European co-operation for Accreditation

Om privacy redenen zijn alle verwijzingen naar personen en instellingen in dit document onherkenbaar gemaakt.

Evaluation report

EA Report

of the

Re-evaluation

of

Raad voor Accreditatie
(Dutch Accreditation Council)
RvA

at:

Utrecht, The Netherlands

Date(s) of evaluation:
15-29 November 2013 and 21-23 January 2014

EA Evaluation team:
XXX MS Certification ISO 17021, Directives/Regulations, appointed as Deputy TL, but acting as Team leader considering that XXX XXX, at the very last minute was not able to participate to the evaluation.
XXX Product Certification EN 45011/ISO 17065
XXX Persons Certification ISO 17024
XXX Inspection and Notified Bodies Directives/ Regulations ISO 17020
XXX Testing and calibration laboratories ISO 17025
XXX verification ISO 14065, Directives/regulations
XXX Testing laboratories ISO 17025, ISO 15189
XXX - MS Certification ISO 17021, Directives/Regulations

Date report: 11 March 2014

Contents

Appendices

Appendix 1: Organisation chart with key personnel

Appendix 2: Report on participation in international PT/ILC's

Appendix 3: Statistical Information

Appendix 4: Evaluation plan

0 Executive summary

The Raad voor Accreditatie (Dutch Accreditation Council) RvA is the sole national accreditation body of The Netherlands, with a well established and comprehensive management system developed in agreement with and covering of all requirements of ISO/IEC 17011 and applicable EA, ILAC and IAF guidelines.

The management and the staff of RVA allowed very open and constructive discussions. The documents, records and files reviewed during the evaluation in the office and the assessments witnessed by the EA evaluators gave the team the opportunity to get a full picture of the operation and performance of RVA.

The staff members of RVA appear to be really competent and have good knowledge of the aspects of the relevant accreditation activity. Also the external assessors and experts were found to be competent for their duties and tasks.

Many the positive remarks made by the team:

1. All the personnel met has been very transparent, fair and collaborative
2. RVA is performing on on-going basis several training events for its internal and external personnel
3. Scheme evaluation: RVA developed an evaluation process to verify the reliability and competence of the scheme and of the scheme owner. Considering the fast growing of new schemes, this is a good tool to manage this process.
4. Competence for product: the qualification scheme take clearly into consideration also the competence on the conformity schemes (inspection, testing and MS) linked to the product certification scheme
5. Cross frontiers policy: the AB has the full control of critical locations of accredited CABs, performing regularly on site assessments and witness audits. The tool developed seems to be effective, and the attention to the problem of all the people interviewed is high.
6. Report: is comprehensive and clear. All the relevant information are available and easy to be used by the planner, assessment teams and decision maker.
7. Generally, the competence of the assessment teams witnessed was high.
8. Wiki project (web based tool, used to share information on interpretation on standards, that collects the interpretation of all the members of the network, handled by a coordinator)
9. The Q Project: a mapping of the core processes, giving responsibilities, goals, and tool to measure the performance.

The findings raised during the last evaluation visit were considered by RVA and planned actions have been implemented according to the proposed timing.

A number of findings was raised during the evaluation by the team and presented to RVA at the final meeting. These findings are classified as 8 Non-Conformities (NCs), 12 Concerns (CNs) and 4 Comments (for details see chapter 4 of the full report). RVA will have to consider these findings and to provide objective evidence on the implementation of effective corrective actions for the NCs and action plans for the CNs.

The team is confident that RVA operates according to the international standards and proposes that RVA under condition of proper closure of the findings remains signatory of the EA MLA for

- **Testing laboratories according to ISO/IEC 17025 and ISO 15189**
- **Calibration laboratories according to ISO/IEC 17025**
- **Inspection bodies according to ISO/IEC 17020**
- **Certification bodies for:**
    - **Management systems according to ISO/IEC 17021**
    - **Products according to EN 45011 / ISO/IEC 17065**
    - **Personnel according to ISO/IEC 17024**

And becomes signatory for

- **Verification bodies for GHG according to ISO 14065 and Regulation (EU) 600/2012**

The EA Team recommends that Raad voor Accreditatie be admitted to the EA MLA for ISO 14065 & EU ETS, under the framework of the AVR, since all related findings regarding ISO 14065 and AVR as NC22 and NC23 from the peer-evaluation have been closed to the satisfaction of the EA Team.

XXX 11.03.2014

*) The summary report with the original signatures has been provided with the draft evaluation report

1 General information

1.1 Evaluation details

Evaluation is requested by MAC on October 2011 for the purpose of re-evaluation in the fields of calibration, testing, inspection and certification of Management Systems, Products and Persons.

RVA is also under evaluation for extension to GHG verification 14065 Directives/regulations.

1.2 EA Team

XXX MS Certification ISO 17021, Directives/Regulations, appointed as Deputy TL, but acting as Team leader considering that XXX at the very last minute was not able to participate to the evaluation.

XXX Product Certification EN 45011/ISO 17065

XXX MS Certification ISO 17021, Directives/Regulations

XXX Persons Certification ISO 17024

XXX Inspection and Notified Bodies Directives/ Regulations ISO 17020

XXX Testing and calibration laboratories ISO 17025

XXX GHG verification ISO 14065, Directives/regulations

XXX Testing laboratories ISO 17025, ISO 15189

1.3 Time-schedule, place and scope for the evaluation

The full evaluation was scheduled at the first stage to start on 25th of November, until the 29th

The Team leader XXX couldn't attend to the evaluation, so during the week from 25th of November to 29th the Deputy TL XXX took the coordination of the group, with the specific support of XXX

The team followed the schedule as decided in advance. However, the Deputy TL XXX on Wednesday morning attended to the Accreditation Committee, instead of the TL XXX that was not present that week.

Refer to the evaluation plan in appendix 5 for details of the evaluation.

From January 21 to 23 the Deputy TL XXX acting as Team leader, went back to RVA to complete the evaluation, considering that the appointed Team leader XXX was not available any more.

1.4 Name and contact details for AB

Dutch Accreditation Council (RvA) [*Raad voor Accreditatie*]

RvA Chief Executive:	Jan van der Poel, Chief Executive
Visiting Address:	Mariaplaats 21 D, 3511 LK Utrecht
Postal Address:	P.O. Box 2768, 3500 GT Utrecht
E-mail:	postmaster@rva.nl
Phone:	+31 30 2394500
Fax:	+31 30 2394539
web:	www.rva.nl

1.5 Legal status and description of structure

The RvA is an independent foundation registered by the Chamber of Commerce in Utrecht under number 41187815. The Articles of Association of the RvA (document RvA-R01 “Statuten”) set out the general rules for operation and for the structure. Refer to appendix 1 for details on the structure and key-staff.

1.6 Fields of activity

The RvA provides accreditation for all conformity assessment activities included in the current scope of the EA-MLA. Refer to appendix 3 for detailed information on fields and subfields or activities. The RvA published its scope of work in document RvA-BR010, which is available on www.rva.nl.

The RvA signed the following MLA’s / MRA’s:

EA	Calibration:	December 1989
	Testing:	May 1992
	Certification of Products, QMS and Persons:	November 1994
	Certification of EMS:	November 1998
	Inspection:	October 2003
ILAC	Calibration and Testing:	November 2000
	Inspection:	November 2012
IAF	Certification of QMS:	January 1998
	Certification of Products and EMS:	October 2004

1.7 Short History

The Raad voor Accreditatie, or Dutch Accreditation Council, RvA, was founded on 15 September 1995. The RvA is a merger of two accreditation bodies, NSS (NKO / STERIN / STERLAB) and RvC (Raad voor Certificatie). As a result of the merger in 1995, the RvA has taken over all duties and obligations of RvC and NSS. NSS itself was the result of a merger between NKO and STERIN/STERLAB in 1993.

NKO was the accreditation body for calibration laboratories. Before the merger it was part of NMi (Nederlands Meetinstituut), the Dutch Metrology Institute. NKO started its activities in 1975. STERIN and STERLAB were one organization dealing with the accreditation of inspection bodies and testing laboratories. The STERLAB activities started in 1986 and the STERIN activities followed around 1991.

RvC was established in 1981 for the purpose of supervising certification bodies. RvC was one of the first bodies in the world for accreditation of certification bodies and due to this it has always been very active accrediting certification bodies world-wide.

On 1 January 2008 the RvA merged with CCKL, an accreditation body for medical laboratories. CCKL was established in 1991.

In February 2004 the Dutch Government formalised the position of the RvA as a national accreditation body, after an evaluation of the accreditation and certification structure in the Netherlands. On the 1st of January 2010 the new Dutch law on accreditation came into force. This law “*Wet aanwijzing nationale accreditatie-instantie*” (law on the appointment of the national accreditation body), also referred to as Wanai, is the Dutch implementation of the EU Regulation (EC) No 765/2008/EC. With this law the RvA is appointed as the Dutch national accreditation body and is entrusted with the operation of accreditation as a public authority activity. The RvA is considered a so-called “*Zelfstandig bestuursorgaan*” (Autonomous Administrative authority) to which the Dutch Administrative Law Act (Awb) and the Framework Law on Autonomous Administrative Authorities apply.

1.8 Additional information

Cross Frontier activities:

The RvC started to provide accreditation outside the Netherlands in the eighties of the previous century, mainly in the field of certification of management systems (ISO 9001). Also after accreditation bodies were established in those countries, foreign CABs very often maintained the RvA accreditation. After the implementation of the European regulation (EC)765/2008 the RvA started to cancel the accreditations in Europe, except for those situations as described in article 7 of the Regulation.

Starting 1 July 2013 the RvA implemented a new CFA policy (refer to RvA-BR007). For countries outside the EA-MLA region having an AB which is signatory of the IAF-MLA or ILAC-MRA, this new policy means that the RvA will require the CAB to have an accreditation from the local AB before it can apply for an RvA accreditation. For existing accreditations in these countries the accreditation will be withdrawn on 1 July 2017, unless the CAB is, at that date, also accredited by the local AB. The RvA will in principle only conduct joint assessments at the foreign CABs together with the local AB. With this new policy the RvA implements the European principle of non-competition between ABs world-wide and also aims at improving international harmonisation between ABs.

Activities outside MLA scope

In addition to the activities mentioned in section 1.6, accreditation is provided to PT-organizers based on ISO 17043 and to Reference materials producers based on ISO Guide 34. The first PT-organizer was accredited (based on ILAC-G13) in August 1996. The first RM producer was accredited in May 2009.

Since the merger with CCKL in 2008, the RvA is responsible for the accreditation of medical labs according to the CCKL system. CCKL accreditation differs from the RvA accreditation on two main issues. First the criteria for accreditation are the CCKL requirements, which are slightly different from the ISO 15189 criteria, and second the accreditation procedures are not completely complying with the ISO/IEC 17011 requirements. CCKL is at the moment still a separate brand using its own mark, processes and procedures. A project for the transition of the CCKL accreditations to RvA accreditation is started in 2011. See clause 4.6 in section 2.1 for more details.

The RvA provides accreditation for ISO 14065 for the EU-ETS scope. The RvA has applied for inclusion in the MLA as soon as the MLA will be established. The first ISO 14065 accreditation was granted in May 2013.

Accreditation/assessments in the regulated area and cooperation with the authorities:

The RvA significantly improved the cooperation with the authorities in the last three years. With a number of ministries a system of regular meetings was established and with others the RvA succeeded in being invited to discuss accreditation and conformity assessment on case-by-case basis. Structured activities are for example:

1. On request of stakeholders the RvA reports annually on specific accreditation issues. For example for the Ministry of Infrastructure & Environment we report each year on the results of assessments at bodies accredited for EU-ETS. For the same ministry annually a report is made on accreditations in the field of soil protection and sanitation.
2. For the ministry of Social affairs the RvA performs assessments of (notified) bodies based on a specific set of requirements, which are for >95% overlapping with the accreditation standards. These assessments do not result in accreditation but are reported to the ministry together with a recommendation. Considering the EA resolution in this field and the recent discussions with the ministry, the RvA expects that the ministry will change its assignment/notification system the coming years and will use accreditation as the basis for assignment/notification.

3. For the Dutch Authority Consumers and Markets the RvA conducts assessments at bodies owing and issuing quality marks on consumer products. These assessments are based on a specific set of requirements and result in a grading of the marks which are published on the website www.consuwijzer.nl/Keurmerken.
4. The ministry of Internal affairs (department of housing) recently decided to use RvA – accreditation as the basis for notification for the Construction products regulation (with the exception of TABs).

2 Compliance with requirements

This section contains the report on the self-evaluation conducted by the RvA according to document IAF/ILAC-A3:07/2011 for each of the clauses in ISO/IEC 17011 (section 2.1) and the supplementary EA-MLA requirements (section 2.2). In section 2.1 and 2.2 also references to the documented system of the RvA are included. In these references the Dutch titles are printed in italic in case the document is only available in Dutch. For each of the clauses (or sub-clauses as appropriate) the evaluation team comments on the statements of the RvA. In section 2.3 the self-evaluation of the actions for the findings from the previous EA evaluation is included.

2.1 Clauses ISO/IEC 17011

Clause 4. ACCREDITATION BODY

Clause 4.1 Legal Responsibility

The RvA is a private not-for-profit foundation registered by the Chamber of Commerce in Utrecht under number 41187815. The Articles of Association of the RvA are published on the website, as document RvA-QA002 ("*Statuten*"). On the 1st of January 2010 the Dutch law on accreditation came into force. This law "*Wet aanwijzing nationale accreditatie-instantie*" (Law on the appointment of the national accreditation body), also referred to as Wanai, is the Dutch implementation of the EU Regulation (EC) No 765/2008/EC. With this law the RvA is appointed as the Dutch national accreditation body and is entrusted with the operation of accreditation as a public authority activity. The RvA operates under the ultimate responsibility of the Ministry of Economic Affairs.

Reference in AB's documentation:

RvA-QA002: Articles of association (*Statuten*)

Wanai (reference but not part of AB's documented system):

HTML Document

Team comments:

RVA is a Private company (not for profit).

RVA is a Foundation: Stichting Raad voor Accreditatie

The establishment of The Foundation has been sponsored by the Government and by Industries Association.

The appointment of Chief Executive is approved by Government (Ministry of Economic Affairs)

Annual account has to be verified by financial auditor, nominated by the Supervisory board, and then approved by Ministry of Economic Affairs.

Annual budget / fees: user council gives and advice, first approval by Supervisory Board and final approval by Ministry of Economic Affairs.

RVA has to follow the Administrative law (for appeal, public procurement).

The employees however are not civil servants.

Clause 4.2 Structure

The organization chart of the RvA is included in Appendix 1 of this report. The governance structure of the RvA consists of the Executive board, the Supervisory board, Chairs for Court of Appeal, Accreditations Committee, User council, Advisory Panel and the RvA office. The structure is formally detailed in RvA's bylaws ("*Huishoudelijk Reglement*") contained in RvA-R006. A major revision of this R006 documents will be published in the fourth quarter of 2013.

Executive Board

The RvA is managed by the Executive Board (EB) composed of two persons of which the Chief Executive is appointed by the Supervisory Board. At this moment the EB consists of the Chief Executive of the RvA and the Director Operations. The tasks, responsibilities and powers of this Chief Executive and the Director Operations are documented in job descriptions which are derived from the Articles of Associations (RvA-QA002). Besides the responsibility for managing the RvA, the EB is also responsible for the decision making on accreditation, for supervision of the finances, for developing and implementation of policies, rules and procedures and for contractual arrangements.

The Chief Executive is the RvA´s governor (so called *Bestuurder*), legal representative and is the chair of the EB. In absence of the Chief Executive the Director Operations is mandated to act on his behalf. The current Chief Executive was appointed on 1 January 2002.

The Director Operations is responsible for the accreditation processes in the RvA. He directly supervises the management of the four operational units. On 1 March 2013 a new Director of Operations was appointed after the previous Director left the RvA in December 2012.

A detailed description of the decision making authorities of the EB members is included in document QA003. In general the EB meets every one or two weeks. The decisions in these meetings are documented in minutes of the meetings.

Supervisory Board

The Supervisory Board (SB) is responsible for the supervision of the policies of the board and the general affairs of the foundation. The SB assists the EB by providing advice. In fulfilling their role the members of the SB act in the best interests of the foundation taking into account the social interest served by the foundation. The SB at this moment consists of five independent natural persons who are appointed based on their professional expertise. The composition of the SB is such that it ensures knowledge of the private and public sector, health care, quality management, research and technology. The members are not bound by mandate from interest groups. In performing their duty in the SB the members are guided by the interest of the RvA and the role of the RvA. The SB meets 3-5 times a year. The EB attends these meetings. The duties, powers and working procedures of the SB are described in the Articles of Association (RvA-QA002) and the Internal rules and regulations (RvA-R006).

Chairs for Court of Appeal The Chairs for Court of Appeal is established by the Supervisory Board to chair the objection (appeal) advisory committees that will advise the RvA´s Executive Board on objections (appeals) against any decision taken by the RvA. The members of the Chairs for Court of Appeal are graduated in Dutch Law (Master of Law). Currently the committee has two members; a third member will be appointed in September 2013.

Accreditations Committee

The Accreditations Committee advises the Executive Board on the granting of initial accreditations and of reaccreditation. Also the committee advises on the withdrawal of accreditations. The committee is composed of four independent individuals with expertise in one or more of the accreditation fields.

The members have no relations with the RvA's clients or other parties that could have an interest in accreditation and are not involved in assessments. With this the committee ensures the RvA's independent and impartial decision making. The committee's tasks, powers and procedures are described in RvA-R007. The committee meets every month, and reports annually to the SB. The advice of the Accreditation Committee is binding.

Advisory Panels

One of the objectives of the RvA is to establish and operate a transparent and harmonized system of accreditations, to ensure the market support for its accreditation services and for the conformity assessment activities conducted under its accreditation. It is the prime task of the Advisory Panels to advise the Executive Board on all matters that could improve this market support and to ensure that independency and impartiality are incorporated in the RvA's accreditation systems. Also refer to clause 4.3. The advisory panels that are currently active are:

1. User Council- a fixed advisory panel as stated in the articles of association
   The RvA has established a Council composed of the direct clients of the RvA. This council advises the Executive Board on operational issues, and ensures a systematic feed back on the RvA performance. The duties and powers of the User Council are described in the regulation for the User Council (RvA-R014). The initiating of the transition of the CCKL accreditation of medical labs to RvA accreditation was reason to reconsider the composition of the Council in 2013 in the field of the representation of these laboratories.
2. Stakeholder panel
   See under 4.3

The RvA Office

Operations

The RvA has four operational units responsible for the accreditation processes.

- Unit Team Leaders consists of the lead assessors active in the RvA accreditation system. External contracted as well as the permanent staff lead assessors are managed by the Manager of this unit. Also the unit is responsible for management of accreditation expertise within the RvA.
- Unit A and Unit B are responsible for the accreditation processes for testing & calibration laboratories, certification, inspection & verification bodies, PT-providers and RM-producers. It is the objective of the RvA to have two more or less equivalent units, both with a balance in types of accreditation, experience and back-ground of staff.
- Unit Health Care is responsible for accreditation of medical laboratories. In this unit also the accreditation system of CCKL is operated. In 2011 the transition of the CCKL accreditation to RvA accreditation is initiated.

Within the units A, B and Health Care we distinguish the positions of unit manager, account manager/project manager and project assistant. The Unit Team Leaders consists of the unit manager, lead assessors and a secretary.

Human Resources Management (HRM)

The main responsibility of the HRM department is to develop and implement the HRM policies to ensure that the RvA has the appropriate human resources available. This includes the recruitment, selection, contracting, training and qualification of internal and external contracted staff.

Finances, ICT and Facility Management

The department Finances, ICT and Facility management is responsible for the financial activities, budgeting and reporting, for the ICT systems and for facilities such as office, reception etc.

