Dutch Accreditation Council (RvA)

Policy rule Scope of Accreditation

Document code:	**RvA-BR003-UK**
	Version 8.0, 13-01-2022

RvA policy rules describe the RvA rules and the policy on specific subjects.
A current version of the policy rules can be obtained through the RvA web site (www.rva.nl).

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1 Scope and definitions

Article 1.

This policy rule is applicable to the accreditations under EN ISO/IEC 17020, EN ISO/IEC 17021-1 (including the EMAS Regulation (EC) 1221/2009), EN ISO/IEC 17024, EN ISO/IEC 17025, EN ISO/IEC 17029, EN ISO/IEC 17065, EN ISO 15189, EN ISO/IEC 17043, EN ISO 17034 and EN ISO 14065.

Article 2.

1. This document describes policy of the RvA on the definition of scopes for the different types of accreditation.
2. If specific rules for the definition of the scope have been established for a specific conformity assessment activity, these are described in a so-called 'Specific Accreditation Protocol' (SAP) for this activity and published on the RvA web site (www.rva.nl).

Article 3.

This document shall come into force on the day of publication in the Government Gazette.

Article 4.

The term "scope of accreditation", or scope, means the statement by the RvA of the activities and/or fields of activity to which the accreditation of a conformity assessment body (CAB) is applicable. In addition to the location of the head office as registered with the chamber of commerce, the scope of accreditation also includes the locations of a CAB as referred to in Article 5.

Article 5.

1. Locations of the CAB that will be included in the scope are locations:
   a. where one or more key activities are carried out, or
   b. from where remote personnel is managed that do not work from one of the locations of the CAB, or
   c. where no key activities are carried out, but which are included in the scope of accreditation at the request of the CAB.
2. The term locations is understood as a building or group of building used by the CAB, that can be identified by one address, where the CAB durably conducts activities.
3. A key activity in this context is an activity of the CAB that according to RvA's opinion has a significant impact on the results of the conformity assessment. This policy rule gives further details of the activities to be regarded as a key activity for the different types of accreditation in chapters 0 - 11.
4. The scope specifies the locations at which the different conformity assessment activities are conducted under accreditation.

2 General rules

Article 6.

1. A location is included in the scope by entering the complete address where the location may be visited and, if the location is outside the Netherlands, with the country (if necessary the state will be entered also).
2. In case of specific security risks for a location the board of the RvA may decide not to include the full address in the scope at the request of the CAB.
3. The RvA will not include any names of legal entities in the scope other than the name of accredited body, because this would create the impression that this other entity is accredited.

Article 7.

1. In case staff members of the CAB, normally not working from a location as defined in Article 5, conduct key-activities as defined in Article 5 and the CAB has established an online environment for this, a separate location named ‘virtual location’ will be included in the scope.
2. In case the CAB only operates from a virtual location, thus not from a location as meant in article 5, this term ‘virtual location’ will be added to the heading ‘Head office’ on the scope.

Article 8.

The RvA will include locations in the scope of accreditation (the term multisite accreditation is used for this) after the RvA has confirmed during its assessments that:

1. the head office and all of the locations to be included under the multisite accreditation operate under the same management and the same global management system;
2. the head office has the means to substantially influence and control the activities of the locations. The head office has demonstrated that such influence and control is in place and is effective;
3. the locations do not offer RvA accredited services under another name and/or logo than the name and/or loge of the head office;
4. the head office of the accredited CAB has the final responsibility for the activities performed by the locations covered under the scope of the multisite accreditation of the head office and this responsibility is clearly stated in the contracts with its customers;
5. the locations offer conformity assessment activities under the multisite accreditation only on behalf of the head office of the accredited CAB;
6. the certificates and reports issued under the multisite accreditation contain the name and address of the accredited legal entity (the head office) without the name of the entity or logo of the location. (these certificates and reports may however make reference to the contact details of the location);
7. the documents issued by the CAB do not create any confusion as to the entity which holds the accreditation;
8. the multisite accreditation only includes companies within the same organisation for which the head office has the final responsibility for the activities performed and certificates or reports issued by the locations;
9. the responsibility has been demonstrated on the basis of contractual or equivalent legal relationships between the head office and the location(s) and internal regulations in the organisations that further specify these relationships in terms of management and responsibilities; and
10. the CAB has assured the compliance with the above mentioned nine conditions in its management system.

