Raad voor Accreditatie (Dutch Accreditation Council RvA)

Specific Accreditation Protocol for Accreditation of Certification of Management Systems

(general, based on EN ISO/IEC 17021-1)

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A Specific Accreditation Protocol (SAP) describes the assessment service for a specific accreditation. It should be read in conjunction with the generic RvA regulations and policy documents.
A current version of the SAP is available through the website of the RvA. (www.rva.nl).

Content

1 Relevant documents

1.1 Accreditation standard

EN ISO/IEC 17021, Conformity assessment - Requirements for bodies providing audit and certification of management systems.

1.2 Additional standards

A number of additional standards have been drawn up for EN ISO/IEC 17021-1 (for example ISO/IEC 17021-2, -3, etc.). These are not cited in this general Specific Accreditation Protocol (SAP) because they specifically belong to a defined scheme (EMS, QMS, etc.). These are (will) therefore (be) referred to in the SAPs for those schemes. In addition, there are other normative documents that specify additional requirements in a similar or broader way for the use of EN ISO/IEC 17021-1 for specific schemes, such as ISO 50003 (for EnMS), ISO/TS 22003 (for FSMS) and ISO 27006 (for ISMS) for example. These documents will also be cited or explained further in the relevant SAPs (also see Annex A).

1.3 Additional documents

EN ISO/IEC 17021-1:

- RvA-T033; Explanation of the requirements for Conformity Assessment Schemes;
- RvA-T040; Shadow assessments;
- RvA-T043; Accreditation of notified bodies on the basis of European directives/regulations;
- IAF MD 1; Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization (also see Annex C);
- IAF MD 2; Transfer of Accredited Certification of Management Systems;
- IAF MD 3; Advanced Surveillance and Recertification Procedures (ASRP);
- IAF MD 4; The Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes;
- IAF MD 5; Determination of audit time of quality and environmental management systems
- IAF MD 9: Application of ISO/IEC 17021 in the Field of Medical Device Quality Management Systems (ISO 13485);
- IAF MD 11; IAF Mandatory Document for the Application of ISO/IEC 17021 for Audits of Integrated Management Systems;
- IAF MD 22; Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS);
- IAF MD23; Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies;
- IAF ID1; QMS and EMS Scopes of Accreditation;
- IAF ID3; Management of Extraordinary Events or Circumstances affecting ABs, CBs and Certified Organizations.

The current version of these documents can be obtained from the website of the relevant organisation: IAF (www.iaf.nu), RvA (www.rva.nl).

The following additional remarks can be made with regard to the scope of EA and IAF documents:

- Some documents have a specific scope within one type of management system, for example IAF MD9, MD13 or EA-7/04. This is stated clearly in the title and/or the scope of the document, and the guidelines are therefore only applicable to that scheme. These will be cited as extra in the SAP of that scheme.
- Various other documents have been developed for QMS and EMS certification, however, they can be used more widely. This is then described in the document's introductory statement. The RvA must therefore apply these documents to all certification schemes covered by EN ISO/IEC 17021-1.
- A number of other documents are written in principle for one or two schemes (for example IAF MD5), the basic principles however, provided they are not related directly to a scheme, can be used more widely. For example, the tables in this guideline are specific to QMS and EMS, however the basic principles (1.1 up to and including 1.9, 2 up to and including 7, 8.i and 8.iv, 9 up to and including 11) are also applicable to other schemes unless this is specified differently in those other schemes (as in ISO 50003 or ISO/TS 22003 for example).

1.4 Additional documents (indirectly applicable)

EA and IAF have adopted various guidelines that contain requirements for the RvA and its assessments (and which are therefore also important for the certification body). For example, this applies to:

- IAF MD 8: Application of ISO/IEC 17011: 2004 in the Field of Medical Device Quality Management Systems (ISO 13485);
- IAF MD 10; Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011;
- IAF MD 12; Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries;
- IAF MD 15: Collection of Data to Provide Indicators of Management System Certification Bodies' Performance;
- IAF MD 16: Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies;
- IAF MD 17; Witnessing Activities for the Accreditation of Management System Certification Bodies.