Quality Assurance

The Quality Manager of the RvA is responsible for maintaining the quality system, for coordination of the implementation of corrective and preventive actions and for coordination of the complaints and disputes. The Quality Manager coordinates the internal audit and management review activities. The Quality Manager reports to the Director Operations; the results of internal audits are reported directly to the Chief Executive.

Strategy and Development

The department Strategy and Development includes a Manager Strategy and Development a Legal advisor and a Policy officer. Depending on the need for development projects the department may include specific project managers, on a temporally and part-time base. The department is responsible for developing new services and methodologies and for establishing strategic plans.

General support

Two positions within the RvA report directly to the Chief Executive: The manager Strategy & Development and the Assistant to the Executive Board. The International Executive Secretary who is fully dedicated to the EA-MAC secretariat also refers to the Chief executive, but reports to the EA-Mac Chair.

Internal Committees

Within the RvA structure a number of (semi-)permanent committees are established. The terms of references of these committees are documented.

Having access to expertise is considered on two levels. First on policy level the RvA maintains a network of professionals in (quality) management as member in the Dutch Network for Quality experts (NNK), by having contact with several Universities (for example Erasmus University Rotterdam and technical University Twente), and taking part in seminars and other events on topics related to for example accreditation, conformity assessment, law enforcement and risk management. Also the improved relationship with Dutch authorities gives the RvA access to expertise on policy level. The regular contacts with its direct clients and with scheme owners, gives input for policy development and also for the second level of access to expertise, the operational level. In this level is also the large group of external experts (see under clause 6.1) important. Finally the RvA staff participating in national and international technical committees (EA, IAF, ILAC, ISO) and the cooperation with other ABs gives the RvA access to international expertise. The RvA encourages its staff to participate in network events, symposia and organisations for professionals like e.g. the association of safety experts, EMC experts, welding, College of Engineering, etc.

In the medical fields the RvA established over the past years an extensive network of contacts with organisations of all laboratory specialisms, with the Inspectorate for Health care, medical insurance companies, standard setting bodies for the medical field, the organisation for the ”Accreditation” of hospitals, the Ministry of health care, etc.

The stakeholder panel will, next to the Scheme owners we deal with, provide even further access to expertise.

Reference in AB’s documentation:

RvA-QA002: Articles of association (*Statuten*)
RvA-QA003: *Taakverdeling Directie RvA* (Allocation of tasks of the RvA Executive board)
RvA-R006: *Huishoudelijk Reglement* (Internal rules and regulations)
RvA-QM001: Quality manual chapter 5

Team comments:

The Supervisory board

The Supervisory Board of the RvA is comparable to the Supervisory Board of a commercial organisation. This Board ensures that the Executive Board realises the objectives of the RvA. Selection of the Members takes place on the basis of expertise and competencies.

It is preferable for the following competence areas to be represented on the Supervisory Board:

• commercial sector,

• public sector,

• research/technology,

• healthcare/medical,

• food and goods,

• quality.

The Members of the Supervisory Board are appointed for a period of three years and can be appointed twice for the same period.

Composition: Industry association make a proposal. The Supervisory board decides the numbers of people to be in the supervisory board, it is self-regulated. Seen the document that explain the job profile, membership (minimum 3, maximum 8 members, the best is to have 5 people). Supervisory board meets usually 5 times per year, and it is compatible with all other rules in RVA.

Supervisory board nominates the Chief Executive (that last 4 years, but can be renewed), and the Chief Executive appoints the Director of Operation.

Accreditation Committee

The Accreditation Committee consists of four members. They are appointed by the Supervisory Board on the basis of their expertise in accreditation, their integrity and independence (the Chief Executive and the chair of the Accreditation Committee makes the proposal to the Supervisory Board, that takes the decision on the members composition). The Accreditation Committee meets once a month. Its duty is to advise the Director/ Chief Executive about granting accreditations. In addition, the Committee has the power to advise on the suspension or withdrawal of accreditations of bodies that have been granted accreditation. It receives information from the Executive Board and the management about measures and sanctions against bodies. The Accreditation Committee does not take decisions. The decision-making is entrusted to the Executive Board. If the Executive Board has a different view from the advice of this Committee, the Supervisory Board will be heard. The Accreditation Committee reports annually on its activities to the Supervisory Board

User Council

The User Council is an advisory panel laid down in the Articles. This Council consists of representatives of the direct RvA clients. The Supervisory Board receives the minutes of the meetings, so that it can include the opinions of users in its deliberations.

The User council consists of 10 people (including 3 people from RVA) - this body gives advices on the Level of the fees, the service level.

Executive Board

The Director/Chief Executive is responsible for the realization of the Accreditation Council's objectives, its strategy and policy, and the developments resulting from these. He accounts for this to the Supervisory Board.

Objection Chairmen Committee

It is possible that there may be an objection to a decision by the RvA.

If that is the case, a Committee for Objection will be established which is chaired by one of the members of the Chairman Committee. This Chairman Committee consists of at least one and not more than five legally trained Members. If a notice of objection has been received, the Executive Board will appoint a Member of the Chairmen Committee to form an advisory committee for that objection. The Members of this Committee are independent.

They will never be Members of the Executive Board of the RvA and do not carry out any activities under the responsibility of the Executive Board. They are appointed by the Supervisory Board. This guarantees impartial treatment of objections.

There are six internal team/group/committee established in RvA. Regular meetings are kept and also memos of meetings are recorded. Former TAO (Technical Accreditation Committee) has been replaced 2012 by new committee (SATO). In SATO many important items have been handled e.g. transition period of new standard versions and relevant CPR-items (Construction Product Regulation).

The developing of accreditation of verifiers according to ISO 14065 and (EU) 600/2012 is handled and followed up. Other developing projects at AvR are CPR accreditation, shadow assessments and risk based assessments.

Besides internal committees RvA is involved with external/international committees in EA/ILAC/IAF-level. RvA is involved in the EA HHC-committee's Directive Nets by G. N. (Expertise holder in the field of 17020). G.N. is the representative of RvA in Network 15: Directive 98/37/EC Machinery Directive.

Clause 4.3 Impartiality

Impartiality of the RvA is assured at the levels of policy, operations and decision-making. The Supervisory Board approves the policies established by the Executive Board. The Supervisory Board is composed of persons with no specific interest in conformity assessment activities. The members of the board have sufficient background and operate in networks which enables the SB to safeguard our impartiality on policy level.

Stakeholder panel

In 2010 an analysis of stakeholders was conducted and based on that a new structure for participating of interested parties was proposed because the structure at that time was not effective. One permanent advisory panel was established. The proposed composition is as follows:

- CABs: 3 members;
- Clients of CABs: 3 members;
- Market: 2 members;
- Authorities: 3 members;
- Scientific Institutes and Scholars: 1 member;
- Standardisation: 1 member.

In 2011 and 2012 the RvA discussed this structure with relevant parties. Meetings took place for example with representatives from:

- Health care sector (laboratories, authorities, medical professionals, insurance companies);

- Agricultural and food related sector (producers, NGO's, authorities);
- Retailers;
- Industry (chemical industry, safety management);
- Scheme owners;
- Scholars.

At first little interest was shown from parties to participate in the RvA's advisory panel. A panel was therefore not established as timely as planned. The first meeting of these stakeholders is to take place on the 26th September 2013.

Operational impartiality

The following measures have been taken to safeguard the impartiality of the RvA's operations.

- Employees do not have a particular interest in conformity assessment or conformity assessment bodies or other stakeholders;
- Also external hired assessors and experts sign a contract in which they declare to be free from any possible pressure that might jeopardise their impartiality. For each assignment the assessors are requested to inform the RvA if for this assessment their impartiality might be questioned. For some assessments foreign experts are hired when an impartial expert cannot be found in the Netherlands;
- It is the RvA's policy to replace an assessment team for a client after four years, to prevent that the team might lose its objectivity.
- The account manager, who did not take part in the assessment, checks the reports of the assessment teams. Each proposal of the team for follow-up assessments or for changing the scope or to extent an assessment requires confirmation from the account manager;
- The RvA is not providing consultancy or in-house training to CABs.

To safeguard the impartiality of the decision making process the RvA has separated the assessments and the making of the accreditation decision. Assessment teams will provide a report and recommendation and the Chief Executive or the Director Operations will make the decision. The Chief Executive nor the Director Operations takes part in assessments. In case of initial and re-accreditation and in case of withdrawal of accreditation the decision is based on the recommendation of the Accreditations Committee, which is composed of four external experts thus providing an extra safeguard of the RvA's impartiality. The independent position of the Committee is illustrated by the number of cases that the committee did not agree with the recommendation of the team (4% in 2012, 7% in 2011 and 3% in 2010).

Non-discrimination

The RvA's rules for accreditation, as stated in BR002, and the other policy rules are not discriminatory. In policy rule BR010 the technical areas for which a CAB may apply are documented. The harmonised application of our rules and procedures is achieved by regular harmonisation meeting with our assessors, by establishing working instructions for our staff, where considered necessary, and by training of our staff in applying the rules and procedures.

The following changes that will be implemented in the course of 2013 and 2014 could be considered of discriminatory nature:

1. In 2013 the RvA will implement its revised cross frontier policy. This policy implies that the RvA will require a CAB in a country with an IAF/ILAC MLA/MRA signatory AB (outside the EA-

region) to be accredited by the local AB also. This revised policy also implies that the RvA will not provide newly developed accreditation services in foreign countries until sufficient experience is gained in the Netherlands. Beside this the policy implies that RvA will not provide its services in countries where the RvA is not able to provide accreditation at the same level of confidence as is done in the Netherlands. This policy is implemented to strengthen the IAF-MLA and ILAC-MRA and to minimise international competition between AB's on one hand, and to safeguard the level of confidence in accreditation on the other hand;

2. In the transition arrangement for CCKL accreditation of medical laboratories the RvA has implemented the possibility for a medical laboratory to choose for a reassessment regime of two years without surveillance in between, instead of the standard RvA regime of annual surveillances and a reassessment every four years. This possibility is only available for the accreditation of medical labs following ISO 15189 and not for other CABs. It should be understood that medical laboratories do not compete with other CABs. Also the RvA established objective conditions for the laboratory to qualify for this regime.

The RvA does not consider these new policies violations of clause 4.3.3 of ISO/IEC 17011.

Objectivity

Since 2010 2 complaints about lack of objectivity due to lack of the impartiality and independence of RvA personnel were received. They both were investigated and proved not to be correct. In some incidental cases a CAB did not accept a member of the assessment team because of potential conflicts of interests. In several cases the objections were well grounded by the CAB and accepted by the RvA, resulting in another team composition.

Commercial or financial pressure

The RvA is a not-for-profit organization and commercially independent. The involvement of the Accreditation Committee in the decision making is an important measure in this respect. The solid financial situation (see under clause 4.5) and the large number of accredited bodies ensure that the RvA will not be reluctant to withdraw the accreditation from a body because of financial or commercial reasons.

The RvA has no turnover targets, the budget is based on an estimation of the required assessments, based on our policy rules, for the accredited bodies in a given year.

If a tendency would be developed to spend more assessments days than strictly required (to increase the turnover) the clients of the RvA, through the User Council, have the possibility to inform the Supervisory Board.

Other activities

Besides accrediting CABs based on the harmonized standards, the RvA provides the following services:

- Accreditation of PT-providers and reference material producers (the RvA was appointed by the Ministry of Economic Affairs as the national accreditation body);
- Assessment of bodies for appointment/notification by the ministry of Social Affairs and Employment;
- Assessment of organizations that own private consumer marks for including the mark on the website Consuwijzer.nl, according to the requirements of the Dutch Authority Consumers and Markets;
- Assessment and acceptance of owners of conformity assessment schemes;
- Providing consultancy and training services to developing accreditation bodies.

None of these activities affect the impartiality of the RvA. Although the RvA itself is no longer providing training services to the market, the RvA staff may be involved in training activities, for example act as trainer in training activities organized by the Dutch Standardisation Institute NEN. On ad-hoc basis the RvA organizes meetings with groups of CABs or other stakeholders to provide information on specific subjects. Examples are:

- The use of the revised RvA-T033 for the assessment of schemes (two meetings in 2011);
- Implementation of EA-2/17 (one meeting in 2012);
- Accreditation of medical laboratories (one meeting in 2011 and three meetings scheduled for 2013 and 2014).

Related bodies

Until 2010 the RvA has been an independent private body. After implementation of the new law on the appointment of the national accreditation body in 2010, the RvA is no longer completely independent from the government. According to Dutch law the following influence from the government exists:

1. The appointment of the Governor(s) of the RvA requires approval from the Minister of Economic Affairs.
2. Modification of the Articles of Association of the RvA requires approval from the Minister.
3. The annual budget, including the fees-schedule, requires approval from the Minister.
4. In very exceptional situations, where the RvA has taken a decision that may be a violation of the constitutional rights or may impose a threat to state security, the Minister of Economic Affairs has the power to annul such a decision.

As the Ministry of Economic Affairs has no direct interest in accreditation, except that, as a notifying authority, it may use accreditation, the above possibilities of influence are not considered undue.

Under the same Ministry of Economic Affairs the Food and product safety authority (NVWA) resorts. This agency has accredited laboratories and an inspection body. The RvA communicates with the Ministry through the Director of the Department Competition and Consumer Policy, which is part of the Directorate-General for Energy, Telecommunications and Competition. The NVWA is headed by the Inspector General Food and Consumer Product Safety Authority who reports directly to the Secretary General of the Ministry. This means that the activities of this related body do not compromise the confidentiality, objectivity and impartiality of the RvA.

The Ministry of Defence, Ministry of Finance and Ministry of Security and Justice have testing laboratories that are accredited by the RvA. Also the activities of these related bodies do not compromise the confidentiality, objectivity and impartiality of the RvA.

Communications with the Ministry of economic Affairs are governed by a Protocol that has been Published in the Dutch national gazette.

In a recent review (april-may 2013) by the College of Secretaries General about the necessity of maintaining the status of ZBO for all Autonomous Administrative Authorities it was concluded that the ZBO-status for the RvA has to remain untouched in view of the European Regulation 765/2008. The final conclusions still have to be reported to the Minister of Interior Affairs, the coordinator for the relevant paragraph in the Cabinet Plans for their current mandate.

Reference in AB's documentation:
RvA-QA002: Articles of association (*Statuten*)
RvA-QM001: Quality Manual Chapters 5 and 8
RvA-R007: *Reglement Commissie Accreditaties* (Regulation for the Accreditation Committee)
RvA-ToR019: *Terms of Reference Adviespanel* (Terms of Reference Stakeholder panel)
Communicatieprotocol EZ-RvA (reference but not part of AB's documented system):

Adobe Acrobat Document

Team comments:

Stakeholder panel

The rules are self-decided by the Panel. Seen the draft report of the first meeting (item discussed: analysis of interested parties, terms of reference, involvement of interested parties, arrangements for bi-annual event, scheme owners grouping).

The assignment in the committee is to the organization, and not to the person.

Balance is guaranteed by the fact that no party predominates the others, even if the numbers of people are not the same for all the parties. The composition is balanced.

The parties mentioned in the ToR are (max. members):

- *Governmental Authorities (3)*
- *CABs (3)*
- *Market/ clients of CABs (6)*
- *Scientists/scholar (2)*
- *Supporting institute: NEN, NMI (2)*

The stakeholder panel itself has confirmed that the composition is adequate and that they themselves as a group are a balanced representation of the parties interested in accreditation.

Voting is described in the ToR. A vote is valid if in group of the persons that are present no single party is dominating and the quorum of 2/3 of the members is reached. This ensures that there will be no decisions taking dominated by one party. However it may occur that a party is not be represented during a meeting in which a decision has to be taken. This is the responsibility of the person representing this party. For voting the majority is the majority of the members present when the voting is done.

Training service: open to everybody, usually for free and with the collaboration of the local standardization body.

Decision maker

Competence is required in Accreditation activities, and not on the accreditation standard or certification scheme.

C607 – EN 45011 – positive proposal of the lead Assessor. However the committee 8 April 2013 said that the Lead Assessor did not investigated enough about impartiality / independency, and so the committee required to do another assessment. The AB gave this information to the CB by phone (and recorded this communication - 27.03.2013 mail). It is recommended to formally give the information about the decision taken by the Accreditation Committee (see finding #5)

Financial pressure

- the biggest CAB is responsible for a percentage of 4-5% percent of RVA turnover.

- RVA analyses also the outcome, in order to detect it is too much linked to one supplier (eg: external assessor)

Related bodies

Finding: the risk analysis for related bodies, included into the management review, does not take into considerations the related bodies that are linked to RVA by a contractual arrangement (eg: cooperation agreements with agencies of some Ministries, such us Dutch Authority consumers or Food Inspection Agency – this last one has some accredited laboratories and an inspection laboratory). (see finding #1)

Clause 4.4 Confidentiality

All information relating to RvA clients is considered to be confidential, as stated in RvA policy rule RvA-BR002. The RvA only publishes information concerning the status and scope of accreditation. All RvA

personnel and external assessors and experts maintain confidentiality of information, and have signed a written declaration to do so before carrying out any work. The same requirements apply to the members of the Accreditation Committee because they are provided with reports of assessments.

The confidentiality issue has been subject to discussions with legal experts. The special status of the RvA since 2010 implies that the RvA is considered a governmental body to which the Government Information (Public Access) Act applies. This act makes it possible for everybody to request information related to an administrative matter, and accreditation is considered an administrative matter. The RvA has had six of these requests since 2010 and for one of these cases currently an appeal case in the court is open, following the refusal of the RvA to provide specific information on an assessment conducted by the RvA. Based on a study and recommendation from a Dutch legal expert in this field, the principle applied by the RvA in this is that no details of the processes of the CAB or details of the assessment results or personnel information will be provided.

Computers and the network are protected by password access. Access to the RvA offices is restricted via an electronic pass; visitors are registered. It is the RvA's policy not to allow representatives of clients or other stakeholders to the areas where accreditation files are processed. Visitors to the RvA are accompanied.

Companies involved in subcontracted activities (IT-services, Cleaning services, Archive disposal) have signed contracts including confidentiality requirements.

Reference in AB's documentation:
RvA-QM001: Quality Manual, chapter 13
RvA-BR002: Policy Rules Accreditation, chapter 12
RvA-W027: *Dossiervorming tijdens en na het accreditatieproces* (Working instruction Keeping records in the accreditation process)

Team comments:

As the whole confidential items are in a good level. When looking personnel records it was verified that assessors and experts have signed declaration of confidentiality. The accreditation body has confidentiality policy (BR-002) to handle client's material in confidential way. Anyway sometimes client's documents are sent to technical experts by e-mail without encrypting. It is not clear how the accreditation assure the confidentiality of client's documents in case mentioned. (see finding #13)

Assessors has to sign two documents before working: F008 conflict of interest / F007 confidentiality (eg: ADP in 2012 and CLS in 1996, HJB in 2006).

F007 is also used for internal people.

Procedures and policies are in place in order to avoid bad behaviour of users of IT appliances.

Seen the internal room server that is located in the building.

No strategic plan is in place to minimize the risk to lose confidential data (eg: penetration test, security audit to the internal IT department and to the external datacentre, plan the maintenance on IT devices and keep the relevant records) (see finding #13)

Clause 4.5 Liability and Financing

Liabilities of the RvA are covered by the Professional Indemnity insurance under number 72931398 of 16/12/2010 (€1.25m). Besides this the RvA has insurance to cover potential liabilities for members of the Board and Supervisory Board under number VCB9601130 of 7/4/2011 (€2m).

The RvA is a not-for-profit organization. The policy is to have a fair financial reserve as this contributes to the independency of the RvA from its clients. The upper limit of this reserve is set at 60% of fixed staff costs. In case of additional profits these will be used for investing in means to improve our services or lowering the fees for accreditation.