Explanations of the terminology used in this article are provided in Annex 1.

Article 9.

Prior to the assessment of a CAB, the RvA defines the scope based on a proposal of the CAB. The scope will be formulated taking into account the aim of the RvA for optimally harmonised descriptions of scope.

Article 10.

In the case of accreditation of conformity assessment activities in the context of recognition, designation and/or notification by the government, the RvA will establish the scope description in consultation with the recognizing, designating or notifying authority, where necessary.

Article 11.

For reference to legislation in the scope of accreditation the following rules apply:

1. RvA only includes legislation in the scope for which the governmental authorities have decided that accreditation is a prerequisite to be recognised, designated of notified, in case the CAB applies for this accreditation to be recognised, designated of notified. For example: a scope of accreditation will not refer to a European directive for which the CAB needs a status a notified body, if the CAB does not have this status or the intention to be notified for this directive.
2. Legislation will only be included in the scope in case this legislation defines methods or requirements for the conduct of conformity assessment activities or for the object of the conformity assessment in question.
3. Conformity assessment activities, which are not defined in legislation, that include assessment against legal requirements may be part of the scope of accreditation provided that:
    a. the conformity statement (such as a certificate) resulting from a conformity assessment activity of the CAB only declares that justified confidence exists of compliance with the specific legal requirements specified in the statement;
    b. the conformity statement explicitly mentions the conformity assessments activities and the specific legal requirements.

Further explanation of this policy is provided in Annex 2 of this policy rule.

Article 12.

The names on the scopes in terms of the legal entity, and where relevant the name(s) of the part(s) of the organisation, is defined by the RvA based on the assessment performed. The name is identical to the name on the accreditation declaration. On an English translation of the scope the name of the entity may be translated provided that this is also the case on the accreditation declaration.

Article 13.

The RvA only includes conformity assessment activities in the scope of accreditation for which the CAB is able to demonstrate at all times that these are conducted in a correct and controlled way and that the results are correct and reliable. For this the RvA requires evidence of validation of the methods applied and periodical re-validation, based on a risks analysis concerning the validity of the results. Document RvA-T033 provides an explanation of the concept of validation.

Article 14.

The RvA only includes conformity assessment activities in the scope of accreditation for which the CAB has demonstrated to have itself the necessary competences and facilities. Activities systematically outsourced completely and not conducted by the CAB itself will not be included in the scope of accreditation.

Article 15.

The RvA does not include activities in the scope for accreditation that consist of assessment against requirements of a standard that the RvA applies for accreditation, or that compete with accreditation in another way. An explanation of this policy is described in Annex 3.

Article 16.

1. If RvA has granted accreditation for a conformity assessment activity according to an international standard, such as an ISO, IEC or EN standard, then this accreditation also applies to a Dutch or other national translation of this standard, provided that the CAB has confirmed, before applying this translation, that the standards are equivalent.
2. The other way around an accreditation for a national translation of an international standard also applies to the original standard or another national translation, under the conditions of the first paragraph.

Article 17.

1. Unless requested by the CAB, as a rule the RvA does not mention the version of documents (normative documents, schemes, procedures, et cetera) in the scope of accreditation. The accreditation in this case applies to the current version of a document.
2. In case the CAB holds an accreditation for another version than the current version, the version will explicitly be mentioned in the scope.

Article 18.

1. In the list of conformity assessment schemes for which RvA provides accreditation (see RvA-BR010), the version of a scheme that has been evaluated by the RvA, is indicated. Also for these schemes the accreditation applies to the current version.
2. In the event that the CAB uses a version of a scheme which is not included in the list referred to in RvA-BR010, it is the responsibility of the CAB to demonstrate the suitability of this version by means of a self-assessment as described in RvA-T033. The RvA may decide to assess whether the suitability of the version used by the CAB has been demonstrated. Possible non-conformities then raised by the RvA may require the recall of previous results (such as certificates or reports) by the CAB.

Article 19.

1. In the event that during a transition period the superseded and the new version of a document may both be used, the RvA may decide to mention both versions in the scope.
2. In the event RvA is of the opinion that a new version requires different competences from the CAB than the old version, the RvA may decide that the CAB will need to apply for extension of the scope for the new version conforming to the rules in chapter 0. The RvA will notify the CABs of such a decision.

