Raad voor Accreditatie (Dutch Accreditation Council RvA)

Specific Accreditation Protocol (SAP) for Accreditation of Certification of Products (general)

Document code:	**RvA-SAP-C008-UK**
	Version 4, 25-9-2018

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 from the website of the RvA. (www.rva.nl).

Contents

1. Relevant documents

1.1 Accreditation standard

- EN ISO/IEC 17065; Conformity Assessment – Requirements for bodies certifying products, processes and services

1.2 Additional documents

- 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
- EA-6/02; EA Guidelines on the Use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834
- EA-6/04; EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites

The current version of these documents can be downloaded from the website of the relevant organisation: EA (www.european-accreditation.org) and RvA (www.rva.nl).

1.3 Documents related to conformity assessments to be carried out

The Conformity Assessment Body (CAB) uses a certification scheme for (each group of) products, processes or services. The name of the certification scheme is stated in the scope.

The method of conformity assessment must be specified in accordance with the terminology from EN ISO/IEC 17065:2012; 6.2.1./6.2.2:

- testing
- inspection
- audit

The requirements against which a product, process or service is certified are included in regulatory documents.

The following documents provide information about product certification (schemes):

- ISO/IEC TR 17026: Example of a certification scheme for tangible products;
- ISO/IEC TR 17028: Guidelines and Examples of a certification scheme for services;
- ISO/IEC 17067: Fundamentals of product certification and guidelines for product certification schemes.

1.4 Specific requirements from legislation and regulations

Linked to specific schemes, if applicable. The RvA has set out in RvA-BR012 and RvA-T033 how the assessments of schemes involving requirements from legislation and regulations are handled.

If schemes are based on Dutch or European legislations and regulations then the name of the relevant legislation or regulation is included in a subheading on the scope. See the scope examples in the SAPs for the various European Directives.

2. Scope of accreditation

The general rules for defining scopes are set out by the RvA in policy rule RvA-BR003. The scope is formulated as follows specifically for product certification.

Product / product group	Certification scheme	Standard / normative document
(Group of) products, processes or services specification.	*The name of the certification scheme.* *The method(s) of conformity assessment must be specified in accordance with EN ISO/IEC 17065:2012 6.2.1./6.2.2. Including the statement testing, inspection or audit.*	*Specification of the regulatory documents which contain requirements against which the product, process or service is to be assessed.*
Product example: Alarm products	Example: Alarm product certification scheme Initial assessment: • Product test (testing) • Initial inspection of production control (inspection) Periodic surveillance: • Product test (testing) • Initial inspection of production control (inspection)	Example: EN 123, EN 456, EN 789
Process example: Fusion welding of metals	Example: Quality requirements for fusion welding of metals Initial assessment: • process inspection (inspection) • Audit of supporting management system (audit) Periodic surveillance : • process inspection (inspection) • Audit of supporting management system (audit)	Example: EN ISO 3834-2
Service example: Care services	Example: Certification scheme – Care Sector. Initial assessment: • Service inspection (inspection) • Audit of supporting management system (audit) Periodic surveillance : • Service inspection (inspection) • Audit of supporting management system (audit)	Example: Certification scheme – Health Care Sector Quality Criteria Set

3. Accreditation assessments

3.1 Documents to be submitted

For the RvA assessments the assessors have to be provided with documents, as referred to in application forms RvA-F001a or RvA-F105 and RvA-F006-1, or the Annex of RvA-BR005.

Additional documents/registrations of the (client of the CAB) can be requested in a SAP for specific activities.

3.2 The nature and content of the assessments

In addition to the general rules for the nature and content of the RvA assessment, as set out in RvA-BR002 and RvA-BR005, the rules contained in the table below are applicable for product certification. The nature and content of the assessment depend on the requested accreditation scope, any existing accreditation and the organisation's past performance (where applicable).

Assessment method	Initial assessment	Regular assessments during the accreditation cycle[2) 3)]	Scope extension[1)]
Quality system documentation assessment	√		√[5)]
Office assessment - system	√	Annual: implementation of specific system elements	√
- activities and/or product groups[3)]	Initial: (client) files: 2 files per product group[3) 4)] + Competence files: 25% of the competence files; at least 2[4)] Re-assessment: See next column	Twice during the cycle per activity or product group[3)]: (Client) files: 1/4√n; at least 2 files[4)] + Competence files: 25% of the competence files; at least 2[4)]	√ (Client) files: at least 2 files per product group[3) 4)] + Competence files: 25% of the competence files; at least 2[4)]
Witnessing	Initial: minimum 1 per product group[3)]	Minimum 2 per product group[3)] in the cycle	√

[1)] Based on the request (form RvA F105) the RvA will determine how extension assessment will be conducted.