The fees and fee structure are documented (decision RvA-D001); a revised version is published every year. The policy is that clients of the RvA pay for the assessments that are needed to obtain or maintain accreditation, based on the man days spent for an assessment. Besides this the accredited bodies pay a fixed annual fee which reflects the general costs of accreditation.

For tasks that are beyond the direct interest of our clients, but where there is a national interest, the RvA receives a limited governmental financial support (approx. €200.000/year).

Every year the RvA makes an estimation of the resources needed, and the revenues needed to cover the costs associated with these resources, based on the expected number of assessment days to be spend. Based on this the RvA will allocate budgets and the fees are established. By law the budget and the fees of the RvA need approval from the Minister of Economic Affairs. The published annual report includes the financial figures which are approved by an independent accountant. Based on this report and the approval of the Supervisory board, the Minister of Economic Affairs has to approve the annual accounts. Table 4.1 summarizes the financial results since 2010, distinguishing the work under and outside the Law on accreditation. The latter mostly concerns the CCKL accreditations.

Table 4.1: Financial figures (1.000€)

	2010	2011	2012
Activities under Law of accreditation			
Incomes	8.439	9.046	9.975
Costs	8.367	9.023	9.799
Results	72	23	176
Activities outside Law of accreditation			
Incomes	2.244	2.194	2.447
Costs	2.277	2.077	2.413
Results	-33	117	34

Reference in AB's documentation:
RvA-D001: Fees and Charges Decision
RvA-QM001: Quality Manual, chapter 3

Team comments:
Not for profit company. 3 millions of Euro of reserves.
The income of the RvA is generated particularly from activities carried out on the basis of rates. RvA determines the rates on the basis of a discussion of the budget with the User Council and after approval by the Supervisory Board and the Minister of Economic Affairs. The activities level was approx. 5% higher than estimated. This was particularly caused by:

- *extra assessments in connection with the transition to the new version of the 17021 standard which appeared in 2011;*
- *a larger number of extension assessments than anticipated;*
- *the SZW project.*

Although this involved having to hire an extra number of external assessors, nevertheless a higher positive result was able to be achieved. The result is added to the reserves.

Coverage for professional indemnity.

Professional Risk - Damages for job performed by RVA and its collaborators: 2.5 Million per case, and 3.5 million totally

Decision taken by Supervisory board on 1.12.2010, to increase the insurance coverage from 1.1 million to 2 million.

Insurance 1.250.000 per case for damage to person or things

Insurance 1.250.000 per case for financial damage to other organization

Total maximum is 2.5 Million

No ethic code in in place – however some rules in Quality Manual and labour contract (eg: gift policy, usage of IT devices)

Income for Activities outside Law of accreditation: approximately 2 million of incomes for CCKL Medical laboratory scheme (that will be moved to Accreditation in few years). Other activities are training, consultancy to other AB (Moldova the moment), support for Ministries (assessment that are not accreditation), EA for EA Secretary…

According to transition plan (CCKL to ISO 15189) until summer of 2019 all medical laboratories will be accredited under ISO 15189:2012. So until 2019 most of the work (and finances) outside the Law of accreditation will move inside the Law of accreditation.

Clause 4.6 Accreditation Activity

The accreditation services provided by the RvA are stated in document RvA-BR010. The following accreditation services are provided under the EA-MLA:

- Calibration laboratories ISO/IEC 17025;
- Testing laboratories ISO/IEC 17025;
- Medical Laboratories ISO 15189;
- Inspection bodies ISO/IEC 17020;
- Management System Certification Bodies ISO/IEC 17021 covering the standards ISO 9001, ISO 14001, ISO 13485, ISO/IEC 20000, ISO 22000, ISO/IEC 27001, OHSAS 18001, ISO 50001, ISO 3834 and a number of national schemes;
- Product certification bodies EN 45011 and ISO/IEC 17065;
- Personnel certification bodies ISO/IEC 17024.

Outside the EA-MLA the RvA provides accreditation of:

- Verification bodies using ISO 14065;
- Environmental verifiers under EU Council Regulation (EC) No.1221/2009 on an Eco-Management and Audit Scheme (EMAS);
- Proficiency testing providers ISO/IEC 17043;
- Reference Material Producers ISO Guide 34. In 2013 the RvA changed its policy with respect to use ISO/IEC 17025 in addition to ISO Guide 34 for these accreditation in line with ILAC resolution GA 16.20;
- Medical laboratories using the CCKL code of practice, roughly based on ISO 15189:2003.

Since 2010 a number of new fields were developed by the RvA, for example the accreditation of:

- Certification based on ISO 50001 Energy management;
- Opinions and interpretations for DNA testing;

- GHG validation and verification (ISO 14065);
- Notified Bodies using EA-2/17 as a guidance.

Appendix 2 provides details of the statistical data on the RvA's activities. The development in the number of RvA accreditations within the EA-MLA fields is illustrated in table 4.2. Mergers have had a decreasing impact on these numbers in testing and certification area; new applicants compensate this decrease slightly. In management system certification also the number of foreign accreditation decreased. A overall lack of interest in the Dutch market for persons certification caused a decrease in this area.

Table 4.2: Accreditation in last four years (at 31 December of the year)

	2009	2010	2011	2012	July 2013
Calibration - 17025	62	60	57	59	58
Testing -17025	231	233	242	246	243
Medical testing - 15189	7	8	11	11	11
Inspection - 17020	118	123	128	134	134
Product Certification - 45011	49	50	50	52	53
Man. Sys. Certification - 17021	92	91	92	86	81
Persons Certification - 17024	12	10	9	7	6

Whenever an application for accreditation is received, the RvA reviews the application to determine whether the requested application:

- Should be accepted considering the policy of the RvA and the requirements of the European Regulation (EC) 765/2008/EC;
- Can it be accepted considering the competence of the RvA (RvA-BR10).

If the result of the review is that the field in question is not yet covered by the RvA (not included in RvA-BR010), but it is also decided that the RvA should develop accreditation for this field, a development project is initiated. Because the development of new fields showed to be not as effective as expected, it was decided in 2011 to establish the Steering Committee for Accreditation Developments (SATO). This SATO decides on development projects and coordinates the projects. The department Strategy & Development was extended with 0.5 people early 2013 and will be extended by another person later 2013.

The development with the most significant impact in 2013 and coming years is the transition of the CCKL-mark accreditation of medical labs to a RvA-mark accreditation based on ISO 15189;2012 as practised in the EA and ILAC agreements. The RvA already started accreditation of ISO 15189 in 2004 and currently has granted eleven accreditations in this field. Despite this and despite the fact that the CCKL-mark accreditation criteria are covering for more than 80% the ISO 15189 requirements, the transition of the accreditations based on the CCKL system to RvA-mark accreditation is considered a development project. The main reasons for this are:

- Accreditation procedures of CCKL do not comply with requirements with respect to frequency and extent of assessments (clause 7.11 of ISO/IEC 17011);
- The ILAC and EA documents are not considered by the CCKL system (e.g. scoping, proficiency testing);
- The practices in grading of findings do not ensure that non-conformities are closed within an acceptable time frame;

- Procedures for qualification and monitoring of assessors and experts are not in line with ISO/IEC 17011.

The transition to RvA accreditation will start in 2014 (after a number of pilots in 2013). It is expected that the last CCKL accreditation will be transferred to an RvA accreditation before July 2019. The RvA will conduct the transition assessment during a re-accreditation assessment but a pre-assessment consisting of a document review will first be conducted. The 2012 version of ISO 15189 will be used from the start. The transition arrangement is documented in a position paper; the plan is documented in a project plan.

It is the RvA's policy to draft a specific accreditation protocol (SAP) for activities in case specific rules are established for accreditation (for example for scoping, for witnessing or for documents required). See our website for the list of SAPs.

The RvA uses the guidance and application documents published by EA, ILAC or IAF. Our policy is not to have explanatory documents on issues covered by international guidance or application documents. If however the RvA feels the need, based on the experience during assessments, to draft explanations to standards these will be published as so-called T-documents. Also T-documents may serve to explain accreditation procedures. See our website for the list with T-documents.

In the Netherlands a number (currently 28) of scheme owners is accepted by the RvA. These organizations are assessed based on our Regulation RvA-R013. In addition to this an important document is explanatory document (RvA-T033) for assessment of schemes for conformity assessment.

Reference in AB's documentation:
RvA-RB002: Policy rule accreditation, chapter 3
RvA-BR010: Policy rule for the field of Activities of RvA
RvA-QM001: Quality Manual, chapter 4

Team comments:

SATO: at the moment 15 project are running.

ISP - Amount of the inspection bodies has been quite stable (appr. 130) during the last years. Accreditation has been started to be used explicitly for notification purpose more than earlier. Anyway also earlier same standards have been used. There are accredited inspection bodies involved with directives e.g. MI-directives. RvA has implemented the guidance EA-2/17 in use when assessing notified bodies. Also the reference to EA-2/17 has been added to the scopes when relevant. RvA makes separate accreditation decisions (e.g. inspection, testing, certification) covering all needed modules of directives covering clients' needs.

Med. Lab - In the field of medical laboratories there are 2 transition periods overlapping (Transition from ISO 15189:2007 to ISO 15189:2012 and transition from CCKL to ISO 15189:2012). Both transition procedures were checked and fulfil the requirements. First accreditations according these transition procedures are performed (2 labs 15189:2007 to ISO 15189:2012 and 1 lab (witnessed Pilot-Lab) CCKL to ISO 15189:2012). After having experience with 5 Pilot-Labs from different sectors (Pathology, Genetics, IvF, Clinical Chemistry, Microbiology) the Transition procedure will be reviewed.

RvA has to transit 260 medical labs from CCKL to ISO 15189. Transition includes not only performing the assessments but also inform the laboratories and train sufficient assessors. RvA started a Transition project to manage this task. The project includes all relevant points that are necessary to organise such a transition under the requirements of EA-MLA e.g. getting technical expertise, getting acceptance in the market, preparing the required documents etc. Because of its long experience in accreditation, even in accreditation of medical labs according to ISO 15189, RvA organized the transition based on the project very well and in a way that fulfils the requirements of the MLA.

Even for such an experienced AB it is a big challenge to organise the transition of such a big number of laboratories incl. all the appropriate work.

The way chosen by the RvA (transition latest during the next re-assessment of the labs) is accepted by the market, by the scientific societies and seems to be possible considering the resources that are available.

GHG - A project plan was developed for the accreditation processes on accrediting verification bodies according to ISO 14065 and AVR and includes the development of e.g. AVR SAP V001 and training of personnel. The plan covers the start of the project in 2012 and ends with the implementation of the process in 2013 and 2014.
During phase I and II of EU/ETS accreditation of verifiers was done according to ISO 17020 and EA 6/03.

Certification: Steering Committee for Accreditation Developments (SATO) decides on development projects and coordinates the projects. The Strategy and Development Department is responsible for developing new services and methodologies and for establishing strategic plans.

Information on on-going projects is kept in spread sheet of projects with adequate information on the project plan template.

Following projects were reviewed during the office evaluation

- *End of Waste programme,*
- *Accreditation of opinions & interpretations in DNA analysis.*

Transition to new standards is made in a systematic way. RvA established a transition arrangement for ISO/IEC 17065. There is a plan for transition to ISO/IEC 17065:2012. This plan is consistent with the international arrangements. The RvA informed all accredited and applicant bodies about this arrangement and published T037 Implementation of ISO/IEC 17065:2012 document.

The detailed procedure including the technical preparation, communication plan and planning of transition assessment is suitable to ensure a smooth and effective transition.

RvA assesses scheme owners. These organizations are assessed based on Regulation RvA-R013 (Regulation for The Assessment and Acceptance of Scheme Managers).

For assessment of schemes for conformity assessment RvA published RvA-T033 document which is in line with EA 1/22.

RvA accredits product certification schemes based on International / National standards or specific requirements of professional organisations. Some examples for product certification schemes are as follows; GlobalGAP, KOMO certification scheme , GMP+ Feed safety assurance, BRC, etc.

All the policy rules and Decisions of financial issue are announced in the Government Gazette directly by RVA.

Clause 5. MANAGEMENT

Clause 5.1 General / **Clause 5.2** Management System

The management system of the RvA is based on ISO/IEC 17011 and the RvA Articles of Association. Also the requirements from the Regulation (EC)765/2008, the Dutch Law on Accreditation and the requirements derived from the EA-MLA, IAF-MLA and ILAC-MRA are incorporated in the management system.

Due to the appointment of the RvA as the Dutch National Accreditation Body (public accreditation services) as of 01/01/2010, the RvA developed a new type of document, the policy rules (BR-documents). These policy rules replace the regulations and policy documents that the RvA used before.

Because the already accredited clients have an agreement with the RvA based on the previous regulations and policy documents these documents will remain active until all accreditations have been transferred to the new system. For the RvA accredited CABs the transition period of EC regulation 765/2008 will end 31/12/2013 because all accreditations which were valid on 1/1/2010 will have expired before that date.

Documents that are of interest for accredited or applicant bodies are written in Dutch and/or English. The internal documents are written in Dutch. Some of these documents are also translated into English. The Dutch version of all RvA documents is the legally binding document.

At the end of 2012 the RvA started a Quality improvement project aiming at a major revision of the documented management system. A revised description of the processes will be included in the Document Control System Vivaldi and the internal documentation will be reviewed and revised where necessary. It is expected that the revision will be completed by the end of 2013. An external consultant was hired to assist the Quality Manager in this project.

Based on the mission, vision and core values, the RvA has formulated its policies and objectives. At least annually, during the review of our management system, the adequacy of these policies is reviewed, and where relevant, reconfirmed or modified. In 2012 the RvA introduced the so-called A3 planning system. In this system the annual objectives and performance indicators are established. Actions are derived from these indicators and monitored during the regular management meetings. The use of this A3-method is supported by a web tool.

One of the actions planned for 2013 is the revision of the SWOT analyses. In several meetings with different groups of staff and stakeholders the Strengths, Weaknesses, Opportunities and Threats are identified (July – September 2013). The first meeting took place on 1 July 2013; more than 70 persons (internal staff) participated in this meeting. In October 2013 the management team will redefine the policies and objectives for 2014 and the coming 4 years based on the results of this analysis.

Effective implementation of the documented system has been identified during the internal audits as a weakness of the RvA. In the Quality improvement project therefore several meetings have been organised to explain and discuss procedures and processes. Also the training of new staff in the RvA quality system has been improved. Finally the involvement of staff members in the development and revision of documents improves the knowledge and acceptance of the documented system. Since 2011 project groups for example achieved:

- Revision of application forms;
- Developing new instructions for processing applications;
- Improvement of the cross frontier planning;
- Development of instructions for the decision making process

The RvA has appointed a Quality Manager who is responsible for the control of the management system, including for reporting on the performance of the system to the top management. The Director Operation holds final responsibility for the quality management system.

Reference in AB's documentation:
RvA-QM001 Quality Manual, chapter 7
Functieprofiel Kwaliteitscoördinator (Job description Quality Manager)
Functieprofiel Operationeel Diecteur (Job description Operational Director)

Team comments:
The quality manual follows the ISO 17011 structure, with reference to the relevant procedures and instructions, when needed.

Clause 5.3 Document control

The documented management system consists of documents for internal use and documents for external use. The procedures for development, control and distributions of RvA-documents are documented in procedure RvA-P010.

For use by the staff the documents are made available through the RvA intranet (supported by the Vivaldi system). Also the external assessors have access to the intranet. The Quality Manager, who is supported by a secretary, is responsible for the control of the system and also for the publication of external documents on the RvA website.

The Vivaldi DCS ensures that documents are approved by the right persons prior to publication, that always the correct version is available and that the documents are reviewed on a regular basis.

The management system related to the CCKL accreditation system still is a separate system. In the frame work of the transition project the systems will be integrated.

Reference in AB's documentation:
RvA-P010: *Procedure voor het opstellen, beheren en distribueren van RvA-documenten* (Procedure document control)

Team comments:

The approved documents of the quality systems as policies, procedures, templates and job descriptions are available in the database system Vivaldi Document Control though much of the documents that has been updated (however due to the implementation of ISO 14065 and AVR in the accreditation scope was not approved and available the database Vivaldi) See finding #23.

During the evaluation it was noticed that Vivaldi is easy to use. All evaluated documents in the assessment were approved in use

Vivaldi is giving the opportunity to share the responsibility on the developing of the documentation, so to avoid too much work on too few people, and it gives the opportunity to receive the inputs from the people really competent on each issue. Another good thing is that it is possible to look for one single word in all the documents. With the module P2F (process to flow)is also possible to follow the process step by step, tracing the activity that the relevant functions have to do.

Clause 5.4 Records

The policy of the RvA is to develop recording and filing procedures that minimize the use of physical files and space. Developing digital records is a consequence of this policy and, with the up-date of the computer system RADAR, this will be further implemented in future.

The consequences of the Dutch Law on accreditation on the system for keeping records were analysed in 2012 and resulted in a proposal for a project to revise the filing system. In the meantime the current instruction W027 remains valid.

The IT-staff in the Department FIF is responsible for the control of the network and for back-up procedures.

Clause 5.5 Nonconformities and corrective actions / **Clause 5.6** Preventive actions

Whenever audits, reviews, client feedback, complaints, disputes or other events reveal needs or opportunities for improvements an action is formulated by the manager responsible for the process to be improved. The Quality Manager coordinates and supervises the implementation of the corrective actions and initiates the verification of the effectiveness, where necessary by organizing extra internal audits on the issues in question.

During the internal audits in 2011 and 2012 findings were raised that implementation of corrective actions was often not effective, resulting in re-occurrence of findings and long periods needed for closing findings. In 2012 the management team decided to start a Quality Improvement project to improve the mechanisms for implementation of corrective actions and to improve the process control in the RvA. An external consultant was hired to lead the project. Major achievements of the Quality Improvement project thus far are:

- Process owners have been defined for all key processes;
- Process descriptions have been improved;
- Staff has been involved in establishing the process improvements and the descriptions;
- Using the Plan-Do-Check-Act cycle has been introduced in 2012 for all internal projects.

It is the responsibility of each employee of the RvA to identify actions to prevent possible quality problems or to improve our system. The Vivaldi system gives each user the possibility to make proposals to improve procedures, instructions or other parts of our system. In 2012 a total of 54 improvements proposals were filed in Vivaldi. In 2013 until June a total of 28 proposals were recorded.

In 2011 the RvA started a Steering group for review of the business processes (SBB). In the SBB the possibilities for improvements in our processes were identified and used to revise procedures, instructions and other elements of the management system. A total of 15 projects were identified and initiated by the SBB; the achievements were, for example:

- Scope extensions: resulted in improvement of the forms and a new instruction;
- Decision making document: resulted in a new instruction and templates;
- Suspension procedure revised and working instruction was established;
- Collecting information for the next assessment: resulted in changes in RADAR and a working instruction.

Besides these projects a number of ad-hoc preventive actions were initiated in the last years, for example:

- In case of a CAB not responding adequately to the raised nonconformities the unit managers will first take actions instead of the Director Operations, to ensure more distinct levels of escalation;
- The expiry date on the RvA certificates and the scopes are set to the first of the month instead of the date of the decision to prevent that certificates expire before the decision on a reassessment is taken;
- The tasks and mandates for decisions were clarified and documented;
- Establishing of performance indicators for the different parts of the process;
- The RvA legal expert conducted a risk assessment on the issue of confidentiality related to legal requirements in the field of the Government Information (Public Access) Act, resulting in a better understanding of the limits of legal validity of the confidentiality statement;
- The RvA legal expert reviewed the contracts with our external assessors and experts to clarify responsibilities and liabilities;
- The RvA legal expert together with legal experts from the Ministry of Social Works established a protocol for information exchange to clarify the expectations of both the Ministry and the RvA and prevent exchange of information that could jeopardise the confidentiality requirements.

In the second half of 2013 the use of Process-to-Flow (P2F) module, which is part of the Vivaldi system, will be introduced to assist in controlling deadlines and completion of actions.