3 Calibration laboratories

Article 20.

The scopes of accreditation for calibration laboratories follow the adapted EA Harmonised Classification Scheme (HCS), which has chapters for each physical quantity that are further subdivided. The supplementary application form RvA-F003 (see www.rva.nl) contains details of the coding in this system.

Article 21.

The following activities are considered the key activities for calibration:

- development of calibration methods, processes and procedures;
- performance of the calibrations;
- training and qualification of technical personnel;
- review of orders and contracts;
- review and approval of results, reports and certificates.

Article 22.

If calibrations are (also) carried out in the field (*in situ*), that is outside the said head office and locations mentioned in the scope, this is stated as such in the scope. This includes calibrations carried out in mobile laboratories or in semi-permanent facilities.

4 Testing laboratories

Article 23.

1. The scope of accreditation for testing laboratories includes the material, subject or product (the matrix) on which or in which the tests are carried out, the type of test, including the component, parameter or characteristics that are measured and the method used.
2. Document RvA-T001 (see www.rva.nl) describes the way in which the reference to methods is included in the scope.
3. Document RvA-SAP-L000 provides more details about the descriptions of scope for testing laboratories, including the application of the so-called flexible scope.

Article 24.

The following activities are considered the key activities for testing laboratories:

- development of test methods, processes and procedures;
- performance of the tests;
- training and qualification of technical personnel;
- review of orders and contracts;
- review and approval of results (including opinions and interpretation as applicable) and reports.

Article 25.

If tests are (also) carried out in the field (*in situ*), that is outside the said head office and locations mentioned in the scope, this is stated as such in the scope. This includes tests that are carried out in mobile laboratories or in semi-permanent facilities.

Article 26.

If the laboratory holds an accreditation for opinions and interpretations, as referred to in EN ISO/IEC 17025 and further explained in RvA-T015 (see www.rva.nl), then this is explicitly stated in the scope.

5 Medical laboratories

Article 27.

The scope of accreditation for medical laboratories is based on document EA-4/17 and EA-2/15. This means that the scopes preferably are defined as 'Flexible scopes' and that the medical laboratory field is specified, such as Clinical Chemistry, Haematology, Immunology, Microbiology. Besides this the scope specifies the types of examinations (also referred to as 'Diagnostic questions', the method or technique, and materials or products). More explanation on the scopes of accreditation for medical laboratories are given in RvA-SAP-M000 (see www.rva.nl).

Article 28.

The following activities are considered the key activities for medical laboratories:

- development of examination methods, processes and procedures;
- performance of the examinations;
- training and qualification of technical personnel;
- review of orders and contracts;
- review and approval of results and reports.

Article 29.

If examinations are (also) carried out in the field (*in situ*), that is outside the said head office and locations mentioned in the scope, this is stated as such in the scope. This includes examinations that are carried out in mobile laboratories or in semi-permanent facilities, and point of care testing (POCT).

6 Inspection bodies

Article 30.

The scope of accreditation for inspection bodies specifies the field of the inspection (for example products or group of products, installations, processes and services that are the subject of the inspection) and the type of inspection activity (for example design review, new build inspection or inspection in use) that is carried out. The inspection methods and procedures (for example EC directives, statutory regulations, standards and specifications or in-house methods) are also specified. RvA-F005 (see www.rva.nl) provides an explanation of the way in which scopes are described for inspection.

Article 31.

The following activities are considered the key activities for inspection:

- development of inspection methods, processes and procedures;
- initial selection, training and qualification of inspectors;
- review of orders and contracts;
- planning of inspections;

- review and approval of inspection results, reports and certificates.

In case laboratory tests are conducted as part of the inspection activity, the rules in Article 25 also apply.

Article 32.

The scope of accreditation for inspection bodies identifies the type of independence that has been established for the body (type A, B and/or C as referred to in EN ISO/IEC 17020).

7 Certification

Article 33.

In the scope of accreditation for certification bodies the RvA specifies the subject of certification, the normative document against which the subject is certified and the name of the certification scheme. In addition to this the RvA has described the details for definition of scope for different types of certification in Specific Accreditation Protocols.

Article 34.