The guidelines that concern specific schemes (IAF MD8 and MD16) are incorporated in the relevant SAPs (C021 and C001 respectively). The IAF MD10 regulations are not recorded specifically in RvA's procedural or assessment documents, but are used during training and for harmonisation meetings involving the RvA assessors for EN ISO/IEC 17021-1. RvA-BR007 sets out the policy rules with regard to conducting assessments of certification bodies with cross-frontier activities (IAF MD12) and RvA-BR005 sets out the policy rules with regard to surveillances and reassessments. The requirements of IAF MD15 are incorporated in the system of reporting (Part A). Witness assessments are to be conducted in accordance with the generic regulations of IAF MD17. Specific regulations for selection, frequency and quantities shall be recorded in the specific SAPs, as will any clustering of technical areas in order to give direction to this.

1.5 Documents related to the conformity assessments to be carried out

Not applicable; linked to specific schemes.

1.6 Specific requirements from legislation and regulations

If applicable, these are linked to specific schemes. The RvA has set out in RvA-T033 how schemes are to be assessed against requirements arising under legislation and regulations.

2 Scope of accreditation

The generic rules for defining scopes have been defined by the RvA in RvA Policy rule RvA-BR003. Within the various schemes the scopes (technical sectors) shall be stated for which technical areas (technical sectors) the accreditation is valid. In principle this shall be related to the IAF codes from IAF ID1 (potentially linked to a NACE code, for examle to indicate limitations in scope), unless alternative arrangements have been made for this in the scheme or internationally.

3 Accreditation assessments

3.1 Documents to be submitted

For the RvA assessments, the assessors must be provided with relevant documents as stated on the relevant application form and/or in the annex to RvA-BR005.
A SAP can require additional specific documents/registrations from the client or the certification body(CB).

3.2 The nature and content of the assessments

In addition to the generic regulations for the nature and content of RvA assessments as defined in RvA-BR002 and RvA-BR005, for this accreditation the requirements from the following table apply. The type and size of the assessment depend on the requested scope of accreditation, other accreditations possibly existing and the functioning of the CB in the past (where relevant).

Assessment method	Initial assessment	Regular assessments during the accreditation cycle [1]	Scope extension[2]
Document assessment	√		√
On-site assessment	Random sample: at least 1 certification and personnel file[3] per cluster[4]) per scheme.	Annual for 17021-1 Per scheme: at least once per cycle. Random sample: at least 1 certification and personnel file per cluster per scheme per accreditation cycle.	Random sample: at least 1 certification and personnel file per cluster.
	Total number of certification files to be inspected: see Annex B, unless the random sample above specifies a larger number. Any higher frequencies of on-site assessments will be specified further in a specific SAP.		
Witness assessment[5]	√	√	√

(1) An accreditation cycle refers to a period of four years, starting after a decision concerning an initial assessment or reassessment has been taken; the cycle includes therefor the surveillance assessments and the reassessment in this period
(2) On the basis of the request (Form RvA-F105) the RvA shall determine how the assessment of the extension is to be conducted.
(3) An assessment of certification or personnel files will take between 1 and 2 hours.
(4) The clusters are specified per scheme in a SAP
(5) See also 3.2.3.

3.2.1 Initial assessments and extension of scope

During the initial assessment, the implementation of the policies and procedures of the CB are assessed at their office (or offices, where applicable).

The application of IAF MD documents shall be verified where applicable.

The Chairman of the Committee safeguarding impartiality (or representative for any other mechanism chosen to safeguard impartiality) shall be interviewed or a meeting of this Committee shall be witnessed. This happens in consultation between the RvA Lead Assessor and the CB

3.2.2 Surveillances and reassessments

The application of IAF-MD1 (multisite), IAF-MD3 (ASRP) and IAF-MD4 (CAAT) will be assessed at least once during the accreditation cycle, if applicable.

The functioning of the impartiality Committee of the CB (or other mechanism) will be assessed in depth at least once during the accreditation cycle. The RvA Lead Assessor determines the method, that may consist of an interview (e.g. in person or by phone), with a non-CB representative of this Committee, or by witnessing (a part of) one of their meetings.