Reference in AB's documentation:

RvA-QM001: Quality manual, chapter 11

Team comments:

RVA is analysing all the processes (re-engineering), in order to avoid mistakes and duplications. The project should be finalized by 1 July 2014.

There is a table with the summary / handling of all the findings issued in the year, from internal audit, external audit, or internal findings.

The idea is to include in this table all the action, in order not to lose the improvements that is changing the Management System.

The same is for Preventive actions, now days are included in Management review and internal meeting.

After the meetings the actions are recorded and responsibilities are assigned.
Seen the Operational manager meeting report, taken at the 14.01.2014
19 different regular internal meeting take place in RvA, with a different frequency established.

Clause 5.7 Internal Audits

The internal audits are carried out according to an annual programme which ensures that on a yearly basis the audits will address all elements of the system and all types of activities. Also the closure of findings from previous audits and external evaluations will be verified

The Quality Manager is responsible for establishing the programme, which needs approval from the Chief Executive, and for assigning the audit team. Internal audit teams are knowledgeable of the criteria in ISO/IEC 17011 and the members are independent from the processes to be audited. To ensure effective audits in all fields of accreditation the team will be competent in all accreditation standards. At least one member in the team is a trained EA evaluator.

Since the previous EA evaluation in 2010 the following audits were performed:

September 2013:	Follow-up of the findings in 2012 and of the effectiveness of the quality improvement project, and vertical audits on the accreditation process, by a two person team (results not yet available when drafting the self-evaluation report)
June 2012:	A four person team spent more than twelve man days and audited all units and departments and verified implementation of corrective actions for previous audits and peer evaluation. Result was one overall NC stating " … the (continuous improvement of the) effectiveness of the management system in accordance with the requirements of the standard is not demonstrated…";
September 2011	A three person team spent more than twelve man days. Twelve NC's were reported amongst others in the field of corrective actions, monitoring, personnel records, complaints and the management system documentation. As of 2011 also the Unit Health care (Unit Z) is included in the internal audit programs in preparation of the transition at hand.

Reference in AB's documentation:
RvA-QM001: Quality Manual, chapter 11

Team comments:
Instructions are in the Quality Manual.
Audit team: only qualified auditors, and at least one team member has to be a peer evaluator.
At least 1 file for each accreditation standard, and not for each scheme
16 days, 4 assessors.
In 2012 the internal auditors raised 1 NC, linked to the fact that some time there are problems that came back in few time, not solved (effectiveness of continual improvement measures).
In order to sort out this finding, RVA decided to map all the processes in Vivaldi, going through the activities, giving responsibilities and goals, and identifying the owner of the processes (The Q Project).

Clause 5.8 Management Reviews

The review of the management system by the RvA's management is conducted during various meetings of the Management Team under the responsibility of the Chief Executive. During these meetings several issues (e.g. new areas of accreditations or other changes that could affect the management system, feedback from interested parties, trends in non-conformities, participation of the RvA in international activities, related bodies) that relate to the adequacy and effectiveness of the management system in satisfying the relevant requirements are discussed.

Once a year the overall conclusions are discussed in the context of the planning for next year. To this end the Quality Manager drafts a report in which an overall summary is given on the suitability of the management system.

The results of the discussion of this report in the Management Team meeting and the conclusions are included in the final revision of the report. During this meeting the actions following the management review will be assigned to the manager responsible for the issue in question. The final report is discussed with the Supervisory Board.

At the time of drafting this self-evaluation report no management review has taken place yet. In 2013 a major revision of our quality system is planned and a SWOT analysis will be conducted (see under clause 5.2). The Management review will be conducted in the context of these activities in October 2013.

In 2012 the review was conducted in October based on the report drafted by the Quality Manager; the final report was discussed in the management team meeting in November 2012 and conclusions were also taken with a focus on the major NC reported by the Internal audit team. The decision to start the quality improvement project was a result of this review.

In 2011 the management review was conducted in November by the Board of Directors and the Manager Strategy and Development based on the report drafted by the Quality Manager. One of the major conclusion was a need to restrict the number of special projects. After having implemented the new information system RADAR and the Law on accreditation it was time for a back-to-basic approach and a focus on the accreditation process. It was also concluded that the next management review should be conducted with the complete management team.

Reference in AB's documentation:
RvA-QM001: Quality Manual, chapter 11

Team comments:
Management review of 6-11-2013.
The document take into consideration many inputs:
- Trends
- New projects
- Complaints, reports and signals
- Internal and external audits
- Feedback from the clients
- appeals
- non conformities…
- Impartiality and accreditation committee
- action taken from previous management review
- targets for the year (A3 annual plan) – distributed annually to all the people and to the Supervisory Board
- Relation with other parties

External audits
- Independent Accountant audit appointed by the supervisory board – 1 time per year – mandatory by the law and by the Article of Association – the balance (the complete account report) is published on the web.
- FALB review for EMAS
- EA peer evaluation

This year has been scheduled an evaluation performed by a third party, appointed by the national Government, to assess the performance of the AB, with regards also to the requirements stated by the law.

Clause 5.9 Complaints

A complaint is defined as a signal in which a direct client or stakeholder indicates to be dissatisfied with the RvA's performance or with the performance of an accredited body. Complaints may concern:

- The RvA, its operations, procedures, staff and decisions;
- Accredited organizations and their operations.

In 2013 a new set of definition for distinguishing these types of complaints was included in the RvA policy rules RvA-BR002 and BR008.

Complaints concerning the RvA

Since 2010 these complaints are to be handled according to the Dutch administrative act (Awb). The processing of these complaints is coordinated by the Quality Manager, unless the complaint concerns the work of the Quality Manager, in which case the Director Operations will coordinate. The investigation of a valid complaint shall reveal the cause of the complaint and, if applicable, the actions required to correct and prevent re-occurrence.

If the complainant is not satisfied with the result of this process he/she may decide to file a complaint about the RvA at the national Ombudsman. In 2012 one complaint resulted in such a complaint at the Ombudsman. The Ombudsman concluded that the complaint procedure of the RvA should be more transparent and that the RvA should make a better distinction between complaints about the RvA and complaints about a CAB. The RvA decided to modify its procedure and published a policy rule on this (BR008).

From January 2011 up to June 2013 the RvA received 51 complaints about the RvA. Approximately 50% was considered to be fully or partially valid.

The main natures of the complaints are:

70% about project management and communication;

25% is about interpretation of criteria and accreditation procedures and

25% about performance of assessment teams.

Note that a single complaint can contribute to multiple natures of the complaints.

Complaints concerning an accredited body

These complaints are dealt with by the RvA account manager for the body in question according to procedure RvA-P005. In principle the complainant shall demonstrate that the complaint has been filed to the body first and the body did not respond satisfactory.

In most cases the accredited body is first invited to respond to the complaint received by the RvA. The RvA will then decide how to deal with the complaint. The RvA may decide to conduct an extraordinary assessment, (instantly) on site, to conduct an extraordinary assessment on documentation or to investigate the complaint during the first regular assessment at the body.

In 2012 a complaint about an accredited CAB resulted in a complaint about the RvA and later in a complaint about the RvA sent to the National Ombudsman. Based on the conclusions of the Ombudsman complaints about CABs are now called Notifications or Signals depending on the expected feedback from the sender.

From January 2011 until June 2013 82 complaints about CABs were received; approximately 25% was not accepted, in most cases because the complaint was not filed at the CAB before. Approximately 40%

of the complaints is about certification bodies and 40% about inspection bodies. About two-third of the complaints about inspection bodies are related to asbestos removal projects. For the RvA this was reason to present alternative approach in dealing with asbestos removals and the law enforcement in this field.

Reference in AB's documentation:
RvA-BR002: Policy rule accreditation, chapter 11
RvA-BR008: Policy rule complaints
RvA-P005: *Procedure klachtenbehandeling* (Complaints procedure)

Team comments:
In the RvA-BR002: Policy rule accreditation there are the following definitions

Complaint: Expression of dissatisfaction, other than an objection, about the way in which the RvA or a person working under the responsibility of the RvA has acted towards the complainant or towards someone else in a particular matter.

Report : Expression of dissatisfaction about the conduct of an organisation accredited by the RvA concerning activities that fall within the applicable scope and on which feedback will be given by the RvA.

Signal: Expression about the conduct of an organisation accredited by the RvA concerning activities falling within the applicable scope that is provided to the RvA for information and on which no feedback will be given by the RvA.

RVA received 68 complains/report/signal in 2013.
Seen the handling of 1 report 22.07.2013 (not admissible because out of the scope of accreditation)
The complaint received about a client of the certification body is not accepted, before it is the responsibility of the complainer to complain first to the CAB (after having complained to the certified company), and only later, if he receive no answer from the CAB, to the AB.

Seen complaint of 14.03.2012 – RVA contacted the CAB, asking information about the complaint. 1.06.2012 the answer was given to the complaint.
Seen complaint of 17.10.2012 – RVA contacted the CAB, complaining for one extension. RVA talked with this person, 18.01.2013 the answer was given to the complainer, apologizing for what happened, and opening an internal action (periodical meeting to analyse the lead-time of the applications).
GHG - The general complaint process addresses the requirements in the AVR on complaint handling and information response to the complainant.

Clause 6. HUMAN RESOURCES

Clause 6.1 Personnel associated with the AB

Currently the RvA has approximately 95 persons employed as permanent or temporary staff. In addition to this internal staff, the RvA has contracted a large number of external experts and assessors (including lead assessors). Table 6.1 shows the overall number of resources. The number of staff completely dedicated to the CCKL accreditations will decrease because the medical laboratories accredited according to the CCKL system will gradually transfer to ISO 15189 accreditation.

Table 6.1: Personnel resources (July 2013)

Position	number
Internal staff	95
account managers	19
project assistant and	19

secretaries	
lead assessors	22
supporting staff	16
managerial staff	9
staff 100% dedicated to CCKL	10
External contracted	882
lead assessors	17
experts	506
CCKL lead assessors & experts	359

The number of assessment resources for the specific fields of accreditation is shown in table 6.2. For the roles in an assessment teams the RvA distinguishes lead assessors, assessors and technical experts. Lead assessors and assessors are qualified for a specific (accreditation) standard. Experts are qualified for technical fields and always work under supervision of an (lead) assessor. The RvA has only few persons qualified as assessor only.

The RvA currently has sufficient resources available in all fields. Some concern exists for product certification because of retirement of lead assessors in near future and the expected increase in demand. As a mid term solution it was agreed with the Users Council to have a little extra increase in fees in order to be able to search for new Lead assessors for product certification to be hired already in 2013. As a shorter term solution in 2013 training of five internal lead assessors started for this field. For ISO 14065 a third lead assessor will start the qualification process in 2013. In 2014 training of new lead assessors in the field of 17024 is planned because of retirement of one of the qualified persons and a resignation of one of the external assessors who was expected to become a lead assessor in this field.

After publication of EA-2/17 the RvA decided to train part of its lead assessors in this field; 7 external and 18 internal lead assessors were trained.

Table 6.2: Number of qualified lead assessors and experts per accreditation standard or field

Accreditation standard	External	Internal	Total
Lead assessors			
14065	1	1	2
15189	2	5	7
17020	9	14	23
17021	9	9	18
17024	2	3	5
17025(cal)	6	11	17
17025(test)	6	12	18
45011/17065	6	7	13
EA-2/17	7	18	15
Experts			
GHG Verification	4		4
Medical	307	6	313
Inspection	96	10	106
Man.Sys. certification	159	15	174
Calibration	42	3	45
Testing	182	8	190
Person certification	26	3	29
Product certification	84	12	96

In 2010 the RvA changed its policy in recruiting account managers. Until 2010 it was not a prerequisite to be knowledgeable of conformity assessment activities to be appointed as an account manager; since

2010 it is a prerequisite. Since that time the RvA has recruited five new account managers that have experience and knowledge in one or more fields of conformity assessment.

For each position within the RvA the tasks and responsibilities are documented. After the new RvA structure was established in 2009 and 2010 a process to revise the job description was initiated. The new job descriptions also specify the key-competences required for each position. Responsible for this activity is the Manager Human Resources within the RvA.

All persons working for the RvA have signed a contract in which they commit themselves to comply with the rules of the RvA and to adhere to the confidentiality and independence requirements.

In 2012 the RvA introduced the so called “Expertise Groups” (groups of experts in certain areas). These groups are organised per accreditation standard.
The chairman of an Expertise Group is called the “Expertise holder”; in principle this is RvA’s representative in the relevant EA/IAF/ILAC committee(s).
Other participants in the groups are scheme and/or area experts and one or more “Coordinators” from the group of account managers / project managers.
These groups improve the interaction between account managers and team leaders and play an important role in the dissemination of knowledge.
They are involved in the drafting of area specific documents, like SAPs, and the handling of disputes.

Reference in AB’s documentation:
RvA-QM001: Quality Manual, chapter 6
RvA-F007: Declaration of confidentiality
RvA-F008: Contract external assessor
RvA-FP and -FR documents; description of jobs and roles

Team comments:

Absenteeism policy and employee satisfaction

In 2012 extra attention was paid to cutting back absenteeism due to illness. The management followed a workshop to improve skills in dealing with absenteeism due to illness and to make uniform arrangements about procedures in this area. The result was that in 2012 absenteeism due to illness reduced by 0.7% to 4%.

In May/June 2012 the RvA had an employee satisfaction survey carried out by an external agency.

This survey showed points for improvement which were already partly addressed in 2012 and which are partly included in the annual plan for 2013.

Training and education

In 2012 over 250 days were spent on education and training by employees of the RvA. Part of this training was given internally by RvA’s own trainer; part of the training was outsourced to external agencies. A lot of attention was paid to training in the area of skills and communication.

RvA-P011 is under revision for various reasons, such as:

- General: present version is of 2009 and does not reflect all the changes in the organisation since then

- Chapter 2: the way the types of team members are described does not seem to be clear enough regarding the tasks they are allowed to perform autonomously without the presence of a lead assessor (or at least this is given as an excuse not to follow the rules)

- Chapter 2, table 1: deleted and replaced by several lines of text due to the implementation of the RvA sub-specialisms in the RvA database Radar. Changes in the organisation implemented.

- Chapter 3 and 4: changes in the organisation implemented

- Chapter 5 and 6: various textual changes

- Chapter 7: new standards included (ISO 14065 and ISO/IEC 17043); alignment of the requirement for lead assessors C, I and T&C; various textual changes

- Annex III: actualisation of the composition of the qualification committee.

Technical expert

The curriculum is split in two parts, one that is public available under request.

Is there are rejection, the decision is taken by the Qualification Committee (4 people).

Almost no assessor is working for certification bodies.

For recruiting people RVA uses Web site and specialized agency.

Training course for technical expert for the accreditation standard – 1 day (15.04.2013)

Usually 2 observation on field before starting to work as technical expert (e.g.: see qualification of testing assessor A.D.P. 14/15 June 2012).

Testing: 5 years in the field.

In Radar all the qualification of the people are available, with the detail for the filed (also the Directive)

For Directive: eg. Directive EMC 94/9/EC, see the qualification of CLS.

No examination is forseen for qualifying people.

Lead assessor P-011

In order to be a lead assessor it is necessary to have the following training:

- Training on ISO 9001 or comparable.

- Accreditation standard: usually 1 day per standard, and a meeting for everybody when there is a big change in the standard

- Harmonization meeting 2 times per year for each standard, prepared by the Expertise Groups (8 groups), that are organized per standard

Expertise Groups: the task is to give interpretation on the accreditation standard, and they prepare the training courses. The Coordinators of the groups are the people that are representing RVA in EA/IAF Committee.

The training to Lead Assessors is provided in Dutch (only 1 Lead Assessor is from abroad, but he ~~can~~ speaks Dutch).

All the interpretation collected by the Expertise Groups are published in WIKI (web based program, useful to share information to a group of people, that can contribute to his development).

ISP - There are trained internal and external lead assessors for the assessing inspection activities. Besides lead assessors there are approximately 100 technical experts in use in the field of inspection. Comparing the amount of the accredited inspection body resources look like to be in line with

Med Lab - RvA started a training program for Lead assessors and technical experts for medical laboratories (part of the transition project CCKL to ISO 15189). Most of the assessors were experienced with assessment techniques from CCKL assessments. They were trained to RvA-Procedures and requirements of ISO 15189.

All relevant assessors and experts checked during the evaluation took part in such a training. Additional trainings are planned to reach all assessors.

.

PRS: For the transition for ISO/IEC 17024:2012, RvA defined a transition programme which included training of internal staff and also external assessors and experts. All the training sessions were conducted by the RvA expertise holder for ISO/IEC 17024.

GHG - The external lead assessor (one of two) for ISO14065 was monitored at the witnessed assessments by a representative from RvA in the process to be qualified as lead assessor level 120-140, see witness report below.

Clause 6.2 Personnel involved in the accreditation process

The qualification of assessors and experts is based on the requirements in procedure RvA-P011. In this qualification procedure and in the database of RADAR a number of levels in qualification is used. The most important levels are illustrated in table 6.3.

Table 6.3 Qualification levels

Level	Qualification
10	Potential assessor or expert
50	Expert or assessor in training
60	Expert
70	Senior expert
90	Expert qualified for witnessing (certification)
100	Assessor
110	Lead assessor surveillances
120-140	Lead assessor initial and reassessments
150	Monitoring

The Assessor Qualification Committee (*Kwalificatiecommissie*) decides on the qualification of assessors and technical experts. The committee also reviews the performance of assessors and complaints about assessors. The committee is composed of the Unit Manager Team Leaders (chair), Assessor manager, Manager Strategy and development and relevant key-experts. The committee meets four to six times a year and may take decisions by e-mail ballots.

For induction training of new staff the plan is recorded on form RvA-F917. Training is provided to all new staff. In 2010 the RvA started to provide training in the field of accreditation to the office staff. This is coordinated by the RvA trainer in the HRM department. Table 6.4 gives an overview of the internal training that was provided since 2011.

Table 6.4: Overview of internal training

Year	Trainees	Issues
2011		
	New lead assessors, technical experts and other staff	Accreditation of inspection bodies based on ISO/IEC 17020
	Lead assessors	ISO/IEC 17020:2012
	New lead assessors, technical experts and other staff	Accreditation of management system certification based on ISO/IEC 17021:2011
	Lead assessors	Requirements in ISO/IEC 17021:2011 on competence of persons
	Account managers	Accreditation of testing & calibration laboratories
	Account managers	Application of flexible scopes in testing
	Lead assessors	Assessment of conformity assessment schemes with RvA-T33
	New staff and assessors	RvA procedures and rules
	Lead assessor and experts	Accreditation of NoBo's based on EA-2/17
	New assessors and account manager	Accreditation of person certification based

Year	Trainees	Issues
		on ISO/IEC 17024
	New supporting staff and management	Introduction to accreditation
	Experts	Reporting and SiteDoc
	Accreditations Committee	Introduction to ISO 14065
2012		
	New lead assessors	Accreditation in the field of food safety
	New lead assessors	Accreditation of management system certification based on ISO/IEC 17021:2011
	Account managers and other staff	Accreditation of management system certification
	Account managers and other staff	Accreditation of product certification
	Account managers and other staff	Accreditation of testing & calibration laboratories
	New lead assessor	Accreditation of medical laboratories based on ISO 15189
	New assessors and staff	Accreditation of person certification based on ISO/IEC 17024
	Experts and (lead)assessors	Reporting and SiteDoc
	New supporting staff and management	Introduction to accreditation
	Accreditations Committee	ISO/IEC 17021:2011, ISO/IEC 17024:2012, ISO/IEC 17065:2012
	New lead assessor	Documenting findings and follow-up assessment
	Lead assessors and experts	Accreditation for CPR
2013		
	New lead assessors	Accreditation of product certification
	Lead assessors / coordinator	ISO/IEC 17065:2012
	Account managers	ISO 15189:2012
	New Director Operations	Accreditation of testing laboratories
		Accreditation of inspection bodies
		Scheme owners
		Business processes

For on-going training and harmonization of lead assessors the RvA has a number of meetings each year: three meetings each year in the field of certification (management systems and products, three in the field of laboratories (calibration, testing and medical), two in the field of inspection and two in the field of certification of persons. Besides interpretation of accreditation requirements also accreditation and assessment methods and procedures are on the agenda of these meetings.