The following activities are considered the key activities for certification:

- development and adoption of certification schemes, processes and procedures;
- initial selection, training and qualification of certification personnel and subcontractors;
- control of the process of monitoring of competence of personnel and subcontractors and the of the results thereof;
- review of orders and contracts, including the technical review of applications and determining the technical requirements for certification activity in new technical areas or areas of limited sporadic activity;
- assignment of conformity assessment tasks (such as for example audits or inspections);
- management of surveillance and recertification programs;
- taking certification decisions, including the technical review of audits, inspections, tests exams or other evaluation activities;
- final decision on appeals and complaints.

In case laboratory tests and/or inspections are conducted as part of the certification activity, the rules in Article 25 and/or Article 32 also apply.

8 Organisers of proficiency testing

Article 35.

In the scope of accreditation for organisers of proficiency testing or interlaboratory comparisons the RvA specifies the schemes, the type of items, the measurand or characteristic or where appropriate the type of measurand or characteristic that are to be identified, measured or tested. Where relevant a range may be specified. By analogy with the scope definitions for test laboratories, as explained in RvA-SAP-P000, also the scope for organisers of proficiency testing may be defined as a flexible scope.

Article 36.

The following activities are considered the key activities for organisers of laboratory comparisons:

- development of methods, processes and procedures;
- preparation of the samples and the recording of the properties;
- distribution of samples or artefacts;
- training and qualification of technical personnel;
- review of orders and contracts;
- review and approval of results and reports.

9 Producers of reference materials

Article 37.

In the scope of accreditation for producers of reference materials the RvA specifies the type of reference material, the matrix or the object, the properties, where applicable supplemented by a characterisation range, and the characterisation procedure or method that the organisation employs. By analogy with the scope definitions for test laboratories as explained in RvA-SAP-R000, also the scope for producers of reference materials may be defined as a flexible scope.

Article 38.

The following activities are considered the key activities for producers of reference materials:

- development of methods, processes and procedures;
- preparation of materials and assignment of property values;
- distribution of materials;
- training and qualification of technical personnel;
- review of orders and contracts;
- review and approval of results and reports.

10 EMAS verification bodies

Article 39.

The accreditation for EMAS verification is granted based on EN ISO/IEC 17021-1 and the EMAS regulation.

Article 40.

In the scope of accreditation for EMAS verification bodies the RvA specifies the economic sectors in terms of NACE and EA codes, as for the accreditation for EN ISO/IEC 17021-1 for EMS-certification. In addition to this the names of the approved verifiers are mentioned.

Article 41.

The following activities are considered the key activities for EMAS verification:

- development and adoption of verification schemes, processes and procedures;
- initial selection, training and qualification of verification personnel and subcontractors;
- the management of monitoring and evaluation of personnel and subcontractors and the results thereof;
- review of orders and contracts, including the technical review of applications;
- review and approval of results and reports.

Article 42.

Locations outside the Netherlands are not included in the scope because of the specific rules for supervision on cross border EMAS verification in the EMAS regulation.

11 Greenhouse gas verification and validation bodies (EN-ISO 14065:2013)

Article 43.

The RvA scope of accreditation for greenhouse gas (GHG) verification and validation bodies based on EN-ISO 14065:2013 specifies the verification or validation activity, the type of emission (components) and the nature of the activities or sectors in which the emissions occur.

Article 44.

The following activities are considered the key activities for greenhouse gas verification/validation:

- development and adoption of verification and validation schemes, processes and procedures;
- initial selection, training and qualification of verification personnel and subcontractors;
- the management of monitoring and evaluation of personnel and subcontractors and the results thereof;
- review of orders and contracts, including the technical review of applications;
- review and approval of results and reports.

12 Validation and verification bodies (EN-ISO/IEC 17029)

Article 45.

In the scope of accreditation for validation and verification bodies based on EN-ISO/IEC 17029 the RvA specifies the validation or verification activity for the type of claim that is the subject of the assessment and the name of the validation/verification scheme, including, where applicable, the normative document. Also specified is the sector to which the accreditation applies. In addition, the RvA has set out the details for the scope definition for different kinds of validation/verification activities in Specific Accreditation Protocols (SAPs).

Article 46.

The following activities are counted among the core activities for validation and/or verification:

- development and adoption of validation and verification programmes (schemes), processes and procedures;
- initial selection, training and qualification of validation/verification staff and subcontractors;
- the management of monitoring and evaluation of staff and subcontractors and the results thereof;
- assessment of assignments and contracts, including the technical assessment of applications;
- assessment and approval of validation/verification statements.