[2)] An accreditation cycle covers a period of four years, which commences after a decision about an initial or re-assessment has been taken; the cycle therefore covers the surveillance assessments and the re-assessment during this period.

[3)] If possible, groups of products will be defined in order to divide the assessment activities of files and witnessing activities equally over the entire accreditation period. A product group concern products with, for example, the same technology, the same materials or same use. This is not applicable for processes and services. The extent of the random sampling is determined for each product group / individual scheme or for each (European) Directive, Regulation or type of legislation. Modules of European Directives are divided over the four-year cycle. In the event of large numbers of certificates (> 2000) it is possible to opt for a main group classification.

[4)] Up to a maximum of 2 assessment days for each product group for client files and competency files combined. A maximum of 4-8 certification or personnel files can be assessed during each assessment day.

[5)] If the system changes as a result of the extension.

3.3 Witnessing activities

The following general rules apply for witnessing activities:

1. A witnessing activity lasts for at least one whole day or as long as the total inspection, check, audit and/or test.
2. When choosing the witnessing activity for initial assessments or re-assessments, activities must be selected that set the highest requirements as regards the competency of the organisation.
3. For each product group in an accreditation cycle the various evaluation methods have to be witnessed twice.
4. A scheme owner can set specific requirements for the size of the random sample or the number of witnessing activities. The number may not be lower than the number specified in this SAP.
5. When the CAB uses results from non-accredited organisations, the RvA will witness at least once during the four-year cycle the evaluation of that organisation by the CAB.
6. If non-accredited testing is undertaken within the certification body then it must be assessed at least twice during the cycle.
7. Generally, all days of an activity are witnessed unless the objective for the assessment activity can also be achieved with a partial witnessing activity (for audit teams consisting of multiple persons or multi-day certification assessment for example).
8. The RvA can replace a witnessing activity with a shadow assessment (see RvA-T040).
9. The RvA will not normally witness any evaluation personnel who have already been witnessed within the current or previous accreditation cycle for that scheme, unless there are no other evaluation personnel.
10. The RvA will not normally undertake witnessing activities at companies where witnessing has previously been undertaken within the accreditation cycle.
11. During the accreditation cycle, if possible, at least one third of the witnessing activities (minimum one) will be undertaken during an initial certification or re-certification.
12. The assessment of the CAB report forms part of a witnessing activity. The CAB must provide the RvA with the report within a maximum of 10 working days.
13. In order to facilitate the selection of witnessing activities, the CAB shall, on the request of the RvA, make its schedule available for a period which is specified by the RvA. For schemes in which only unannounced activities are undertaken, the RvA must be periodically provided with a current list of certification holders, with at least the same frequency as the unannounced witnessing activities.

4. Specific issues for the RvA assessment

For product certification the RvA assessment team will cover the following subjects (if applicable):

1. compliance with the relevant requirements of the accreditation standards ISO/IEC 17021, ISO/IEC 17020 and ISO/IEC 17025 for audits, inspections and/or testing activities as part of the product evaluation activities;
2. copy of a recent certificate;
3. the qualifications/competencies of the personnel involved in the certification for each certification scheme (application assessor, evaluation personnel, reviewers, decision-makers);
4. use of (approval) marks;
5. surveillance activities (also related to the use of approval marks);
6. compliance of the certification scheme with the requirements of RvA-T033;
7. transfer of non-accredited certificates (can only be undertaken if the CAB itself has established that the products comply with the requirements).
8. the operation of the CAB's impartiality committee (or another mechanism). During the accreditation cycle this will be assessed in details at least once and always during an initial assessment. The RvA Team Leader (TL) shall determine the method for this, which can consist of an interview (in person or by telephone) with a non-CAB representative of the Committee, or the witnessing of (part of) a committee meeting.

5. Other information

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6. Changes with regard to the previous version

The following significant changes have been made compared to Version 3 of April 2015:

- methods of conformity assessment specified in more detail on the scope;
- rules for the nature and content of the assessments in 3.2 amended to meet the amended requirements in the new EN ISO/IEC 17011;
- paragraph about witnessing activities (3.3) added;
- assessing the operation of the impartiality committee (or another mechanism) added;
- possibility for shadow assessments added;
- RvA Coordinator 17065 added.