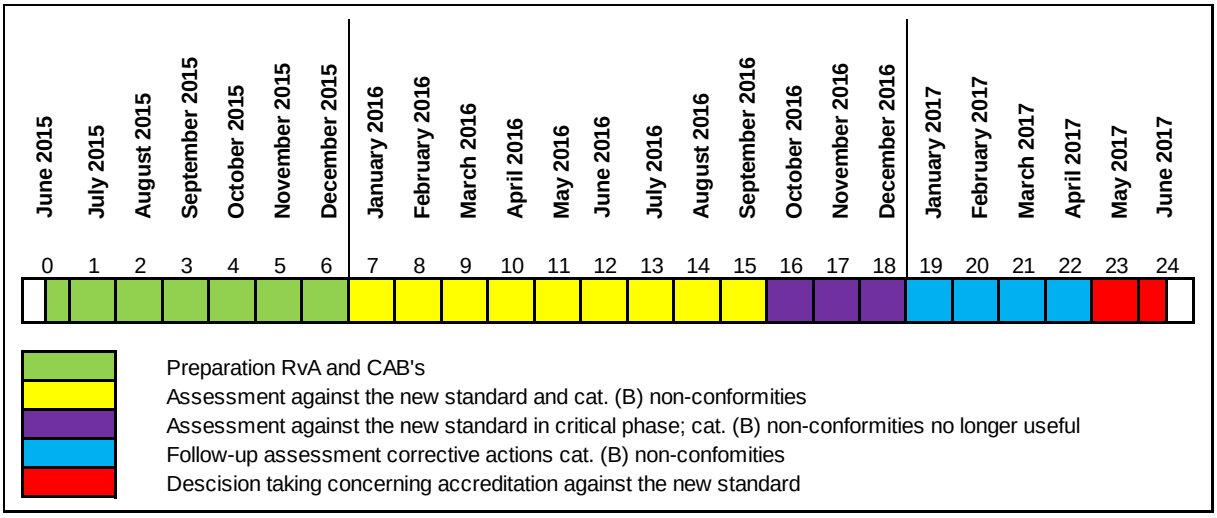
New applications for accreditation:
For new accreditations the new standard ISO/IEC 17021-1:2015 will be used from 1 January 2016;

Existing accreditations:

1. Annex A contains the comparison between the ISO/IEC 17021:2011 and the ISO/IEC 17021-1:2015. The most important new or changed requirements in the ISO/IEC 17021-1:2015 have been mentioned explicitly.
2. As from 1 January 2016 during regular assessments the RvA will assess against the requirements from ISO/IEC 17021-1:2015. Section 2.2 contains details about the method of assessing.
3. For nonconformities raised against the new or changed requirements of the new standard that are identified during assessments in the period from 1 January 2016 until 1 October 2016 and which would not have been nonconformities against ISO/IEC 17021:2011, special provisions for corrective actions apply. These special provisions are described in section 2.4 of this explanatory document.

4. The RvA shall issue a new declaration of accreditation and scope of accreditation after it has determined that the ISO/IEC 17021-1:2015 requirements are met, and a positive decision has been taken (see section 2.4 of this explanatory document).
5. If this decision has not been taken before 15 June 2017, the existing accreditation against ISO/IEC 17021:2011 will be withdrawn.
6. For situations deviating from the above described situations, the RvA Executive Board will determine the procedure.

The timeline for the transitions is schematically shown in the figure below:



2.2 RvA assessment of the transition to ISO/IEC 17021-1:2015

The implementation of the new and changed requirements will be assessed by the RvA as follows:

- With an document review in preparation of and during the transition assessments the RvA assessment team will verify whether or not the new and changed requirements have been adequately integrated in the documented management system;
  To this end, and prior to the assessment, the accredited organisation will make available to the RvA assessment team, a cross reference list of the in Annex A mentioned clauses and their documented management system;
- The RvA expects that the accredited organisation has carried out an internal audit and management review regarding the new and changed requirements and will verify these during the assessment.
- Based on document review, interviews and observations of activities, the assessment team will verify the implementation.