13 Granting of the scope

Article 47.

The basis of a scope of accreditation granted by the RvA is given by:

1. the documents and records that the body has made available to the assessment team in the course of the assessment and where relevant the demonstration of competence by means of interviews with those who carry out the activities, and/or observation, or verification afterwards of the performance of activities;
2. the degree to which the information obtained in the previous paragraph is representative for the body's field of activity.

Article 48.

The RvA will only include a conformity assessment activity if the RvA:

1. has ascertained that the calibration, testing or medical laboratory, the inspection body, the organiser of PT or the producer of reference materials has carried out this activity in a competent manner and is able to demonstrate this competence during the assessment;
2. has ascertained that the certification or verification/validation body has at least completed a full certification or verification/validation procedure in a competent manner for the schemes in the scope and that, if a subdivision in technical areas or sectors is applied in the scope, competence can be demonstrated in the areas or sectors mentioned in the scope during the RvA-assessment.
3. has ascertained that the EMAS verification body has completed a full verification procedure and that competence has been demonstrated for the fields given in the scope. The verifiers must have been observed by the RvA prior to being mentioned on the scope.
4. has been given the opportunity to select and observe the concerned conformity assessment activities (audits, calibrations, tests, inspections, verifications, exams, et cetera), or to verify these activities afterwards by means of shadow assessments.

Article 49.

In exception to Article 47, the RvA can decide to grant a temporary accreditation with restricting conditions as explained in BR002, in case the body was not yet able to conduct the respective conformity assessment activities.

14 Maintenance of scopes

Article 50.

A scope may be maintained unchanged during the specified validity period when during the assessments the RvA has been able to ascertain that the records of the body show that the management system is effectively implemented and has been effective for the activities and/or areas or sectors given in the scope, since the RvA initial assessment or previous reassessment or since the granting of the respective part of the scope.

Article 51.

1. Where the body is unable to demonstrate that conformity assessment activities in the scope have been carried out during the last two years, the RvA removes these activities from the scope. It is however possible that expertise and the meeting of the requirements for these conformity assessment activity are demonstrated in some other way, in which case the activity is not removed from the scope.
2. If the removal of an activity from the scope on the basis of the previous paragraph means that the whole scope is removed, the accreditation of the body will be withdrawn. If the body re-applies for accreditation for the same activities following such a withdrawal, then the RvA will decide which assessment effort is required for the re-granting of the accreditation.

Article 52.

1. During the accreditation cycle the RvA may assess whether the CAB has implemented possible changes in documents mentioned in the scope correctly in its processes and management system. This assessment may concern the self-assessment that the CAB is supposed to conduct for such changes.
2. Irrespective of the previous paragraph, the RvA considers it the duty of each accredited CAB to inform RvA on significant changes in methods and procedures. Changes in documents mentioned in the scope are considered to be significant if these changes require the CAB to make use of competences in its activities, that have not yet been demonstrated to the RvA.
3. The RvA may decide to conduct extra assessments (as referred to in BR002) aimed at changes in documents mentioned in the scope of accreditation.

Article 53.

In case a nonconformity is raised at a location within a multi-site accreditation, the RvA will assume that this finding is also applicable to the other locations, unless the CAB demonstrates that this is not the case. Only in case it is demonstrated that the finding is specifically applicable to the location where it was raised, the consequences of the finding may be limited to this location. In case this is not demonstrated, the nonconformity may have consequences for the complete accreditation scope of the CAB.

15 Extension of scopes

Article 54.

The RvA will process an application for an extension of the scope after the body has provided sufficient information on the conformity assessment activities or locations for which extension is being sought. This information shall consist as a minimum of the data requested in RvA-F105 (see www.rva.nl) and the relevant supplementary application form.

Article 55.

The RvA will determine the necessary assessment effort for the assessment of a scope extension. Depending on the nature and extent of the desired extension, the RvA will carry out an assessment that can range from:

1. a document review, followed by an office assessment and an observation/witness or shadow assessment of activities, according to the basic principles in Article 47, where the extension concerns an entirely new field of conformity assessment activity for the body for which it needs a new kind of expertise or the activities of which have a greater complexity than conformity assessment activities already accredited, to
2. a document review only, if the extension concerns a conformity assessment activity that, in terms of expertise and complexity, is similar to conformity assessment activities already accredited.