3.2.3 Witness assessments

For witnessed assessments, the following generic rules apply:

- If related to an initial accreditation or an extension of an accreditation a witness assessment has to be carried out, the preliminary assessment may demonstrate that essential requirements are not met. In that case the witness assessment will not be carried out till the applicable non-conformities of the preliminary assessment have been removed. This, among others, will be the case with non-conformities regarding the competence management or the system of audit time calculation.
- Normally, the full on-site audit will be witnessed, unless objectives for a particular activity can be satisfied with partial witnessing (e.g. in the case of multi-person or multi-day audits). In principle, opening and closing meetings are always witnessed.
- In case an audit cannot be witnessed completely, the RvA reserves the right to carry out additional investigations, whereby the activities carried out by the CB are verified by means of discussing the results of the activities with the person(s) who carried out the activities. Almost the same information that was available to the person(s) who carried out the activities therewith has to be available.
- For an initial accreditation, RvA shall per scheme witness both stage 1 and stage 2 audits, for at least one of the CB's clients. Prior to witnessing the stage 2 of the same audit, the applicant CB shall submit the completed report and / or conclusions from the stage 1 audit to RvA's assessment team. If the CB does not have any new clients, it is possible to witness one renewal or two surveillances which cover the key processes.
- In principle, some of the witness assessments (at least 1 per cycle, never more than 50%) will be replaced by a shadow assessment afterwards (see RvA-T040).
- The assessment of the audit report is part of the witnessing of the audit. This audit report must be sent to the RvA within ten working days after the audit.

Besides the abovementioned considerations for selection of audits to be witnessed, RvA will *consider* the following:

- The RvA will normally not witness the same auditors that have been witnessed in the same scheme before;
- The RvA will normally not witness an audit at the same organization;
- If possible, during an accreditation cycle at least one third (with a minimum of 1) of the audits to be witnessed should be initial or recertification audits.

Witnessing of audits also includes the review of the audit report.

To be able to select the audits to be witnessed, the CB shall on request of the RvA provide a planning for the audits to be conducted in a certain period. The information on these audits shall include as a minimum:

- type of audit (initial, recertification or surveillance);
- name and address of auditee;
- audit standard(s);
- scope of certification;
- name(s) of auditors(s) and expert(s);

- date(s) of the audit.

For further specifications, see the SAP's per scheme.

4 Specific issues for the RvA assessment

In addition to the system aspects (complaints/appeals, internal audits and management review), which will always be reviewed, for an EN ISO/IEC 17021-1 assessment the following topics/processes will also always be assessed:

- management of impartiality (can be omitted in the event of limited extension without new impartiality risks; the lead assessor will state this in the assessment plan);
- the result of the consultation process with "suitable interested parties" (in the case of initial or extension) (EN ISO/IEC 17021-1; 5.2.3);
- management of competency;
- certification process.

In addition, a part vertical assessment will be conducted annually by reviewing the practical implementation of a number of personnel and certification dossiers.

5 Changes with regard to the previous version

In comparison with version 4, dated November 2018, the following significant changes have been made in this document:

- paragraph 1.3, added: IAF MD23;
- paragraph 1.3, updated: Title of IAF MD4, RvA-T033 and RvA-T043;
- Appendix A, updated: SAP C006, referring to ISO 45001;
- Appendix A, added: SAP C025;
- condition related to performing witness assessments during an initial assessment or an extension of the accreditation added to 3.2.3;
- possibility for additional investigations added to 3.2.3, in case of incomplete witnessing of audits.

Annex A: Applicability of SAPs to certification schemes:

SAP-ID	Title:	Applicable to:
C001	Certification of food safety management systems	All certification schemes for food safety *management* systems, such as FSSC 22000, ISO 22000, Dutch HACCP for example, but excluding IFS or BRC for example.
C002	Certification of IT Service management systems based on ISO/IEC 20000-1	Only for IT service management systems in accordance with ISO/IEC 20000-1
C004	Certification of Quality Management Systems in accordance with ISO 9001	All certification schemes for quality management systems for which an ISO 9001 certificate is (also) issued (therefore including the Foundation for the Harmonisation of Quality Assessment in the Health Care Sector (HKZ) for example.
C005	Certification of Environmental Management Systems in accordance with ISO 14001	All EMS certification schemes based on ISO 14001 (therefore also including the Foundation for Coordination of Certification of Environmental Management Systems (SCCM) scheme).
C006	Certification of Occupational health and safety management systems (OH&SMS) in accordance with BS OHSAS 18001 and ISO 45001	All certification schemes for occupational health and safety management systems (incl. SCCM).
C007	VCA / VCU (Contractor Safety Checklist / Secondment Organisation Safety Checklist)	Only applicable to certification schemes of the Central Board of Experts /Foundation for Cooperation for Safety (CCvD SSVV) for VCA and VCU.
C009	HKZ (Foundation for the Harmonisation of Quality Assessment in the Health Care Sector) and NEN-EN 15224-certification	Only applicable to the Foundation for the Harmonisation of Quality Assessment in the Health Care Sector (HKZ) certification schemes and NEN-EN 15224 certification in accordance with NTA 8224 of scheme manager NEN Kwaliteit Zorg en Welzijn (NEN Care and Welfare Quality) (as a supplement to C004)).
C010	ISMS certification based on ISO/IEC 27000	Only applicable to ISMS certification scheme ISO/IEC 27001
C013	Verification and validation in accordance with the EMAS Regulation	Only applicable to EMAS verification and validation. NB: also applicable to bodies accredited abroad who wish to operate in the Netherlands.
C015	Certification of Energy Management Systems	Applicable to all schemes whereby an EnMS certificate is issued in accordance with ISO 50001.
C020	CO_2 Performance Ladder	Applicable to the CO_2 Performance Ladder schemes of scheme manager the Foundation for Climate Friendly Procurement and Business (SKAO).
C021	Certification in accordance with ISO/IEC 13485 (medical devices)	Applicable to certification schemes for quality management systems for medical devices in accordance with ISO/IEC 13485.
C023	Certification of Asset Management Systems in accordance with ISO 55001	Applicable only to the Asset Management certification scheme in accordance with ISO 55001.
C025	Certification of management systems for information security in healthcare in accordance with NEN 7510-1 (NL)	Applicable only to the ISMS certification scheme for Healthcare in accordance with NEN 7510-1

