Raad voor Accreditatie (Dutch Accreditation Council RvA)

Specific Accreditation Protocol (SAP) for certification of products, processes and services based on EN ISO/IEC 17065 - General

Document code:	**RvA-SAP-C008-UK**
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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 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

The current version of these documents can be downloaded from the website of the 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. (EN ISO/IEC 17065:2012; 7.1.1. The certification body shall operate one or more certification scheme(s) covering its certification activities) The name of the certification scheme is stated in the scope.

Based on EN ISO/IEC 17065, clauses 6.2.1 and 6.2.2. the method of conformity assessment shall be specified in accordance with the applicable terminology from:

- testing (EN ISO/IEC 17025);
- inspection (EN ISO/IEC 17020);
- audit (EN ISO/IEC 17021-1);
- validation and verification (EN ISO/IEC 17029).

Validation and verification can also be considered an evaluation activity (method of conformity assessment) when the terminology in accordance with EN-ISO/IEC 17029 is used.

Therefore, for all the methods of conformity assessment mentioned above, the CAB should comply with the applicable requirements from the above international standards.

Product requirements can be specified in normative documents such as regulations, standards and technical specifications.

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 TR 17032: Guidelines and examples of a scheme for the certification of processes;
- ISO/IEC 17067: Fundamentals of product certification and guidelines for product certification schemes;
- ISO/IEC 17007; Guidance for drafting normative documents suitable for use for conformity assessment.

1.4 Specific requirements from legislation and regulations

RvA-T033 provides an explanation of requirements for conformity assessment schemes, including an explanation if schemes include requirements from laws and regulations.

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, audit, validations and/or verification..*	*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 purpose of the RvA assessments, assessors should be provided with relevant documents as specified in the application tool (for initial assessments and assessments of a scope extension) or as listed in the annex of policy rule RvA-BR005 (for other assessments).
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 depends on the requested accreditation scope, any existing accreditation and the organisation's past performance (where applicable).

Assessment method	Initial assessment[2)]	Regular assessments during the accreditation cycle[1) 2) 3) 4) 5)]	Scope extension[6)]
Preliminary assessment[7)]	√		√
Assessment of documentation			if applicable[8)]
Office assessment - system	√	√	√
Office assessment - activities and/or product groups[2)]	(client) files: at least 2 files per product group[4)] + Competence files: 25%; at least 2 files[4)]	Twice during the cycle per activity or product group[3)4)]: (client) files: 1/4√n; at least 2 files[4)] + Competence files: 25%; at least 2 files[4)]	√ (client) files: at least 2 files per product group[3)4)] + Competence files: 25%; at least 2 files[4)]
Witnessing	Initial: minimum 1 per product group[3)4)]	Minimum 2 per product group[3)4)] in the cycle	√

[1)] 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.

[2)] The nature and extent of assessments depend on the requested scope of accreditation, any existing accreditation, and the CAB's past performance (where applicable). A scheme may contain additional requirements.

[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. The nature and extent of assessments depend on the requested scope of accreditation, any existing accreditation, and the CAB's past performance (where applicable). A scheme may contain additional requirements.

[5)] Changes to a CAB's own schemes are assessed during regular assessments. The RvA may determine a different method of assessment based on the nature and extent of the change(s).

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

[7)] Evaluations of new own schemes are conducted during the preliminary assessment.

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

3.3 Table for purposes of determining sample size of file assessment

The total number of client files to be verified per regular office assessment is determined by the number of valid certificates under RvA accreditation per activity or product group and is determined according to the formula: 1/4√n in which n equals the number of valid certificates under accreditation.

Number of valid certificates	< 100	100 – 195	196 – 323	324 – 483	484 – 675	676 - 899	≥ 900
Number to be assessed	2	3	4	5	6	7	8

For an initial assessment or scope expansion, the guideline is the number of certificates issued until then (of which can reasonably be expected to be issued in due course under accreditation).

3.4 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 take place at an initial certification or recertification.
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 EN ISO/IEC 17021, EN ISO/IEC 17020, EN ISO/IEC 17029 and/or EN ISO/IEC 17025 for audit-, inspection-, verification-, validation- and/or testing activities as part of the product evaluation activities; and in particular outsourcing and acceptance of evaluation results.
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 Lead Assessor (LA) 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. Changes with regard to the previous version

Compared to version 4.0 dated 25-09-2018 the following changes have been made:

- Title specified
- EN ISO/IEC 17029 added as methods of conformity assessment
- Update scope examples
- Adaptation to new SAP template (a.o. 3.2)
- 3.3 added for PCA
- Adjustment attention points
- RvA coordinator and RvA expert EN ISO/IEC 17065 have been removed.