Article 56.

For extension of the scope with a new location the RvA will carry out an assessment at this new location, including the observation or shadow assessment of activities that are carried out there. An assessment will also be carried out at the head office with a view to assessing the degree of operational control from this office over the new location.

Article 57.

A request for a change in the scope not being an extension of scope, is treated according to the nature of the change. The amendment of text and change in reference to normative documents are examples of changes that could be made without an extension assessment. The RvA may be advised about the need for an extension assessment in such cases by technical experts and/or team leaders.

16 Changes compared to the previous version

Article 58.

Compared to version 7, dated 17 April 2018, the following significant changes have been made:

- Article 1, Article 46, paragraph 4 (old numbering), Article 45 (new numbering), Article 46 (new numbering), chapter 11: changes relating to addition of description of policy on validation and verification bodies (EN-ISO/IEC 17029). Specific policy for this new subject has been introduced in new chapter 12 (new Article 45 and new Article 46). References to this new standard have been added in Article 1 and Article 46, paragraph 4 (old numbering); the scope of these Articles has therefore increased. To prevent confusion regarding the (multiple) rules for validation, chapter 11 specifies that it relates to EN-ISO 17034.
- Article 4, Article 27, Article 35, Article 37 and Article 43: references to SAPs have been updated.
- Renumbering: with the addition of Articles 45 (new) and 46 (new) the numbering of some Articles has changed. Articles 45 to 56 are now Articles 47 to 58.

Annex 1: Explanation of the terminology used in chapter 2

1. Same organisation

Definition:

Group of (legal) entities, composed of head office and locations connected with the head office on the basis of contractual or equivalent legal relationships, operating under the same commercial name and logo.

Comments to definition:

The names of the individual (legal) entities may be slightly different but shall include the (commercial) name of the entity that is accredited as the head office of the organisation. The names of the individual legal entities may e.g. include letter codes defining the type of organisation (e.g. “Ltd.” or “GmbH”) or regional identifiers (e.g. “Svenska” or “Deutsche”). The commercial name may be translated, partially or in full, to accommodate the local market.

2. Same management

Definition:

Same set of persons or organisational entities of the **same organisation** taking **final responsibility for the accredited activities**.

3. Same global management system

Definition:

Set of linked rules and procedures defined by **same management** to allow it to take the **final responsibility for accredited activities**.

Comments to definition:

The linkage is to be achieved through a table of contents or by a reference table. In order for the management system to be considered as the same it shall be designed to provide the same outcome of accredited activities regardless of where the activities are carried out or by whom. The policies governing conformity assessment activities shall be the same throughout the organisation. To provide consistency of results:

- The same management is to define in the same management system any sub-sets of alternative rules and procedures, used e.g. by different local sites or throughout different geographical regions.
- All conformity assessment activities defined by the same management system are covered by an internal audit program managed and approved by the same management. The outcome of individual audits, including decisions on corrective actions, are discussed with affected management at all levels as the situation warrants.
- All conformity assessment activities of the same management system are subject to a management review by the same management. The outcome of the management review, including any decisions, are discussed with affected management at all levels as the situation warrants. The same management has the authority and legal means to enforce corrective and preventive actions.

4. Final responsibility for the activities

Definition:

The total of operational, financial and legal responsibilities for the performance and outcome of accredited conformity assessment activities.

Comments to definition:

In order to take responsibility for accredited activities the head office shall have full operational, financial and legal control over these conformity assessment activities. To this end, the head office shall have appropriate technical competence and the resources to assure control over the full scope of accreditation. To take responsibility for the outcome of accredited activities is to take responsibility for:

- the competence and resources used,
- the rules and procedures applied,
- the consistency obtained and quality achieved through the application of these rules and procedures,
- the impartiality displayed applying these rules and procedures, and
- the contents of issued reports and/or certificates.

The responsibility is to be upheld:

- towards the customer,
- towards authorities,
- towards the public and
- in court.