2.3 Non-conformities against new requirements

Any nonconformities, which would not have been nonconformities against the ISO/IEC 17021:2011, identified during assessments in the period from 1 January 2016 until 1 October 2016 will be categorised as cat. (B).
Annex A of this explanatory document specifies against which requirements a cat. (B) nonconformity can be formulated. The certification body has the opportunity to introduce corrective actions prior to 1 January 2017, and report this to the RvA (refer to RvA-BR004). RvA will conduct the follow-up assessment to verify these actions and the assessment team will advise the RvA Executive Board at the latest on 1 May 2017. The RvA Executive Board will take a decision granting accreditation for ISO/IEC 17021-1:2015 before 15 June 2017.
If the RvA has not been able to take a positive decision regarding granting accreditation for ISO/IEC 17021-1:2015, as a result of non-closure of nonconformities, the accreditation against ISO/IEC 17021:2011 will be withdrawn per 15 June 2017.

2.4 Declaration of accreditation

The declaration of accreditation (including the scope annex) will be adjusted to make accreditation against ISO/IEC 17021-1:2015 visible, after an assessment against the new standard has been completed successfully and a decision on accreditation has been taken. The accreditation number for existing accreditations will remain unchanged.

The date of the declaration of accreditation will be the date of the decision on accreditation to the new standard.
The date of the first accreditation for the granted accreditation(s) against a previous version of the ISO/IEC 17021-1:2015 will also be mentioned on the new accreditation certificates. The expiration date for the new accreditation will be copied from the previous declaration of accreditation.

If an existing declaration of accreditation or scope annex need to be replaced during the transition period, but no positive decision has been taken on granting accreditation against ISO/IEC 17021-1:2015, the new declaration or scope annex shall include an expiration date not later than the end date of the transition period.

3. Changes compared to the previous version

Changes in this version compared to version 4:

- title of annex A;
- clarification in the text of article 9.4.8.2 of annex A.

Annex A: Summary of most important technical changes

This annex gives an overview of the most important changes in the normative document for which clauses the RvA can identify nonconformities cat. (B).

Clause	Change
5.2.3	The standard's text now explicitly demands a process to identify, analyse, evaluate, treat, monitor, and document the risks related to conflict of interests and impartiality. In the 2011 version this was "automatically" covered by the commission of independency, however this shall be treated in a different way now. Partly the requirements have been tightened, partly clarified.
6.1.3	The top management shall now develop "processes and procedures" (a) and ensure impartiality (c). These are partly new requirements, but no new concept. However, procedures and processes have to be determined explicitly.
6.2.1	Compared to IAF MD12 a tightened requirement: The certification body shall have a process for the effective control of certification activities delivered by branch offices, partnerships, agents, franchisees, etc., irrespective of their legal status, relationship or geographical location.
6.2.2	The certification body shall consider the appropriate level and method of control of activities undertaken including its processes, technical areas of certification bodies' operations, competence of personnel, lines of management control, reporting and remote access to operations including records.
7.2.10	• Its explicitly demanded that the certification body shall monitor each auditor considering each type of management system to which the auditor is deemed competent. • The documented monitoring process for auditors shall include a combination of on-site evaluation, review of audit reports and feedback from clients or from the market.
8.1	Different approach of "publicly accessible information" ; now this is in line with ISO/IEC 17024. • Make public, without request, information about; – audit processes; – conditions for granting certification; – types of management systems to be certified; – the use of the certification body's name and logo; – processes for complaints and appeals; – policy on impartiality. • Shall provide, upon request, information about: – geographical areas in which it operates; – the status of a given certification; – the name, related normative document, scope and geographical location (city and country) for a specific certified client. A publicly accessible directory of certified clients is no longer a requirement.
8.2.2.b	It is now possible (under conditions) to maintain the original certification date, even if this means that for a period there will be no valid certificate. Note: The certification body can keep the original certification date on the certificate when a certificate lapses for a period of time provided that: — the current certification cycle start and expiry date are clearly indicated; — the last certification cycle expiry date be indicated along with the date of recertification audit.
8.2.2.f	The scope of certification shall mention the type of activities, products and services as applicable at each site without being misleading or ambiguous;
8.3.3	– A CAB shall have rules governing the use of any statement on product packaging or in accompanying information that the certified client has a certified management system. – The statement shall in no way imply that the product, process or service is certified by this means. – The statement shall include reference to the certified client, the type of management system (name and standard) and the CAB body issuing the certificate.