Reference in AB's documentation:

RvA-QM001: Quality Manual, chapter 6

RvA-P011: *Procedure Werving, selectie en kwalificatie* (Procedure recruitment, selection, qualification)

RvA-F917: *Introductie- en inwerkformulier* (Form for training new staff)

Team comments:

RvA established an Assessor Qualification Committee that is composed by four permanent persons (all RvA internal staff). This Committee is responsible for all assessors/experts qualifications. The qualification of a new expert/assessor may occur after an email consultation to the persons composing this committee.

PRS: Procedure RvA-P011 describes the qualification procedure for assessors/experts in all fields. However this procedure is not very clear for all areas. It was confirmed that this procedure is not always being implemented in practice (e.g. witnessing assessments are not always being performed by assessors with the necessary qualification level. However, the competence of assessors was confirmed during the witnessing.).

For ISO/IEC 17024 all assessors/experts meet every year to discuss and harmonize the interpretation and assessment in this field. In 2013 two meeting took place. The attendance list, agenda and minutes were checked.

TES/ CALIB - Internal trainees to account managers about calibration and testing in 2011 were linked with the answer of RvA to the previous findings Cm1.

GHG - Training and information of technical experts and lead assessors is performed with a frequency of twice a year. Attendance and content on information and training are recorded.

For accreditation on ISO14065 RvA has one fully qualified lead assessor, one in progress to be qualified and further one planned to be qualified. Four technical experts are qualified for verification of GHG which one for the aviation sector. Three of them qualified for the level of 90 and one on the level 60.

ISP - There have been many training sessions for lead assessors and technical experts. In the area of directives e.g training of accreditation for NoBos based EA-2/17 was kept 2011. Besides that also new version of the standard ISO/IEC 17020:2012 have been in training program. Technical experts have also been informed the changes of the standard. They have had possibility to take part in information meetings concerning new standard version.

There is RvA's procedure document P011 (version 4) that contains the selection of team members. According to discussions with RvA persons (expertise holder, unit manager, account managers) the document is understood different way in the case of selecting technical expert to make witnessing in inspection without Lead assessor. One opinion was that the technical expert shall have qualification points 70 and other opinion was 60 points is enough. (see finding #9)

ISMS: During the witnessing assessments AB in management systems certification body (C548, C466), the RvA assessors demonstrated easy familiarity with requirements of the accreditation standards (ISO 17021:2011, ISO 27006:2011), relevant EA & IAF documents and RvA procedures. All of them have participated in relevant training. In accordance with RvA procedure, rotation of team leader should be every 4 years. Reviewed personal records (XXX) confirm, that assessors, including lead assessor, fulfil requirements Procedure RvA –P011 about education, training, technical knowledge.

The scope of accreditation C548 granted by RvA includes: QMS (code:29, 31, 32, 35) and EMS (code: 29).RvA qualify their assessors for QMS and EMS using codes IAF/EA. Assessor XXX leading the assessment of QMS/EMS did not have any qualification for any of the above codes IAF/EA.

To carry out witnessing in activities of CABs (C548, C466), RvA appointed personnel qualified for the programs and codes IAF/EA within the scope of accreditation C548 and C466.

The assessment plan for surveillance C548 lists interpretation-documents, including: IAF MD1, IAF MD2, IAF MD5, ISO-IEC/TS 17021-2, ISO-IEC/TS 17021-3. RvA showed no evidence for the training of the personnel of the requirements ISO-IEC/TS 17021-2 and ISO-IEC 17021-3. It was confirmed, that RvA only developed a draft plan to implement the above mentioned documents and prepare draft the appropriate message of ISO-IEC/TS 17021-2, -3.

Clause 6.3 Monitoring

An adequate performance of the assessment teams is the fundament of a reliable accreditation. The RvA considers it important to monitor the performance of the teams and especially the lead assessors. The RvA has several mechanisms in place for this purpose.

- Review of the assessment reports and the non-conformity notes. This involves both the expert and the (lead) assessor parts of the report. These reviews are reported using form RvA-F142.
- The results of the evaluation of reports by the Accreditations Committee are recorded on form RvA-F921 and evaluated by the Manager Assessors.
- Feed-back received from the assessed organisation either verbally or in writing. In the second half of 2013 the RvA will start with sending customer satisfaction surveys to assessed CABs.
- On site monitoring of assessment teams according to procedure RvA-P007 Monitoring. The aim is to monitor each lead assessor once every 3 to 4 years. If required on the basis of other findings the frequency for specific assessors may be increased. In June 2013 the review of the

status of the monitoring confirmed that all lead assessors have been monitored at least once the last three years.

- Experts and assessor are monitored by the lead assessor. The lead assessor is required to complete form (RvA-F030 *Overdrachtsformulier*) for the appraisal of the team members. These forms are evaluated by the Manager of the Assessor Unit.

The Qualification Committee of the RvA evaluates all information concerning the performance of assessors and will identify needs for training, harmonization, modifications of qualifications, etc. At least once every two years the Manager of the Unit Team Leaders has an appraisal meeting with each lead assessor in which the qualifications and performance are evaluated.

Reference in AB's documentation:

RvA-P007: *Procedure Monitoring* (Procedure monitoring)

RvA-F045: *Rapportage monitoring* (reporting template for monitoring)

RvA-F030: *Overdrachtsformulier* (form to be filled in by team leader after each assessment about the performance of the team members)

RvA-QM001: Quality Manual, chapter 6

Team comments:

From June 2013 RvA started to implement the new policy which demands the monitoring of each lead assessor at least once the last three years.

Experts and assessor are monitored by the lead assessor by using the form RvA-F030.

These forms are evaluated by the Manager of the Assessor Unit and by the Qualification Committee.

However, there is no procedure/policy for monitoring the performance and competence of personnel involved in the accreditation decision-making process. (See finding #15)

The RvA monitors the performance of the teams. There are several mechanisms for monitoring like

- *Review of the assessment reports and the non-conformity notes using form RvA-F142.*
- *Evaluation of reports by the Accreditations Committee (RvA-F921)*
- *Feed-back received from the assessed CAB's*
- *On site monitoring of assessment teams according to procedure RvA-P007 Monitoring.*

ISP - According to the discussions and files examined during the evaluation all lead assessors have been monitored during three last year. Technical experts have been monitored systematically every office assessment visit. Records of monitoring are very informative.

Medical Lab - All checked assessor files showed monitoring of the team members by the lead assessor. The results of this monitoring were evaluated in an excel-sheet that produces very informative KPIs for the technical experts and the lead assessors.

All checked lead-assessor files showed monitoring of the lead-assessor by another lead-assessor, but it did not follow RvA P011 (see finding #22).

TES/ CALIB - All technical assessors are witnessed by the team leader at each assessment. The records are form RvA F030 (form F 030 for the assessment L330 H03 21-22/08/2012 seen; ok). There is a note from 0 (not assessed) to 5 (excellent). Each time there are a note of 1 (bad) or 2 (insufficient) the file is given to the Assessor Manager for action.

CERT: RvA has some monitoring tools to evaluate the performance of assessors.

The implementation of this process was checked and it was confirmed that not all the tools mentioned are already in place. The "Feed-back received from the assessed organisation" is not in place yet. RvA informed that this tool would start to be implemented in 2014.

The "Review of the assessment reports and the non-conformity notes" it is only requested by the Account Manager to another team leader if there is any doubt on a report. For ISO/IEC 17024 no examples of this practice were presented.

The on-site monitoring is being performed for all team leaders. According to procedure RvA-P011, a team leader is monitored during an assessment by another team leader qualified with level 150. The on-site monitoring is independent from the accreditation standard. Some examples were checked for ISO/IEC 17024 lead assessors.

Procedure RvA-P007 "Monitoring" is just applicable for lead assessors.

GHG - Technical assessors are monitored during the assessments by the lead assessor. The result of the monitoring is recorded with a grading from 1 to 5 on different aspects of their performance. Records on grading lower than 4 from the monitoring are recorded and act upon. Personal file.

Evidence was shown of monitoring of lead assessors according to RvA procedures.

Clause 6.4 Personnel records

Records of each staff member are kept in separate files under the responsibility of the department HRM. Records contain at least a copy of the contract, information on qualifications and appraisal records. Details about the qualification of lead assessors are recorded in the unit Team Leaders.

Reference in AB's documentation:

RvA-QM001: Quality Manual, chapter 6 and 13

Team comments:

Every 4 years the resumes of Assessors and Technical experts are updated. The database gives the information about last time RVA received the CV of personnel.

Records on contract, information on qualifications and appraisal on external technical expert are also available for account managers who plan the assessment and assessment team.

Clause 7. ACCREDITATION PROCESS

Clause 7.1 Accreditation criteria and information

General information about the accreditation process and the criteria is provided by means of the RvA policy rules (BR documents) which are published on the website. The following documents are relevant to understand the general processes:

BR002 Policy rule Accreditation: Contains the general criteria, rules and process descriptions and elaborates the rights and duties;

BR003 Policy rule Scope of Accreditation: Describes the policies for defining the scope of accreditation;

BR004 Policy rule Non-conformities and Corrective action: describes the policies for grading findings and how to deal with the different types of findings;

BR005 Policy rule Surveillances and Reassessments: Sets out the policies for frequency and extent of surveillances, reassessments and the rules for extra ordinary assessments;

BR006 Policy rule Handling Objections: Describes the rules for lodging and processing objections, which is in fact the appeals process;

BR007 Policy rule for Cross-Frontier Accreditation: Contains the RvA policy for accrediting and assessing outside the Netherlands;

BR008 Policy rule Complaints: Details the rules for dealing with complaints;

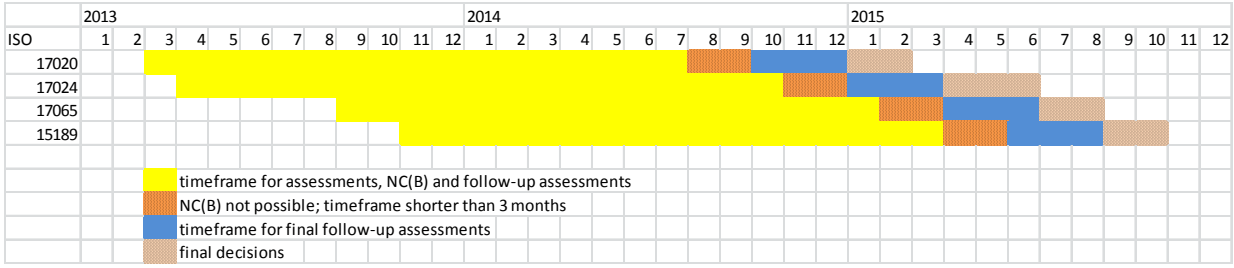
BR010 Policy rule for the field of Activities of the RvA: Describes all conformity assessment activities for which the RvA considers itself competent and for which CABs may apply for accreditation.

The fee structure and the fees are documented in decision RvA-D001 which is updated and published annually.

Specific information on the technical requirements and specific procedures for accreditation for specific conformity assessment activities are published in the so-called Specific accreditation protocols (SAP-documents). In 2011 it was decided to draft a SAP after each development of a new activity and to draft SAPs for activities the RvA is already accrediting but where questions could be raised about the technical requirements and procedures.

Whenever an accreditation standard is changed the RvA establishes a transition arrangement consistent with the international arrangements. The RvA informs all accredited and applicant bodies about this arrangement and publishes a news item on its website. The most recent examples are the transition arrangements for ISO/IEC 17020, 17024, 17065 and for ISO 15189 (see figure 7.1).

Figure 7.1: Summary of transition arrangements



Reference in AB's documentation:

RvA-BR002: Policy rule Accreditation, chapter 3

RvA-QM001: Quality manual, chapter 4

Team comments:

CERT - No Transition has been published to ISO 27001:2011 IAF Resolution 2013–13 – (Agenda Item 8) Endorsement of ISO/IEC 27001:2013. Finding #3 has been raised.

ISP - There is all relevant information on the RvA's website concerning inspection accreditation. Information is easily found. There are many new standard version e.g ISO/IEC 17020:2012. Information concerning transition period has been given to accredited body's.

Med. Lab - The procedure for transition from ISO 15189:2007 to ISO 15189:2012 meets the requirements of RvA procedures and the ILAC requirements (end of transition period)

PRS: The accreditation criteria and information about RvA accreditation process is available in RvA website.

For the transition for ISO/IEC 17024:2012 RvA published a document (RvA-T036) with information about the RvA transition programme. This document is also available in RvA website (just in Dutch).

RvA website also has updated information on accredited CABs including the accreditation scope.

GHG - BR003 does not consider ISO 14065 and AVR regarding scope of accreditation (see finding #23).

PRD: Criteria for assessment of product certification bodies are publicly available on RvA web site.

RvA website provides the applicants for accreditation with all necessary information about: accreditation process, conditions for maintaining, granting, extension, reduction, suspension and withdrawal of accreditation, cost of accreditation, terms and conditions of business, information about complaints and appeals.

Clause 7.2 Application for Accreditation

An organisation interested in obtaining accreditation shall use the RvA application form (RvA-F001a) and the relevant additional application form depending on the accreditation standard. The RvA may be consulted to assist in completing the forms or to explain our procedures and requirements. The RvA requires the applicant to submit the management system documentation and the reports of internal audits and management review together with the application form. With the application form the RvA receives all relevant information such as:

- Name and nature of the entity, and its key staff;
- Address and whether it has multiple sites;
- Activities of the body and if applicable its related bodies;
- Whether the accreditation is to be used for assignment/notification by authorities
- Statement of the applicant to comply with the requirements.

Upon receipt of the completed forms and the required documents, the application is reviewed by one of the unit managers and if necessary by the Coordinator or the Expertise holder. An application is accepted when all requested information and documentation is provided, the application is correct and the scope is defined clearly.

In case an application is not complete or incorrect, the body is given an opportunity to complete or correct the application. If the application is rejected the body is informed about this and has the possibility to object to such a decision.

A similar approach is used for applications for extension of scope, which is filed with form RvA-F105a.

Reference in AB's documentation:

RvA-F001a: Application form

RvA-F105a: Application form for scope extension

RvA-BR002: Policy rules accreditation, chapter 4

Team comments:

Lot of information is asked with application. Information gives good images from the body to be accredited.

Med Lab - The application form has been revised since the last evaluation according Cm3. RvA now has the information about the way the labs perform traceability before RvA start planning the assessment.

GHG - Application form specific for ISO 14065 and AVR has been developed and is used.

Clause 7.3 Resource Review

Applications are reviewed by the unit managers and the results are recorded on special forms (RvA-F022 and RvA-F107). The review of resources is an explicit item in these forms. An application for activities that have been accredited by the RvA before, cannot be refused because of lack of resources. The management will make (additional) resources available if necessary. One of the possibilities is to postpone surveillance assessments. Applications for activities not included in our RvA-BR010 document, which specifies our scopes of work, will not be accepted until this activity has been developed.

In 2012 applications from foreign bodies were refused for accreditation for ISO 50001 certification, because the RvA does not have the resources available to conduct this recently developed work outside the Netherlands. In 2013 an application from a foreign body for ECM certification was refused because of similar reasons. This policy is now explicitly included in the policy rule RvA-BR007 for Cross Frontier Accreditation.

In recent years the RvA did not encounter problem with availability of resources. The man days that had to be spent for assessment (see figure 7.2) could be delivered with the resources as indicated in the table 6.2.

Figure 7.2: Total number of assessments days

Reference in AB's documentation:

RvA-F022 *Beoordeling accreditatie aanvraag* (review of application for accreditation)

RvA-F107: *Beoordeling aanvraag uitbreiding accreditatie* (review of application for scope extension)

Team comments:

There are sufficient personnel resources in file management and assessment.

Once a year there is a direct interview / check between all the personnel and the personnel that is in the above level (appraisal meeting), talking about ambitions, training, need for devices, check of the previous goals

Clause 7.4 Subcontracting the Assessment

The RvA only subcontracts to other ABs in case of activities outside the Netherlands. In case of subcontracting the RvA specifies the issues to be assessed (see RvA-W018). Decision making is never subcontracted. In policy rule BR007 the RvA has included the rules for subcontracting. In the previous version of this policy rule it was possible to assess the critical locations of CABs by using the reports of other AB's. In the new revision this possibility has been removed.

Reference in AB's documentation:

RvA-W018: *Werkinstructie uitbesteding aan collega AB* (Working instruction subcontracting to other AB)

RvA-BR007: Policy rule Cross frontier accreditation

Team comments:

Sub contraction is applicable just in case of Cross Frontiers policy. See the relevant paragraph.

Clause 7.5 Preparation for Assessment

For each assessment the account manager will select the team leader and the team members from the list with qualified assessors and experts. This list is maintained in the project management system / CRM, called RADAR and specifies the field of competence and the level of qualification. See under clause 6.2.

As stated in the policy rules RvA-BR002, the applicant is given the possibility to object against the appointment of a team member if there is a (perceived) conflict of interest.

The documents and records needed for the pre-assessment are specified in the application forms. The specific accreditation protocols may specify additional documents that need to be submitted.

The pre-assessment is conducted by a team leader and one or more technical experts if needed. It is the policy of the RvA to make a visit to the applicant at this stage to present the results of the document review and to discuss the plans for an initial assessment. Such a visit is however not mandatory.

The impartiality of the team members is safeguarded by:

- Team members shall not have any business relationship with the applicant;
- Team members shall inform RvA for each assignment if there is a potential conflict of interest;
- If the pre-assessment was not successful a second pre-assessment at this body may be conducted by the same team leader but the third time another team leader will be appointed.

The procedure RvA-P017 describes the principles of team composition.

The account manager is responsible for establishing the date(s) for an assessment and for deciding on the scope and extent of an assessment. The four year plan which is specified in the part A report for each CAB is the bases for this. The general rules for sampling are stated in RvA-BR003 and in BR005 for surveillances and reassessments. Guidance for the extent of the various assessments and the amount of witnessing to be carried out is provided in the specific accreditation protocols which are drafted for a great deal of the accreditation fields.

The account manager prepares an assessment specification for each assessment. In this specification the team composition is stated, the man-days for each team member, the sites of the assessment and any specific issues that should be addressed. In 2011 the RvA started recording so-called 'project issues' in the database RADAR for each CAB. These recordings (for example complaints or other relevant information about the CAB) are used to specify the assessment issues to be addressed by the teams.

The preparation for an assessment by the office staff (project assistant) is concluded by sending the assignment letters and the assessment specification to the team and the confirmation to the CAB. Also the team is provided with a package containing the relevant forms, the scope and a file to prepare the reporting system SiteDoc for the assessment (according to working instruction RvA-W010).

Reference in AB's documentation:

RvA-BR002: Policy rule accreditation, chapter 5

RvA-BR003: Policy rule scope definitions

RvA-QM001: Quality manual, chapter 8

RvA-P017: *Procedure voor Teamsamenstelling* (Procedure team composition),

RvA-W010: *Werkvoorschrift SiteDoc* (Working instruction SiteDoc)

Team comments:

Selection of assessment team is made by account manager. RADAR data base is used for the purpose. According to observations RADAR is quite simple to use and there are all needed information.

The part A of the report is a strong source of information according to administrative information or the history of the assessment in the current cycle useful for assessment team.

Planning of assessment of all verification bodies so far one account manager has been responsible. This account manager has been involved in the development of the accreditation scheme and also in the information exchange with the competent authority. The responsibility for the planning is now under transfer to the account manager responsible for the specific CAB.