Annex 2: Explanation of the policy relating to conformity assessments against legal requirements exclusively

1. Introduction

The RvA is regularly asked whether CABs are allowed to issue a declaration of conformity exclusively in relation to legal requirements. In particular, if the declarations are issued by private parties that are not designated or notified for such a task by the government, it is important to be aware that such declarations do not have the status of an assessment or inspection by a government inspectorate or private party designated or recognised by the government for that purpose. In this Annex the RvA explains its considerations and the policy on this matter.

2. Considerations

The following documents are decisive for the policy of the RvA with regard to the activities that can be undertaken under accreditation:

- the EN ISO/IEC 17011 and the associated application documents, such as IAF/ILAC A5, as adopted by the European and international umbrella organisations EA, IAF and ILAC[1];
- the European regulation (EC) 765/2008 and decision 768/2008/EC;
- the national Accreditation body appointment act (Wanai);
- the Statutes of the Dutch Accreditation Council (RvA) and the mission and vision;
- the conditions for signing the international equivalence agreements: EA-MLA, IAF-MLA and ILAC-MRA;
- the harmonised standards (mostly from the EN ISO/IEC 17000 series) used for accreditation and the application and interpretation documents applicable to those;
- the 'Government position regarding conformity assessment and accreditation' dated 19 September 2016.

The criteria and the standards that the declaration of conformity relates to (for example a standard or an assessment guideline for certification such as KOMO) are the domain of the market players, including the CABs. The RvA that does not judge the 'level' set by the market players. However, the RvA does assess whether, using such standards and criteria, conformity assessments are possible which meet the requirements specified in the harmonised standard used for accreditation. Important elements for the RvA assessment are the verifiability of the requirements and the reliability of the methods.

The RvA is not a regulator or enforcer of the law and the same applies to private CABs. Government inspectorates ensure compliance with the law. In relevant cases the court will establish whether the law is being complied with. In so doing, if the law provides a decisive answer in this regard, the court can consider the outcomes of an accredited conformity assessment as a 'presumption of conformity' with legal requirements.

The Netherlands has a free market economy. In other words, insofar as not otherwise regulated in law, anyone may freely offer services and products. This is also valid for conformity assessment services. However, with regard to accreditation it is important that these activities do not form a threat to the confidence in accreditation and accredited conformity assessments. Preventing deception is one of the aspects of this. Preventing declarations of conformity being issued under accreditation for activities that conflict with the law is another aspect.

Declarations of conformity (such as inspection reports or certificates) from private parties are often important in business to business relationships. This does not just concern gaining confidence with regard to the quality or other properties of products (such as a KOMO mark) or with regard to a supplier's quality management system (ISO 9001 certification). On the basis of supply chain responsibility, a buyer can ask himself whether his supplier or trading partner is compliant with specific legal rules, in addition to compliance with the private rules. Reducing the risk of liability or reputational damage can also be a reason for a company wanting confirmation that a supplier is compliant with the legal requirements.

Due to the harmonised accreditation standards used, the RvA assessments focus on the independence /impartiality and competence of the CABs, and the way in which these are assured in a management system. These standards provide no restriction regarding permitting (exclusive) legal criteria as the basis for a declaration of conformity. Other standards/guidelines such as ISO/IEC 17007 and ISO/IEC 17067 also do not have such restriction. However, there are standards which stipulate that the use of logos or marks must not be misleading for the consumer/user. On this point the RvA acknowledges that the aim is to prevent deception and to specifically protect vulnerable parties in society. Consequently, a business that knows the facts requires less protection against deception compared to the non-expert consumer.

[1] For abbreviations and terms please refer to the general RvA Policy Rule RvA-BR002.

3. RvA Policy

Article 8(10) of (EC) 765/2008 gives the accreditation bodies in Europe the task of also verifying “that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings….”. This could mean that RvA may not accept declarations of conformity under accreditation which state that something complies with the legal requirements. Everyone is deemed to be compliant with the law and such a declaration from a private party can be regarded as being unnecessary. However, at the moment that, for example, a certification scheme has been created with the participation of all stakeholders, the RvA will not qualify such a declaration as an unnecessary burden. Also if it is demonstrated in another way that there is a market need for a declaration about compliance with specific legal requirements, the RvA will not consider such a declaration as an unnecessary burden.