Clause	Change
9.1.3.4	Requirements with respect to the use of results from other CAB's: – sufficient verifiable evidence shall be obtained and retained; – the CAB shall justify and record any adjustments to the existing audit programme based on this information; – the CAB shall follow up the implementation of corrective actions concerning previous nonconformities
9.1.3.5	Where the client operates shifts, the activities that take place during shift working shall be considered when developing the audit programme and audit plans.
9.2.2.2.2	The role of technical experts during an audit activity shall be agreed to by the certification body and client prior to the conduct of the audit. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor.
9.3.1.2.1	Planning shall ensure that the objectives of stage 1 can be met and the client shall be informed of any "on site" activities during stage 1.
9.3.1.2.4	– If due to areas of concern identified during stage 1 any significant changes which would impact the management system occur, the certification body shall consider the need to repeat all or part of stage 1. – The client shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.
9.4.1	Where any part of the audit is made by electronic means or where the site to be audited is virtual, the certification body shall ensure that such activities are conducted by personnel with appropriate competence. The evidence obtained during such an audit shall be sufficient to enable the auditor to take an informed decision on the conformity of the requirement in question.
9.4.8.2	In this clause 18 subjects are explicitly mentioned, which shall be included in the audit report or be referred to. New in this list of subjects are: – any deviation from the audit plan and their reasons (g); – any significant issues impacting on the audit programme (h); – significant changes, if any, that affect the management system of the client since the last audit took place (l); – a disclaimer statement indicating that auditing is based on a sampling process of the available information (o); – recommendation from the audit team (p); – the audited client is effectively controlling the use of the certification documents and marks, if applicable (q); – verification of effectiveness of taken corrective actions regarding previously identified nonconformities, if applicable (r).
9.4.8.3	New requirement: The report shall also contain: – a statement on the conformity and the effectiveness of the management system together with a summary of the evidence relating to: • the capability of the management system to meet applicable requirements and expected outcomes; • the internal audit and management review process; – a conclusion on the appropriateness of the certification scope; – confirmation that the audit objectives have been fulfilled.
9.5.1.1	The individual(s) appointed to conduct the certification decision shall have appropriate competence.
9.5.1.2	The person(s) (excluding members of committees) assigned by the certification body to make a certification decision shall be employed by, or shall be under legally enforceable arrangement with either the certification body or an entity under the organizational control of the certification body.
9.5.1.3	The persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements as persons employed by, or under contract with, the certification body.
9.5.1.4	The certification decision including any additional information or clarification sought from the audit team or other sources shall be recorded.
9.5.2	The certification body shall have a process to conduct an effective review prior to making a certification decision.

Clause	Change
9.5.3.2	If the certification body is not able to verify the implementation of corrections and corrective actions of any major (refer to 3.12) nonconformity within 6 months after the last day of stage 2, the certification body shall conduct another stage 2 prior to recommending certification.
9.6.3.1.2	The recertification activity shall include the review of previous surveillance audit reports.
9.7.5	The certification body receiving the appeal shall be responsible for gathering and verifying all necessary information to validate the appeal.
9.8.1	The certification body shall be responsible for all decisions at all levels of the complaints handling process.
9.8.2	Submission, investigation and decision on complaints shall not result in any discriminatory actions against the complainant.
9.9.2	Added to the list of items to be included in records on certified clients: – justification of the methodology used for sampling of sites, as appropriate (c); – audit programmes (k).
9.9.4	Records of certified clients and previously certified clients shall be retained for the duration of the current cycle plus one full certification cycle.
10.2.5.2	Added as input for the management review: – the status of actions to address risks (e).
10.2.5.3	Added as output for the management review: – revisions of the organization's policy and objectives (d).
Annex A	Competence requirements in Annex A have been revised and brought into line with ISO/IEC 17021-2 to 7; in the table a content reference is made to the new articles A.2 to A.4 for filling in. Articles A.2 to A.4 have been added. In these articles specific knowledge subjects and skills are described.