For product certification: It was observed that besides the office assessments, witnessing of product certification audits were planned separately. The plan contains sites and activities to be assessed during the accreditation cycle and has been regularly updated. It is given in the Part A of Assessment Report.

- *In one case RvA did not inform the assessment team about the new revision of the applicable certification scheme.*
- *In another case RvA didn't record the information about the applicable version of the certification scheme (See finding #16)*

Clause 7.6 Document and Record Review

Before each initial assessment the lead assessor will conduct and report the review of documents and records provided by the applicant (pre-assessment). If needed also a technical expert will contribute to the pre-assessment. For extensions of scopes the RvA may decide to conduct a pre-assessment first. This will be done if the new scope is significantly different from the activities for which the CAB is already accredited.

As described in the policy rule RVA-BR002 the results of this pre-assessment may be:

1. It is concluded that the applicant, despite any deficiencies found, is ready for the assessment. In that case the pre-assessment report shall not only contain a summary of the results of the pre-assessment, but also a breakdown of the assessment to be carried out and a proposed plan for the assessment.
2. Because of the deficiencies found it is concluded that the applicant is not yet ready for the assessment. In that case the report shall not only contain a summary of the results of the pre-assessment, but also the identified deficiencies that must be demonstrably corrected before an assessment can be carried out. The applicant is then given the opportunity to make corrections which the RvA will verify in a follow-up pre-assessment. The results of this verification are incorporated into the report and are the basis for a new conclusion. Where the follow-up pre-assessment shows that an applicant has not sufficiently succeeded in resolving the deficiencies of the pre-assessment, the RvA takes a decision about the continuation of the assessment in consultation with the applicant.

An applicant may withdraw its application on the basis of the result of the pre-assessment and resubmit it after correction of the documentation.

Based on the results of the pre-assessment, the intended scope of accreditation that will be the basis for the (initial) assessment is defined and also the extent of the initial is agreed. Working instruction RvA-W064 describes the details of the pre-assessment process; the results of a pre-assessment are reported in a report based on template RvA-F021.

Reference in AB's documentation:

RvA-BR002: Policy rules accreditation, chapter 5

RvA-QM001: Quality Manual, chapter 8

RvA-W064: *Werkvoorschrift vooronderzoek* (Working instruction pre-assessment)

RvA-F021: *Rapportage vooronderzoek* (Reporting template pre-assessment)

Team comments:
The implementation of this procedure was confirmed checking files

Clause 7.7 On-site Assessment

The three main assessment methods applied by the RvA are:

Office assessment: an assessment at the premises of the CAB in order to verify the implementation of the management system, by assessing documented evidence and interviewing staff;

Witnessing: observing activities carried out by the CAB (such as for example testing, calibrations, inspections, audits, examinations).

Document review: review of documents and records provided by the CAB. This method is used at the pre-assessment, in preparation of a reassessment, for small scope extensions and for the review of corrective actions.

In 2012 the RvA conducted a number of pilots with a new method, called Shadow assessment. This is an assessment in which an activity already carried out by the CAB is verified on site by discussing the results of the activity with the person(s) who performed the activity. Virtually the same information and facilities are available for this that the persons carrying out the activity had available at the time of the activity. The pilots were successful and starting from 2014 the RvA will start applying this method for ISO/IEC 17021 assessments on a regular base. In 2013 the procedures are developed and training to our staff and assessors is provided.

For each assessment an assessment plan is drafted by the lead assessor based on the template RvA-F121. The plan specifies the activities planned for the assessment. Also the plan identifies the accreditation criteria and the relevant application documents and the scope(s) of accreditation relevant for the assessment. A body applying for multiple accreditations (more than one standard) may have a combined assessment by a team qualified for all relevant standards.

Each assessment starts with an opening meeting to introduce the team and the persons representing the CAB, to confirm the plan, time schedule and arrangements, to explain the procedures and to confirm the confidentiality rules.

It is the responsibility of the team leader to manage the assessment according to the plan, or to decide on deviating from the plan if needed.

Adequate sampling of parts of the scope - to ensure covering of the scope during the subsequent assessments - is supported by chapter 2 of the part A report, in which the parts that have been assessed during the previous assessments are recorded. In Specific accreditation protocols the RvA may include specific rules for sampling.

Reference in AB's documentation:

RvA-BR002: Policy rule accreditation, chapter 6

RvA-F121: Template assessment plan

RvA-F101: Template report part A

Team comments:

Specific accreditation protocol gives extra indications, in needed. Rules to identify the number of man day to do on site, and n° of witnessing are explained in: W031-NL testing and calibration / W032-NL for certification. The procedures are not available to the public.

Shadow assessment: very similar to Market Surveillance visit. At the moment there are 2 pilots.

ISP - Witnessed assessment were made according to RvA's procedure. If there is more than one accreditation (e.g. inspection and testing) in the client, normally combined assessment will be done. Accreditation decisions may be made separately.

TES/ CALIB - In § 6 article 14 of the BR002 version 2, it is written that "one or more of the following assessment methods" is used to carry out an assessment. 6 possibilities are listed (form a. to f.). Some of them are able to be implemented alone (office assessment or witnessing for example) but some other methods cannot be used alone (interlaboratory assessment or shadow assessment for example). There is a doubt about available options.

PRS: *For persons certification bodies witnessing activities are planned and performed separately from the office assessment. The accredited scope shall be covered by witnessing activities during each accreditation cycle. The Account Manager is responsible for designing the accreditation programme and for planning the office assessments and the witnessing activities for the accreditation cycle.*

For the witnessed assessment, an assessment plan was prepared and the reassessment was conducted in the CABs office. The team was composed from a team leader and an expert (supported by an assessor). The accreditation scope was sampled by the team. The programme for reaccreditation included 3 witnessing activities to be performed in a later stage.

At the end of the assessment a closing meeting was conducted by the team leader and the findings were presented to the CAB.

GHG - Criteria and clusters on activity groups for witnessing of verifications are defined in SAP V001. The planning of the witnessing was not yet in place.
Information on planned verifications needed for the witness planning was to be reciewed at the time of the evaluation (15th of November).

PRD: During the witnessing of two product certification assessments it was observed that the team members were competent. The assessments were carried out in accordance with the assessment plan.

CERT – XXX (Unit manager team leader - planning)

Scheme has to be checked 1 time each accreditation cycle.

XXX – audit QMS in XXX – 1 assessor from Netherlands – no local expert in QMS

However, ISO 17021 (9.2.3.1.1 stage 1 - legal aspects of the client's operation, 9.2.3.2 stage 2 - performance as regards legal compliance) is applicable for all MS schemes, also for QMS. Finding #4 has been raised.

XXX – audit ISMS – witness in XXX

Clause 7.8 Analysis of Findings and Assessment Report

Before the closing meeting the team members will discuss their findings and agree on the grading according to the policy rules stated in RvA-BR004. The team leader is responsible for grading a non conformity either as a category A or category B. The following definitions apply:

Category A: The absence of or the failure to have implemented or maintained one or more requirements of the accreditation standard or a situation that, based on objective observations, gives rise to doubts about the quality of the work done by the accredited or applicant CAB. This means that the conformity assessment activities carried out by the CAB have little or no value.

Category B: The failure to maintain one or more requirements of the accreditation standard or a situation that, based on objective observations, gives rise to doubts about the assurance of the quality of the work done by the accredited or applicant CAB. This means that in the future the conformity assessment activities carried out by the CAB may have little or no value.

If the assessment is conducted against new requirements for which the RvA published a transition arrangement a nonconformity is graded as category (B). The following definition applies:

Category (B): A non-conformity in respect of new requirements, for which the transition period laid down by the RvA has not yet ended. This means that at the time of the assessment the CAB meets the requirements that are applicable at that moment. Without timely

corrective action the new requirements will not be met at the end of the transition period.

Currently for example it is possible to raise a category (B) nonconformity against ISO/IEC 17020:2012, ISO/IEC 17024:2012, ISO/IEC 17065:2012 and ISO 15189:2012, based on the explanatory T-documents published by the RvA for the transition to these new standards.

In the closing meeting the team presents in writing a summary of the assessment results and the nonconformities. The nonconformities are also provided as MS-Word document to enable the CAB to record their response to the nonconformities on the NC-Form. The documents are preferably generated with the help of the SiteDoc reporting tool (see RvA-W011).

After the closing meeting the body has a fixed period for providing corrections and corrective actions according to the rules in RvA-BR004. The principles for responding to NC's are the following:

- The CAB makes an analysis of the root cause and the extent of a non-conformity;
- The CAB eliminates the root cause and corrects results supplied (reports, certificates and such) that do not meet the requirements;
- The CAB confirms the effectiveness of the actions for example by means of a special internal audit.

The results of this, including the (reference to) evidence, is contained in the Corrective Actions Report (CAR) which is recorded on the NC-form. The RvA distinguishes between the NCs raised during initial or scope extensions on one hand and surveillances and reassessments on the other hand (see under clause 7.11 for the latter).

Initial and scope extension:

According to Section 5 of the Dutch National Accreditation Body Appointment Act, the RvA shall make a decision about the accreditation within six months of the application. However if the applicant has to take corrective action, this period of time is extended once by another six months. In general the RvA needs a minimum of three months for assessment of the actions, reporting and decision making, so based on the time between application and the closing meeting and these three months the applicant can calculate the due date for a final response to the nonconformities. In practice the RvA is not always able to take a decision after twelve months from the application. Reasons are:

- The pre-assessment results did not justify the timely initiation of the initial assessment;
- Time consuming planning of the assessment activities and of the follow-up assessment to match the agendas of the team and the CAB;
- CAB's response not received in time or problems for the CAB to arrange the necessary witnessing;
- Not being able to close a NC after the first response with corrective actions.

This ruling was implemented on 1 January 2010. The RvA did not yet make negative decisions on new applicants for not being able to make a positive decision within twelve months. Instead the RvA prefers to try to agree with the applicant that the application is withdrawn and a renewed application in filed after implementation of the corrective actions or to try to agree with the applicant to postpone the decision. In 2012 for example six out of 32 initial assessments resulted in withdrawal by the applicant.

The nature and extent of a follow-up assessment depends on the nature, extent and the number of non-conformities. The following policy applies:

1. A follow-up assessment is as far as possible carried out on the basis of the documented CAR, unless the assessment team takes the view that the effectiveness of the actions must be verified in some other way, such as a follow-up office assessment and/or a follow-up assessment in the form of a witness assessment.

2. The assessment team informs the CAB about its proposal for the nature and extent of the follow-up assessment, and, if possible, makes an appointment for this at the closing meeting. Proposals and/or appointments require the confirmation by the RvA office.
3. In the event that not all the non-conformities can be closed during the follow-up assessment, the RvA extends the follow-up assessment, on condition that this can happen within the periods of time referred to in RvA-BR004.

After the follow-up assessment the report is finished (RvA-W011). The RvA uses two reports for a CAB. The part A report contains in chapter 1 general information of the CAB (e.g. name, contact information, legal entity, names of key staff, number of staff, related bodies, sites), in chapter 2 information about the assessment history (overview of most recent assessment results, coverage of scope and sites, etc.) and in chapter 3 the assessment program for the current cycle is specified. This part A report is up-dated by the CAB for chapter 1 before each regular assessment and by the RvA after each assessment. Working instruction RvA-W012 applies to report part A. The part B report is the report of an assessment, preferably generated by means of SiteDoc. The report contains the summary of the results, the details of the observations by each of the team members, the NC's, the assessment plan and the scope of accreditation valid at the time of the assessment, with the proposals for changes if applicable. Working instruction RvA-W011 applies to part B.

Both reports contain a schematic overview of the elements that were assessed. These elements are the aggregated accreditation requirements clustered in eight sections and subdivided in sub elements. These elements are used to make reports more consistent especially for assessments with multiple standards, and to allow for analysis of assessment results over time. RvA-F095 contains the cross reference of the elements with the different accreditation standards.

A CAB may decide not to agree with the interpretation of a requirement on which a NC is issued by the the RvA team. In this case the CAB files a so called dispute within ten working days after the closing meeting. The objective is to identify and resolve diverging interpretations and to ensure a transparent application and shared understanding of the requirements. Disputes are brought to the RvA by the CAB with the special form (RvA-F039) that is available on the RvA website and processed according to RvA-P006. The RvA Quality Manager sends the dispute to the expertise holder for the applicable accreditation standard. The expertise holder appoints the person to investigate the dispute. This investigation may include consultation of experts in or outside the RvA. The conclusion may be to confirm the position of the team (nonconformity is confirmed) or to accept the body's position (withdraw the nonconformity). Also it is possible to reword or re-grade the non-conformity. For the purpose of training and harmonisation, the results of the disputes are discussed in the meetings with lead assessors and experts, when deemed relevant.
Disagreements about nonconformities which do not involve a difference of opinion about the interpretation of requirements will be dealt with as a complaint.

Table 7.1 Summary of disputes

Year	Result	17020	17021	17024	17025	45011	VR003	BR002
2010	accepted	2	3		1	1	0	1
	partly accepted	0	0		0	0	0	0
	not accepted	4	13		2	1	1	0
2011	accepted	2	2		1	0		
	partly accepted	0	0		0	2		
	not accepted	3	8		5	3		
2012	accepted	1	0	0	2	0		
	partly accepted	2	3	3	4	0	1	
	not accepted	1	1	0	1	2		

Reference in AB's documentation:

RvA-BR004: Policy rule Nonconformities and Corrective action

RvA-BR002: Policy rule Accreditation, chapter 6

RvA-QM001: Quality Manual, chapter 8

RvA-W011: *Werkvoorschrift deel B rapportage* (Working instruction part B report)

RvA-W012: *Werkvoorschrift deel A rapportage* (Working instruction part A report)

RvA-W010: *Werkvoorschrift SiteDc* (Working instruction SiteDoc)

RvA-P006: *Procedure Interpretatiegeschil* (Procedure dispute on interpretation)

Team comments:

According to RvA-BR004, Under Section 5 of the National Accreditation Body Appointment Act, the RvA has to make a decision about the accreditation within six months of the application. If the applicant has to take corrective action, this period of time will be extended once by six months.

RVA is developing many tools to keep under control this period (periodical internal meetings

Disputes

The person appointed to investigate the dispute is usually a lead assessor, competent in the field, but independent for the specific audit.

ISP - According to two witnessed office assessment in inspection area, findings and non-conformities were relevant and formulated clearly and an informative way. There was only one unnoticed observation when assessing the use of accreditation mark. (see finding #14)

TES/ CALIB - All non-conformities had to be solved by the assessment team before the decision process. In all assessment reports read, this operation was well done and all needed information was available in detail.

PRS: Before the closing meeting with the CAB, the team performed an internal meeting to analyze the findings. At the closing meeting, the non-conformities are presented and, when necessary, some clarifications are made. The report part B is left with the CAB to prepare and present the corrective action plan. This plan is analysed by the assessors and when necessary, clarifications or additional evidences are requested from the CAB.

The complete report sent by the team leader to the Account Manager will also include the conclusions about the witnessing.

Clause 7.9 Decision-Making and Granting Accreditation

The decision making process for initial and re-assessments and for withdrawals consists of:

- The team leader provides the final report part B and the updated report part A with a recommendation (based on template RvA-F085) to the account manager;
- The account manager checks the report and submits the decision making file (DMF) that includes the report part B and TL-recommendation and the up-dated report A, together with his/her recommendation (based on template RvA-F035) to the Accreditation Committee (CA) according to working instruction RvA-W024;
- The CA meets once a month and reviews and discusses the DMF before making its recommendation to the Chief Executive. The CA may decide (see also RvA-R007):
    - To follow the recommendation of the team leader and recommend in-line with this recommendation;
    - Not to follow this recommendation and recommend differently;
    - Not to accept the DMF and request additional information.

- The Chief Executive takes the decisions based on the recommendation of the CA. In the event the Chief Executive does not want to follow this recommendation he needs to consult the Supervisory Board.

The decision making includes the final definition of the scopes of accreditation, based on the proposal of the team, according to the policy in RvA-BR003.

Except in specific cases an accreditation is granted for an undefined time frame. Based on the recommendation of the Accreditations Committee a decision may be taken to restrict this time frame. Possible grounds for such a decision may be:

- Accreditation in a new area;
- The body needed much effort and time for closure of non conformities;
- Other reasons that justify a limited confidence in the long term continuity of the body.

Although the accreditation is mostly granted for an undefined time frame, the validity of the certificate is normally four years. But also this validity may be shorter if deemed necessary. A reassessment is conducted to renew the certificate.

After decision making the body receives the signed accreditation certificate (within the RvA this is called the accreditation declaration) and the signed scope of accreditation. The scope of accreditation is also published on the RvA website. The declaration specifies:

- The name of the body and its place of establishment;
- The accreditation standard including the version/date;
- The unique registration number of the body;
- The validity dates of the declaration;
- Reference to the scope of accreditation.

In July 2013 the RvA started to renew the existing declarations to include the mandatory statement from EA-3/01 about the EA-MLA.

The scope of accreditation specifies:

- The unique registration number;
- The accreditation standard (in 2013 the RvA started to include the version of the standard in the scope);
- The specification of the conformity assessment activities for which the body is accredited (and for inspection the type);
- The premises at which the body conducts key-activities;
- The dates of validity.

The processing of scopes is detailed in working instruction RvA-W066.

The number of reports reviewed by the Accreditations Committee (excluding the CCKL reports) is illustrated in table 7.2. Also the percentage of reports that were not accepted by the committee is included in this table.

Table 7.2: Reports processed by the Accreditation committee

Year	Total number of reports	Reports not accepted
2010	112	2%
2011	76	6%
2012	81	1%

Reference in AB's documentation:

RvA-BR002: Policy rule Accreditation, chapter 7

QM001: Quality Manual, chapter 8 and 12

RvA-BR003: Policy rule Scope of Accreditation

RvA-F085: *Advies TL aan directie* (Recommendation of TL to the director)

RvA-F035: *Besluitvormingsformulier* (decision making form)

RvA-W024: *Werkinstructie CA (*working instruction Accreditation Committee)

RvA-W066: *Werkvoorschrift Routering en afhandeling van scopes* (working instruction processing and routing of scopes)

Team comments:

XXX Deputy team leader, on 27th of November 2013 attended to the 218° Accreditation committee, that grants a binding proposal to the Executive Committee (Director / Chief). The committee is composed of 4 members, plus the secretary. In the meeting also RVA Top Management is present, in order to be informed on the advice given, and to provide information if requested. The Top Management monitors the activity of the Committee.

The members received in advance all the documentation. Before starting all the people declare any conflict of interest.

All the written recommendation made by the Committee are archived, and information about assessors performance are taken into consideration for the monitoring performance of the assessors.

One certification was withdrawn, due to financial reason, and some extra activities ware requested.

ISO 13485 certificates. 2 certificate (XXX issued on 30-01-2013). Not yet in line with IAF MD08, but under revision (however XXX issued on 23.10.2013 is with technical area, XXX issued on 18-09-2013)

Med Lab - The presenting of the fixed scope of testing laboratories and medical laboratories meets the relevant requirements of ILAC and EA documents. Flexible scope is granted to some testing laboratories and almost all medical laboratories. But there is no procedure defining the flexible scope for medical laboratories and the flexible scope of testing laboratories is sometimes not clearly defined (see finding #19).

GHG - The reviewer and decision makers on accreditation of verifiers do not meet the competence criteria in article 58 of the AVR, see NC Finding #24.

The accreditation certificate of the verifier has a validity period of 4 years. The countries in where the verifierer is conducting verifications are included in the scope of accreditation and made public on RvAs web site

Clause 7.10 Appeals

Because of the Dutch administrative act (Awb), appeals are called Objections (Appeals in the Awb are filed with the Court or another external body).

Objections may be filed against decisions taken by the Board of the RvA. The rules are included in document RvA-BR006. The Board of the RvA shall take a decision on an objection, based on the advice from the Objections Advice Committee. This committee is appointed by the Board and consists of two staff members of the RvA, not being involved in the decision in question, and a chairman chosen from RvA's Chairs for Court of Appeal. However before this committee is involved the RvA first tries to resolve the grounds for the objection together with the appellant.