Annex B: Table for determining the sample size for certification dossier assessment

The total number of certification dossiers, that should be assessed during assessments is determined by the number of valid certificates under RvA accreditation, and is determined by the formula: one fifth of the square root of the number of valid certificates under accreditation with a maximum of 15 dossiers:

Number accredited certification dossiers	< 25	< 100	< 225	< 400	< 625	< 900	<1225	<1600
Number dossiers to be assessed	1	2	3	4	5	6	7	8

Number accredited certification dossiers	<2000	<2500	<3000	<3600	<4200	<4900	<5600	>5600
Number dossiers to be assessed	9	10	11	12	13	14	15	15

The number of valid certificates under RvA accreditation is determined as defined by IAF MD15.
For an initial assessment or scope extension the guideline is the number of certificates issued up to that point (with regard to which it can be reasonably expected that they will be issued under accreditation in due course). For surveillance assessments these quantities apply across the accreditation cycle.

Annex C: Transition arrangement regarding IAF MD1:2018

On 29 January 2018 IAF published a revision of IAF MD1; IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization.
At first no significant changes compared with the previous version were noted in the new version. Thereafter the RvA and the Dutch Association for Certification bodies NVCi however observed an impact which had not been anticipated at first. This concerns the last paragraph of section 1, Scope, which reads:

"This document shall not be used for situations where independent organizations are collected together by another independent organization (e.g. consulting company or an artificial organization) under the umbrella of a single management system."

Also because of a number of other changes, the RvA came to the conclusion that the previous version of MD1 has been applied in situations for which it was not intended to be used. The rational for this conclusion is based on the following:

- The use of the phrase "independent organizations are collected together" implies the assumption that when the situation occurs where organizations that were not dependent before the centralised management system was established, the document does not apply. Although one could argue that the umbrella of the single management system makes the organization dependent, the RvA considers that the dependency should already exists before the umbrella was established.
- Also the RvA assumes that the other "consulting company or an artificial organization", that serves as the umbrella, was an independent organization before the single management system to collect the organizations was established.
- The new version of MD1 introduces new and modified definitions that emphasize that the multi-site organization is an organization which has more in common than a management system. The change in definition of 'Organization' (2.1) indicates that the organization shall have responsibilities and authorities to achieve its objectives. In the old definition the emphasise was on owning a management system.
- In the new version the concepts of 'top management' and 'operational control' are introduced and it is explained that the so-called 'central function' exercises operational control and authority from the top management of the organization.
- MD1:2018; 5.2 states that the central function shall not be subcontracted to an external organization.

Based on the above, the RvA concludes that IAF has changed the document to explain that it shall only be applied in situation where an organization has sites that are not independent organizations and have top management that exercise operational control, and in addition to this have a single management system. So it should not only be because of the management system that the organizations are considered to be dependent.

The RvA recognises that situations may have been complying with the 2007 version, but do not comply with the 2018 version. For these situations the RvA will apply a period of transition of maximum three years, starting 1 August 2018, which should enable CBs to correct the contract at the first re-certification after 1 August 2018. New contracts and re-certifications after 1 August 2018 will not be allowed to conflict with the new version and the explanation above.