There can be a need in the market for confirmation (by an independent expert party) that one can be confident a product or service complies with specific legal requirements or that an organisation adheres to specific legal requirements. Market players can request such a confirmation from a private CAB that is accredited for this by the RvA. These declarations are certainly useful where parties are unable to simply establish for themselves whether there is compliance with specific legal requirements and when there is a need for specific assurances within the framework of supply chain responsibility. However, it is important that the content of the declaration of conformity is not misleading and market players, consumers and (regulatory) authorities are able to assess the value of these declarations. The RvA will therefore only accept these types of declarations under accreditation if it is explained in the declaration what assessment(s) the CAB has carried out and against what specific requirements they have been assessed. If these are legal requirements then on the basis of the established conformity with these requirements it can be concluded that **justified confidence exists** that the product, the service, process or a(n) (aspects of) the management system complies with the specific legal requirements. The private party does not declare that there is compliance with this legal requirements, because such a declaration can only be issued by a government department that has the authority, via the regulator, and ultimately via the judiciary, to interpret the law.

A condition for a declaration that justified confidence exists in relation to compliance with a specific legal requirement, is of course that the declaration has a scope that does not go beyond the activities of the CAB. It is for example not accepted to declare that justified confidence exists that there is compliance with the Buildings Decree if not an assessment has been performed against the entire Buildings Decree. As a rule, the declaration will relate to specific legal requirements and assessment shall therefore have to be against those specific legal requirements. All conformity assessment activities required for making a judgement about compliance with these specific requirements must also be undertaken by or under the responsibility of the accredited body. The declarations which state that confidence exists that there is compliance with specific legal requirements relate to a clearly-defined product or process and not to an organisation in general. Assessing a management system cannot result in such a declaration (unless the relevant legislation requires that a specific management system has to be implemented).

Annex 3: Explanation of the policy relating to the non-inclusion in the scope, of conformity assessment activities that compete with accreditation.

1. Introduction

Article 15 of this policy rule states that the RvA will not include any conformity assessment activities in the scope of accreditation which involve assessment against the requirements of a standard used by the RvA for accreditation, or which otherwise compete with accreditation.

This rule is based on the requirements of EN ISO/IEC 17011, which prohibits the accreditation body from undertaking conformity assessment activities that it accredits, and on Regulation (EC) 765/2008 which prohibits the accreditation body from competing with CABs. If the RvA was to accredit a body for a conformity assessment activity which means the CAB undertakes an assessment and issues a declaration against a standard used for accreditation, then the RvA would be acting in conflict with these requirements. This is phrased in policy rule BR002 as:
"The RvA shall always ensure its independence and impartiality. In this respect the RvA shall not grant accreditation, or maintain an accreditation granted, to a body that conducts or offers activities that could be considered to constitute or to suggest conformity declarations against standards that the RvA applies for the accreditation of CABs."

For certification bodies in particular, this rule can mean that certain conformity assessments will not be included in the scope of accreditation. However, giving a limitative list of what can and what cannot be mentioned on the scope is not possible. This will have to be established on a case to case basis. The policy is therefore explained below. The RvA will review an application for accreditation against this policy.

2. Explanation of the policy

In principle, every conformity assessment activity that the RvA accredits can also the subject of certification. The quality management systems for inspection activities and testing activities can be certified on the basis of ISO 9001 for example. Inspection processes and laboratory processes accredited on the basis of EN ISO/IEC 17065 can also be certified under accreditation. The question is whether these certification activities have that much in common with accreditation that competition may exist between both activities.

When receiving an application to accredit a certification activity, whereby the object of certification could also be the object of accreditation, the RvA will ask the following questions:

a. Are the requirements against which the certification body (CB) certifies, comparable with the RvA requirements for accreditation?
b. Will the CB undertake an assessment that is comparable with an accreditation assessment as far as the method of assessment (method and time spent) and competencies of the team are concerned?
c. Is the declaration of conformity (the certificate) to be issued a declaration about competence of an organisation?
d. Is the scope of the declaration of conformity comparable with a scope of accreditations as issued by the RvA?

If the answer to at least one of these questions is yes, then the possibility exists that the certification activities compete with accreditation. The RvA will not automatically include these certification activities in the scope of accreditation but will first investigate the reasons why market players (and potentially the authorities) have chosen certification as an instrument. This investigation will result in a conclusion and decision by the RvA about whether or not to include this certification activity in a scope. In any case the RvA will not grant accreditation for a conformity assessment activity which due to similarity with accreditation competes with accreditation services provided by the RvA.