In the event the appellant does not agree with the decision on the objection, the case may be brought to court or to the external Dutch body for appeals "*College van Beroep voor het bedrijfsleven*".

Since the new law came into force on 1 January 2010 the RvA received 13 objections. In five cases the Objections Advice Committee had to be involved to resolve the objections. Two objections (for the same case) resulted in a court case.

Reference in AB's documentation:
QM001: Quality Manual, chapter 12;
RvA-BR002: Policy rule Accreditation, chapter 12
RvA-BR006: Policy rule Handling objections

Team comments:
6 appeals in 2013, regarding different issues (Revocation of one accreditation, Accreditation on one year duration, Critical location, payment of the service, inspection in Asbestos).

The Unit manager write a position paper to be sent to the appealing institution, in order to find and agreement before starting the Appeal process.
If this paper in not enough, than the Objections Advice Committee is composed.
Than a meeting between the Objections Advice Committee, the appellant and RVA representative is taken.
RVA pays for the Objections Advice Committee, even if the appellant lose.

The Objections Advice Committee is composed by 3 people. 2 internal people, and a third one (the chief) that is picked up from the Chairmen Committee for Objection. The members of the Chairmen Committee for Objection are nominated by the Supervisory Board. The independence is guarantee.

If the appealing person does not agree with that decision this person has to go to Administrative court.

2 appeals received in 2014 so far, regarding a rejection of information and an initial refusal.

According to national law, everybody that has a direct interest can raise an Appeal against any decision taken by the board of the AB (this is more in relation to ISO 17011, that limit this possibility only to the relevant CAB, and not to everybody that has a direct interest).

GHG - The appeal process is in line with the requirements in the AVR.

Clause 7.11 Reassessment and Surveillance

According to the policy in RvA-BR005, the RvA performs surveillances and re-assessments. Surveillances are normally conducted each year; a reassessment within 4 years from the date the accreditation was granted.

A surveillance is an assessment focussed on the continued implementation of the CAB's system, covering a smaller sample of the scope and the criteria. In general a RvA surveillance always includes an on-site assessment. A lead assessor and technical expertise will be in the team at each surveillance. Decisions on surveillances are taken by the Director Operations. A surveillance may consist of a combination of assessments that are not necessarily conducted at the same time. For example witnessing may be separated from the office assessment. In these situations a decision is taken once a year, so not necessarily for each witness, unless a negative decision is proposed by the team. Until 2011 it was the RvA's policy to change the composition of the team at each reassessment. In 2011 it was decided to change at the first surveillance after each reassessment.

The reassessment is almost as extensive as the initial assessment, however the results of the previous surveillances will be taken into account. Decisions on re-assessments are made by the Chief Executive following a recommendation from the Accreditation Committee.

In RvA-BR005 the grounds for changing the annual surveillance regime are stated. Deciding on the regime is part of the decision after each reassessment or after a surveillance in the second or later cycle. The program for the surveillances in a cycle is specified in chapter 3 of the part A report.

In the case of non-conformities during surveillances and reassessments the procedures are as follows:

Category A non-conformity

1. The CAB must draw up a detailed analysis of the root cause(s) and extent and an action plan to resolve the non-conformity and to recall and correct the certificates and reports produced that do not meet the requirements. The action plan and the analysis must be submitted to the RvA within the period of time that the RvA lead assessor has indicated in the reporting of the NC and the RvA office has then confirmed. The length of this period depends on the severity of the non-conformity; the maximum duration is 20 working days. The RvA will then assess the analysis and the action plan within ten working days of receiving them. A negative result of this assessment will lead to the immediate initiation of the procedure for suspension of the accreditation.
2. Following approval of the analysis and the action plan, the CAB must provide the RvA with the CAR within three months (counting from the date of the closing meeting). The RvA will carry out the follow-up assessment within two months. The RvA assessment team must send a final report and recommendation on the assessment to the RvA within five months of the NC report.
3. The failure to close one or more non-conformities will lead to a recommendation from the lead assessor to suspend the accreditation.

Category B non-conformity

1. The CAB must provide the RvA with the CAR, as explained in RvA-BR004, within three months.
2. The RvA will carry out the follow-up assessment within two months. The RvA assessment team sends a final report and recommendation for decision within five months from the original closing meeting.
3. The failure to close one or more non-conformities will lead to a recommendation from the lead assessor to suspend the accreditation.

For surveillances the decision making file is composed of the report (part B) and the recommendation of the team leader, the up-dated report part A and the recommendation of the account manager. This DMF is reviewed by the Director Operations who takes the decision. Because the former Director Operations left the RvA in December 2012 and a new Director Operation started in February 2013 and is not yet qualified for decision making, the decisions have been taken by the Chief Executive or in his absence by the Manager Strategy and Development since December 2012.

The RvA may decide to conduct an extraordinary assessment as a result of a complaint, changes in requirements, changes at the accredited CAB, or information about the CAB from third parties. The extraordinary assessment shall be carried out according to the rules in RvA-BR002. If necessary these assessments take place without pre-announcement or with a minimal period between announcement and performance of the assessment. The RvA may decide to suspend or withdraw the accreditation as a whole or in part on the basis of the result of an extraordinary assessment. In 2011 and 2012 the RvA conducted 18 and 17 extraordinary assessments respectively.

Reference in AB's documentation:

QM001: Quality Manual, chapter 8

RvA-BR002: Policy rule Accreditation, chapter 8

RvA-BR005: Policy rule Surveillances and reassessments

Team comments:

Most of surveillances are done each year and re-assessment within 4 years. There are assessment plan information table report part A. It is a good way to handle assessment period.

After the first re-assessment it is possible to extend the time between 2 assessments, if the lab fulfils defined criteria (good performer). Even when there was found no evidence that RvA extend the time

between 2 assessments of more than 18 month, the maximum time between 2 assessment is not defined. (see finding #21)

Certif - XXX- Netherlands and XXX Office – request for cooperation (1 man-day + 1 witness QMS and 1 witness EMS). The quotation made by RVA is only a proposal, it is up the local AB to increase the time. Rules for piking files during office assessment: published on the web C004

Seen proposal for collaboration with Ukas and rejection of accreditation in Iran and India.

Transition plan new CFA until 2016: from that date it will be necessary to have also the local accreditation.

Transfer audit from 1 accreditation to another: lighter than initial accreditation.

TES/ CALIB - For a surveillance assessment or extension assessment decision, the filled document F035 was given to the operational director for decision making (seen for extension of the accreditation XXX (report XXX- Flex scope (2013)) or, if not available, to the Executive director (seen for surveillance decision report XXX) following the document QA 003 relating with division of task between operational director and executive director.

*Following a surveillance decision through F035 form linked with the report XXX (2013), the team leader asked for a modification of the accreditation cycle according to the result of the previous assessment, the size (only one person) and the quality of the laboratory. The second surveillance assessment C1.2 could take place between 04/2014 to 09/2014 instead of 01/2014; the third surveillance assessment(C1.3) was deleted and the reassessment H02will take place on January 2016. According with the rules described inBR005 article 20, the Manager Director signed for a positive decision for the new cycle. Nevertheless, the maximum time limit between two following assessment when this kind of deviation was accepted was not defined (*see finding #21*).*

Flexible scope: Flexible scope was described in the document RvA-T025 version 2. A testing laboratory must be accredited under a fixed scope for 2 years before he was able to ask for an extension for a flexible scope. Flexibility could be about "material or product" and/or "analytical method".

*The limit of the flexible scope should be added on the scope to be more clear (*see finding #20*).*

Laboratory must have a list of the item under flexibility. This list must be sent to RvA at least 4 weeks before RvA investigation to allow an adaptation of the assessment team (seen in reports XXX and XXX).

In the part A of the report § 2.4 and in the report part B there was a table with the elements assessed (historical aspect in last 4 years in part A and schematic overview per site in part B). The elements listed in these tables were under RvA classification and wording. This enables RvA to use the template of the report for all CABs for any referential (17025, 17020, ...). The link between the listed item and the paragraphs of each standard was available in the form F095 NL/UK version 3.

PRS: The accreditation programme for the four year cycle is prepared by the Account Manager, including office assessments every year and witness audits. For ISO/IEC 17024 it was confirmed that during reassessments RvA covers all the requirements from the accreditation standard. During the accreditation cycle, the complete accredited scope is assessed.

GHG - Verification bodies: Surveillance is planned once a year and is including at least one witnessing. The accreditation certificate is valid four years.

PRD: For product certification, in one case it is not traceable that all schemes have been assessed at least once in the accreditation cycle as there was no clear explanation in section 2.3 of Report part A and in the assessment plan overview. (See finding #17)

Clause 7.12 Extending Accreditation

When a body requests a scope extension within the scope of an accreditation standard for which it is already accredited, the assessment will be handled as a separate project, but may be combined with surveillances or re-assessments or may be a separate assessment, as agreed between the body, the account manager and the assessment team. The application for extension is filed with RvA-F105. In general the RvA requires the following information to be provided:

- Proposal for scope description;
- Procedures and technical instructions;
- Evidence of validation of the new activity;
- Records of internal audit and management review confirming effective implementation.

The review of an application is conducted by the account manager for the body and recorded on RvA-F107. The assessment will include a pre-assessment in case the activity is a complete new field of activity for the CAB. Otherwise the assessment may consist of a document review, if necessary followed by an on-site assessment and/or a witness. The rules for deciding on the extent of the assessment are contained in RvA-BR003; if necessary the RvA has detailed these rules in specific accreditation protocols. The decisions on extensions are taken by the Director Operations.

Each year approximately 200-300 applications for scope extensions are received.

Reference in AB's documentation:
QM001: Quality Manual, chapter 8
RvA-BR003: Policy rules scope of accreditation
RvA-F105: Application form scope extension
RvA-F107: *Beoordeling aanvraag uitbreiding accreditatie* (form to record the review of application for scope extension)
RvA-SAPxxx: Specific Accreditation Protocols
RvA-W065: *Werkvoorschrift scope uitbreidingen* (Working instruction scope extension)

Team comments:
Seen BR003: Policy Rule Accreditation and checked some files.

GHG - According to the project plan on accreditation verifiers accreditation scope for activity group 10,11, 98 and 99 are considered as extension of the former accreditation in phase I and II in the EU/ETS.

Clause 7.13 Suspending, Withdrawing or Reducing Accreditation

The rules for suspension and withdrawal are contained in RvA-BR002.

Suspensions

Decisions on suspensions are made by the Director Operations. In case the suspension follows the non-resolvement of nonconformities from an assessment, the basis for suspension is provided in the recommendation of the assessment team. Suspension may however also be initiated after noncompliance with requirements was revealed in another way (not paying invoices, not allowing assessment, etc.). As a rule the Chief Executive or the Director Operations will invite the top management of the body for a meeting to discuss the problems and the intentions or plans of the body. Based on this the RvA may decide to suspend immediately or to give the body a number of extra days to resolve the problems.

Suspensions may also be requested by the accredited body. These are referred to as voluntary suspensions. In general a request for suspension, caused by NCs, during an assessment is not honoured if the body is not able to resolve nonconformities. In this case the RvA will suspend and

considers this a non-voluntary or enforced suspension. Suspensions are published on the RvA website, specifying whether this is a voluntary or enforced suspension.

Table 7.3: Suspensions (type V=Voluntary; type N=Non-voluntary)

Year	Type	Certification	Inspection	Calibration	Testing	Medical lab
2010	V	2	1	0	1	
	N	3	1	0	2	
2011	V	2	0	1	3	0
	N	3	1	1	0	0
2012	V	2	2	0	0	0
	N	8	2	1	0	0

Withdrawal

A decision to withdraw an accreditation is made after a recommendation by the Accreditations Committee, based on a decision making file in which the grounds for the withdrawal are explained. The decision is taken by the Chief executive. In the event that the body itself requested withdrawal, involvement of the Accreditations Committee is not required. The list with withdrawn accreditations is published on our website; each withdrawal will be in the list for six months.

The consequences of a withdrawal are stated in the decision and for example for certification bodies these include that the body shall inform the RvA about the certificates issued and about the withdrawal of the certificates within six months after withdrawal. In practise however it is not always possible to ensure that certificates are withdrawn. For a withdrawal in 2012 the RvA therefore informed several parties about the withdrawal and the possibilities of certificates on the market that should have been withdrawn.

Table 7.4: Withdrawals (type V=Voluntary; type N=Non-voluntary)

Year	Type	Certification	Inspection	Calibration	Testing	Medical lab
2010	V	13	4	1	10	0
	N	2	1	0	0	0
2011	V	4	3	4	14	0
	N	0	0	0	0	0
2012	V	11	3	1	1	0
	N	4	1	0	0	0

It should be noted that an accreditation that is not renewed and expired is not counted as a withdrawal. However the same conditions apply and are stated in the decision that is sent to the body.

Reference in AB's documentation:
RvA-BR002: Policy Rule Accreditation
QM001: Quality Manual, chapter 8
RvA-W060: *Werkvoorschrift Schorsingen* (Working instruction suspensions)
RvA-W062: *Werkvoorschrift Intrekkingen* (Working instruction withdrawal)

Team comments:
Seen BR002: Policy Rule Accreditation and checked some files.

GHG - The rules for suspending, withdrawal and reducing of accreditation are in line with the requirements in the AVR.

Clause 7.14 Records on CABs

The policy of the RvA is to develop recording and filing procedures that minimize the use of physical files and space. Developing digital records is a consequence of this policy and, with the revision of the computer system RADAR, will be initiated in future.

The impact of the Dutch Law on accreditation on the system for keeping records was analysed in 2012. The law requires the RvA to implement the provisions of the Dutch Public Records Act (Archiefwet) which means that a so-called selection list is established in which for each type of record it is specified how the files are kept, who has access, how long the files will be active and how to dispose of files after expiry. The RvA has developed a plan to draft this selection list and to develop the management system to control the filing system; it is planned to complete these activities in the first quarter of 2014. The Dutch Cultural Heritage Inspectorate (*Erfgoed Inspectie*) is responsible for the enforcement of the Dutch Public Records Act (*Archiefwet*) which applies to the RvA now. For the moment the rules of our working instruction RvA-W027 applies. This instruction describes how to maintain records related to accreditation activities.

Reference in AB's documentation:

RvA-QM001: Quality Manual, chapter 13

RvA-W027: *Werkvoorschrift Dossiers accreditatieprojecten* (Working instruction records accreditation projects)

Team comments:

During file review, all the relevant documents and records could be found either in electronic system or in paper. This archive is well managed by the Account Managers.

Records were in order on CABs assessments office and witness follow up on NCR and assessment plan, program in papers. All requested documentation on records were available.

Clause 7.15 Proficiency Testing and Other Comparisons for Laboratories

The RvA's policies, including frequencies, on the use of PT for laboratories, inspection bodies and product certification bodies are stated in RvA-T030. Laboratories are requested to submit (together with QA document for preparation of assessments) data on participation in PT schemes of the past year(s). This information is submitted to the assessment teams prior to each assessment. It is the responsibility of the team to verify compliance with the requirements of ISO/IEC 17025 based on the policy in RvA-T030. The defined fields and subfields in RvA-T030 are also used to define the way we expect the laboratories to cover the scopes. The laboratories shall participate on the level of sub-fields and techniques mentioned in the Annex of T030.

Assessment teams are required to address PT participation, scores and follow-up upon unsatisfactory performance during our assessments. In the reports the teams shall state whether the laboratory complies with the RvA policies in RvA-T030. We instructed our assessors and experts not only to verify the performance of the laboratories (for example looking at –z-scores) but also to verify the raw data of the PT samples and tests, to check whether these samples received a special treatment.

The SiteDoc reporting template includes a specific section to report the conclusions of the assessment of PT participation.

In case no PT's are organised in certain areas, laboratories may use the results of bi-lateral or multilateral PT's arranged by themselves or use (certified) reference materials.

Occasionally technical experts may bring items during the assessment as measurement audit. These exercises are not pre-scheduled by the RvA office, and are reported as part of the participation declaration in the report.

The RvA has within its staff a number of experts in PT (also lead assessor ISO 17043 for PT providers) that assist lead assessors and technical experts as appropriate in analysing PT results. The technical experts in the RvA teams are responsible for assessing the use of PT by the laboratories and to report on this. The lead assessors shall assess the policies and systems with respect to PT.

Reference in AB's documentation:
RvA-T030: Interlaboratory comparison

Team comments:

TES/ CALIB - RvA policy about Interlaboratory comparison is well described in RvA-T030 version 2 (28/08/2006). RvA assessment teams well checked ILC and PT done by laboratories during the accreditation cycle under evaluation and detailed their conclusions and observation in the evaluation report. If something missing, a finding had been formalised (many examples observed during the peer evaluation, for example report XXX (2013) including non-conformities about ILC which did not cover all test).

*RvA ~~P~~T-030 just not spoke about the requirement of a plan for ILC and PT according with ILACP09 (see list of findings). This pro-active action was missing (*see finding #7*). Nevertheless, the following of the ILC and PT in laboratory was well done.*

About international ILC and PT, following previous CN3, a coordinator was in charge of the treatment of international proposal for ILC and PT and, using flow chart RvA-FS 006 "international comparison handled by EA/ILAC", he was able to follow the RvA participation at these international comparisons. A list of international comparison was also available with information about the level of participation of RvA.

Clause 8. RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB

Clause 8.1 Obligations of the CAB

The accreditation decisions of the RvA (according to policy rule RvA-BR002) are so-called individual decisions as defined in the General Administrative Law Act (Awb). These individual accreditation decisions specify the conditions applicable to an accreditation granted by the RvA and the obligations of the CAB. The standard text for these conditions and obligations is included as an annex to RvA-BR002. The obligations of the accredited CAB include amongst others:

1. To comply with the requirements;
2. To inform the RvA in case of specific situations (e.g. changes in organization or methods);
3. To allow the RvA to conduct assessments (surveillances and extraordinary assessments);
4. To provide (access to) all necessary information and fully cooperate for the purpose of these assessments;
5. To accept that observers may be added to the assessment team (e.g. from authorities or from EA);
6. To esure that the RvA will be able to conduct witnessing;
7. To use the accreditation mark only according to the rules in VR003;
8. To pay the fees according to the decision D001.

Important information about the body's organization and staff is up-dated before each assessment by the part A report.

Reference in AB's documentation:

RvA-BR002: Policy rule Accreditation, annex 1

Team comments:

Clause 8.2 Obligations of the AB

The information about the current status of the accreditations is published on the website of the RvA, including the full scope of accreditation. Using the address www.rva.nl/search/ a search is possible by the name of the body or by the registration number. It is also possible to search in the text of valid scopes for a certain activity or a certain standard.

The information for CABs to obtain traceability of measurement results is described in document RvA-T018 (Explanatory document for Acceptable traceability), which can be found on the website of the RvA. This document is also to be used by for example by certification bodies.

On the RvA website information about international arrangements can be found (http://www.rva.nl/resources/AMGATE_10218_1_TICH_R6726552723259/AMGATE_10218_0_TICH_R68430685607). Also in each annual report the RvA explains these arrangements.

Whenever an accreditation standard is changed the RvA establishes a transition arrangement consistent with the international arrangements. The RvA informs all accredited and applicant bodies by direct mailing about this arrangement and publishes a news item on its website (see also under clause 7.1). See examples of the news items on www.rva.nl/themes/708431089. Example of introducing ISO/IEC 17065: News item: www.rva.nl/articles/957/AMGATE_10218_1_TICH_R12083927324019/

Reference in AB's documentation:

RvA-T018: Explanatory document Acceptable traceability

Team comments:

No information on the certificate about the date of the accreditation standard in the certificates issued before summer 2013. So, all the new certificates have this information.

No information is available about the date of the certification standard on the certificate.

RvA is considering to put on the web site a warning to contact the office to have more information about the initial date of granting.

Cert - XXX - Certificates for Directives: it is indicated the directive, and the module.

The accreditation is given in different accreditation scheme, for the same directive (eg: Pressure Equipment module D, D1, E, E1, H, and H1 are under ISO 17021 without design + ISO 17020 for design module H).

The most of the assessments are done on the harmonized standards, and not according essential requirements. If it is the case, a technical expert is appointed for the assessment.

No Specific Accreditation Protocol available for Directives, or other information that lead the CB to understand the applicable accreditation standard for each directive.

The accreditation criteria for each Directive and module is not clearly described and publicly available. ISO/IEC 17011 §7.1.2 However, are published 3 documents for CPR (SAP-C018-NL).

For directives and modules it is the notifying authority that decides which accreditation will be needed to notify. That is why RVA have in its application form the question whether the accreditation is needed for notification and for which directives and modules. Based on that RVA consults the notifying authority where necessary and discuss with the CAB the accreditation they need. It is impossible to publish on forehand all possible situations and therefore RvA has a solid application review system in place. Formally it is the responsibility of the CAB to check with the authorities which accreditation he needs for a certain purpose. It then is the responsibility of the CAB to apply for the correct accreditation at RvA.

RVA spends a lot of time in meetings with potential applicants to explain which accreditation and for which scope they should apply.

The reason for publishing SAPs for the CPR is that quite a large number of applications in this field is expected and because of that it seemed to be appropriate to publish a SAP instead of having to explain our procedures to each individual body.

TES/ CALIB – Traceability :RvA policy was well detailed in the document RvA-T018 for calibration laboratories, testing laboratories. The valid version of T018 (version 2 February 2012) is based on ILAC-P10:2002. A new version of ILAC-P10 was published in 2013. The document RvA T018 do not follow the last version of the requirement document ILAC P10). Some points had to be more precise (for example § 2.2 the traceability requirement for calibration laboratories were listed but it was also written "when possible". This was a direct translation of the ILAC P10:2002 document. The new version of this document gave more information to explain "when possible".

For calibration laboratories only National metrology Institutes or calibration accredited laboratories were available for traceability (the option "when possible" to choose another way of traceability was never used).

The way for traceability for testing laboratories which need a "suppliers audit" verifying that all aspects of ISO/IEC 17025 are fulfilled was never used (no example can be shown).

A draft version of the document RvA T018 based on ILAC-P10 :2013 (direct translation) is under discussion before validation. This document will be discussed during the next technical expertise group meeting (2nd December 2013).

NB : there is one per standard. The one in charge of the next version of the document RvA T018 is the "technical expertise group 17025, 17043, ILAC G13" lead by PLT.

Traceability for all quantities was well done through XXX XXX

Most of calibration technical assessors in calibration field XXX were very well found of their field of competence.

GHG - Information on accredited verifier is available in Dutch and English on RvAs web-site. Information on which countries the verifiers are preforming verification is not included but is planned to be inserted. Information on which countries the verifiers are preforming verification is now included in the accreditation certificates and is public available at the web-site.

The accessibility for the pubic and interested parties on the information regarding verification bodies can though be improved.

PRD: RvA informs the CABs about changes in the accreditation requirement and about the transition times. The RvA published T037 Implementation of ISO/IEC 17065:2012 document.

Clause 8.3 Reference to Accreditation and Use of Symbols

The RvA regulation for the use of Accreditation marks is described in document RvA-VR003, which can be found on the website of the RvA. The rules are consistent with the EA-3/01 document.

The accreditation mark of the RvA consists of the logo of the RvA to which the registration number and the field of accreditation is added. The correct use of the mark is an issue during the surveillances and reassessments. Misuse of the mark is in general reason to raise a category A nonconformity.

In case of improper use of the accreditation mark by non-accredited organisations the legal advisor of the RvA will contact the organisation and will demand immediate cancelation of the use of the mark. If the RvA is not able to contact this organization then the incorrect use of the RvA mark is included on the website on a special page on which it is explained that the organization is not accredited (follow link improper use of mark as published on the website of the RvA (Recent – Improper use of mark)).

The RvA has sublicense contracts with CABs that want to use the IAF-MLA or the ILAC-MRA mark in combination with the RvA mark. At the moment 32 Certification bodies have such contract for the use of the IAF-MLA mark and 32 Laboratories for the use of the ILAC MRA mark. In order to facilitate the

verification by the RvA assessment teams the report part A was revised in 2011 to include this information.

Reference in AB's documentation:
RvA-VR003: Regulation for the use of Accreditation marks
RvA-F205-UK: IAF MLA Mark Sub License Agreement
RvA-F206-UK: ILAC Laboratory Combined MRA Mark Sub License Agreement
RvA-F101: Template report Part A.

Team comments:
ISP - It was seen that there was an accreditation mark in the inspection reports between the logos of other organisations so that it gives impression that RvA has accredited other organisation. Use of accreditation was not in line with RvA document RvA-VR003. Although the lead assessor looked inspection reports he did not notice item mentioned. Assessing results of the use of accreditation mark was not in line with RvA-VR003. See finding #14

TES/ CALIB – The use of the RvA mark was well assessed during the assessment witnessed in testing and calibration field via examination of testing or calibration report and by an examination by the TL of the web site of the laboratory before the assessment.

GHG - The RvA- VR003 is planned to be updated to include the use of the accreditation mark for ISO14065 accreditations.

2.2 Arrangement Requirements to be evaluated

EA-2/02 (2011)

Article 4.1 Standards

See section 2.1 under clauses 4.6 and 7.1

Team comments: See section 2.1 under clauses 4.6 and 7.1

Article 4.2 Supplementary requirements for requesting/maintaining signatory status

From the history described in section 1.7 and the results of previous evaluations we may conclude that the RvA is fully operational. The statistical data included in annex 3 demonstrates that the RvA has sufficient experience in all scopes of the MLA. Clause 6.1 in section 2.2 provides information about the access to expertise. The table below provides information about the implementation of EA requirements based on the list with mandatory documents in EA-INF/01.

Mandatory document	Reference to RvA documents
EA 2/13 Cross Frontier Policy for Cooperation between EA Members	The RvA has described the Cross Frontier Policy in document RvA-BR007 (Policy rule for Cross-Frontier Accreditation).
EA 2/14 Procedure for Regional Calibration ILCs in Support of the EA MLA	The RvA has described the procedure for Interlaboratory Comparison in explanatory document RvA-T030 (Interlaboratory comparison)
EA 2/15 Requirements for the Accreditation of Flexible Scopes	The RvA has described the requirements for the accreditation of flexible scopes in the documents: • RvA-BR003 (Policy Rule Scope of Accreditation) • RvA-T025 (Explanatory document Scope of Testing laboratories)
EA 2/17 Guidance on the horizontal requirements for the accreditation of conformity assessment	The RvA has described this requirements in the documents: • RvA-F001 (Registration form Accreditation • RvA-F101 (Report Part A)

bodies for notification purposes	Also, the RvA has held an information meeting for NoBo's, government officials and other interested parties on 26th November, 2012
EA 3/01 Conditions for the use of accreditation symbols, text reference to accreditation and reference to EA MLA signatory status	The RvA has described the terms and obligations for the use of the accreditation mark in document RvA-VR003 (Regulation for the use of Accreditation marks). The RvA has adjusted the declaration of accreditation for the MLA accreditations concerning the reference to EA MLA Signatory Status. Example: form RvA-F011 (declaration of accreditation for ISO/IEC 17025-calibration).
EA 3/11 Food Safety Management Systems – Scope of Accreditation	The requirements of EA 3/11 are included in specific accreditation protocol SAP-C001 (Certification of Food Safety Management Systems). Also, the scope for FSMS is included in the template scope for ISO/IEC 17021; document RvA-F117.
EA 3/12 EA Policy for the Accreditation of Organic Production Certification	Implementation will be initiated in the second half of 2013
EA 4/02 Expression of the Uncertainty of Measurement in Calibration	The RvA has described the expression of the uncertainty of measurement in explanatory document RvA-Tk2.8
EA 4/07 Traceability of Measuring and Test Equipment to National Standards	RvA has described the traceability to national standards in explanatory document RvA-T018 (Acceptable traceability)
EA 4/17 position paper on the description of scopes of accreditation of medical laboratories	The RvA has described this in document RvA-BR003(Policy rule Scope of Accreditation)
EA 5/03 Guidance for the implementation of ISO/IEC 17020 in the field of crime scene investigation	The RvA does not yet accredit organisations for Crime Scene Investigation.
EA 6/02 Guidelines on the Use of EN 45 011 and ISO/IEC 17021 for Certification to EN ISO 3834	No specific RvA implementation document
EA 6/03 Document for Recognition of Verifiers under the EU ETS Directive	The RvA has described this in specific accreditation protocol RvA-I001 (EU ETS Directive; Verification of emission data (CO2 and NOx))
EA 6/04 Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites	No specific RvA implementation document
EA 7/04 Legal Compliance as a part of accredited ISO 14001: 2004 certification	The RvA has described this in specific accreditation protocol SAP-C005 (Certification of EMS in accordance with ISO14001)
EA 7/05 Guidance on the Application of ISO/IEC 17021:2006 for Combined Audits	The RvA has described this in several specific accreditation protocols: • SAP-C004 (Certification of QMS in accordance with ISO 9001) • SAP-C005 (Certification of EMS in accordance with ISO14001) • SAP-C006 (OHSAS 18001) • SAP-C010 (ISMS certification based on ISO/IEC 27000) EA 7/05 is also addressed in the template for the assessment plan, document RvA-F121

Concerning the use of documents from external origin, the RvA introduced in 2010, after the EA peer evaluation, form RvA-F946 for conducting an impact assessment for each new document (or resolution) from EA, IAF and ILAC to ensure proper implementation of these requirements.

Team comments: RVA has included in its procedure (usually SAP documents that are published on the web) the requirements foresee in EA documents. The application of these has been checked during the files evaluations, scheme by scheme.

Article 4.3 Proficiency Testing and other Laboratory Comparisons

The RvA's policy on use of PT and ILC is stated in RvA-T030. Also see in section 2.1 under clause 7.15 and appendix 2.

Team comments: see in section 2.1 under clause 7.15

Article 4.4 Subcontracting

The RvA only subcontracts to other EA-MLA (IAF-MLA or ILAC-MRA) accreditation bodies, for the assessment of locations outside the Netherlands. See section 2.1 under clause 7.4.

Team comments: See cross frontiers.

EA-1/06. EA Multilateral Agreement

The RvA promotes the acceptance of accredited certificates and reports issued by bodies accredited by EA MLA Signatories. For this in 2013 we established templates for 'Statements of equivalence' of accreditation activities based on EA-INF/04. In 2013 one request for such a statement was received.

In February 2013 and earlier in 2010 the RvA failed to inform the EA MLA Signatories and the MLA secretariat about a significant change in its staffing, the appointment of a new Director Operations. The root cause was that having the MLA secretariat at our office made us unaware of the need to inform this secretariat in addition to the information provided to our internal staff. In future the RvA's representative in the EA-MAC will be responsible for informing the other EA MLA Signatories and the MLA secretariat about such changes.

The information presented in the EA-MAC on the peer evaluator days provided to EA, demonstrates that the RvA is providing more than sufficient resources. All evaluators have been participating in one or more EA training activities since 2010.

Team comments:

The RvA promotes the acceptance of accredited certificates and reports issued by bodies accredited by EA MLA Signatories: seen the Statement of equivalence form, based on INF/04, and RVA publish on the web site International resolution.

Requirement in Regulation (EC) 765/2008

Article 4 (1) Appointed by the Member State as the single national accreditation body

The RvA is appointed by law as the single National Accreditation Body in the Netherlands. This law Wet aanwijzing nationale accreditatie-instantie (Law on notification of the National accreditation body) - also referred to as Wanai - came into force in 1 January 2010.

Article 4 (5) Operate accreditation as a public authority activity with formal recognition by the Member State

Although the RvA is not a Governmental organisation, by law we have been entrusted with the operation of accreditation as a public authority. The Wanai states in article 2(2) that the RvA is a so-called *Bestuursorgaan* (Administrative authority) to which the Dutch Administrative Law Act (Awb) and the Framework Law on Autonomous Administrative Authorities apply. The Minister of Economic Affairs is responsible for the RvA. In 2010 by a special decision of this Minister, the RvA was also appointed to

act as national accreditation body for accreditation standards that were not yet harmonised by the European Commission.

Article 4 (6) Have clearly distinguished tasks and responsibilities from other national authorities

The Wanai states in chapter 3 the specific tasks of the RvA. No other national authorities have the responsibilities and tasks that are now entrusted to the RvA.

Article 4 (7) Operate on a not-for-profit basis

The Articles of association confirm that the RvA is a not-for-profit foundation. By approving the budget and financial report the Ministry of Economic Affairs safeguards this principle. See also section 2.1 under clause 4.5.

Article 4 (8) Not own shares in or otherwise have a financial or managerial interest in a conformity assessment body

The RvA does not own shares in a CAB. Nor does it have other financial or managerial interest in a CAB.

Article 6 (2) Not competing with other national accreditation bodies

By cancelling the accreditations in the EA region since 2010 RvA has implemented the principle of non-competition. Also the RvA does not respond to any international tenders for providing accreditation services. The RvA however may compete indirectly with other accreditation bodies through participation in tenders for providing consultancy or training services.

By changing its Cross Frontier Policy in July 2013 the RvA has implemented the principle of non-competition also outside the EA region.

Article 7 Cross-border accreditation

In its policy for CFA (RvA-BR007) the RvA has implemented the conditions of this article 7. With the implementation of 765/2008 in 2010 the RvA started not to renew accreditations of CABs in the EA region. On 31 December 2009 the RvA had 37 cross frontier accreditation in the EA-MLA region. At the end of May 2013 the RvA had 13 accreditations left in the EA-MLA region. These accreditations are either planned to expire before 31 December 2013 or can be maintained based on the exceptions mentioned in article 7 of the Regulation; it is expected that the following accreditations will remain:

- One CAB for 17043 in Bulgaria (PT not part of MLA);
- One CAB for 17024 in Italy (Accredia will not provide this accreditation);
- One CAB for 45011 in Ukraine (NAAU not MLA signatory for 45011);
- One CAB for 45011, 17020 and 17025 in Slovenia (SA requested the RvA to provide this service);
- One CAB for 17043 in Slovenia (PT not part of MLA);
- One CAB for 17025 Calibration in Cyprus (CYSAB not MLA signatory for calibration).

Outside the EA-MLA region the RvA had 54 accreditations (end of May 2013) compared to 49 on 31 December 2009.

Article 8 (11) Publish audited annual accounts

The approved annual accounts (*Jaarrekening*) are published on the RvA website.

Team comments:

The RvA is appointed by law as the single National Accreditation Body in the Netherlands.

No competition with other AB in Europe.

The full annual accounts as prepared and adopted after approval by the Supervisory Board and the Minister of Economic Affairs and provided with an unqualified report, can be viewed on www.rva.nl.

Seen the Cross frontiers policy, and some files has been checked (it was closed also a finding of the previous evaluation).

Minister of Economic Affairs

Pursuant to EU Regulation 765, the Dutch National Accreditation Body Appointment Act (Wet aanwijzing nationale accreditatie-instantie) and the Dutch Independent Executive Agencies Framework Act (Kaderwet ZBO), the Minister supervises the RvA via regular communications as laid down in the protocol dated 18 November 2010, by approval of rates, budgets, annual accounts, amendments to the Articles, appointment of Director and by attending the EA Peer Review.

Cross frontiers policy

There is a List of the critical Location (critical location and certification body established outside the Country). The file gives the information on the way to assess the location and the period.

For sampling during regular assessments RvA considers each location abroad as a self-standing certification body.

This means that RvA each year perform assessment in all the location. If there are more location in the same country, however RvA assess all the scope, but sampling the location for the on-site visit.

The process is fully under control.

The AB have the procedure for sampling fixed office locations, including remote personnel, where other activities are performed or from which personnel performing these activities are managed. The procedure ensures that a representative number of these locations are assessed within a defined timeframe.

For ISO/IEC 17024 the file of the Italian CAB was reviewed and the communications with ACCREDIA were checked. The cross frontier policy is being followed.

2.3 Closing of findings from previous evaluation

Findings of previous Peer Evaluation:

NC1: In a number of cases the RvA's records do not confirm that they have complied with their cross frontier policy.

The details for planning and execution of visits to Key Location is not fully recorded and justifications for not assessing some locations are not fully explained

Note: some of the details on the Cross Frontier IAF returns were found to be in error.

Status: In 2012 five of the 126 critical locations are not assessed. The Cross-Frontier documents are adapted. The inclusion of the assessment of cross frontier location in the 4-year assessment programmes is ready. In 2013 a survey will be conducted to re-establish the key locations based on the new requirements in EA-2/13 and the RvA implementation of these requirements in RvA-BR003.

NC2: Currently the RvA is operating two accreditation processes [Public (within EU) and Private (Rest of the World)] which have differences as detailed in a Gap Analysis supplied to the evaluation team by

the RvA. This approach is considered to introduce discrimination into the process in contravention of ISO17011.

For information some examples are the Application Process, Appeals and Complaint Process.

Status: RvA stopped with considering the work outside the EU as being private work and now also considers this work to be part of the public task. As a consequence no discrimination is introduced into the process.

NC3: the RvA has issued accreditation schedules that do not fully describe scopes as required by the current international agreements.

The RvA has taken action to implement a policy to utilise NACE 2 classification for scoping of EMS certification activities under ISO17021. However document (W032) and some scope schedules (C345, C223) continue to refer to NACE1.1 classification.

The scopes in the medical field are not yet addressed according to the EA-4/17 document.

Status: First part of the NC concerning NACE 2: Scopes are corrected and a revision of document W032 is awaiting final approval upon which the 2007 version will be withdrawn. Second part of the NC concerning EA-4/17: all scopes are now consistent with EA-4/17 meaning that the fields are indicated. The scopes are in almost all cases (except for M012) referred to as being 'flexible' but could easily be considered as fixed scopes because the individual tests are very often still mentioned. A project is started in 2013 to make the scopes really flexible and to decide on the principles for scope definition for each field within the medical laboratory professions. It is expected that the first proposals will be ready for the pilot assessments in the last quarter of 2013.

CN1: Based on the current organisation intended to provide the structure for safeguarding impartiality it is not evident that the current committees fully provide opportunity for effective involvement by interested parties to ensure a balanced representation of interested parties with no single party predominating.

During the 2010 internal audit this issue was raised by the RvA and is now the subject of a corrective action programme which is planned to be completed during 2011.

Status: It was planned to have the establishment of the advisory panel completed by the end of 2011 by having a meeting with all stakeholders. However little interest from our stakeholders prevented us in preparing the first meeting to start the panel. But the RvA is able to demonstrate that it significantly increased its communication with all stakeholders since 2010. An analysis of Interested Parties and Terms of Reference for the Stakeholder Panel have been discussed with the Supervisory board and are in place. The panel will have its first meeting 26th September 2013.

CN2: In some cases the RvA has not made publically available information relating to accreditation criteria

Examples

Criteria/requirements to accredit medical laboratories for ISO22870 POCT (point of care)

Criteria/requirements to accredit laboratories for CEN TS 15675 for gas emissions field

Status: the RvA is still not accrediting for ISO 22870 and the procedures for this will be established in 2014 as part of the CCKL transition project. However mentioning of ISO 22870 is included in policy rule RvA-BR010. Based on this finding the RvA made an inventory of all the accreditations for which special requirements are applicable. A large number (approx. 15) new or revised specific accreditation protocols have been published since.

CN3: the RvA's Policy for its participation in internationally organised PT activities is not fully implemented, in that there are a number of cases where a lack of effective internal communications has resulted in either the non involvement of RvA CABs or the lack of effective reporting and follow up of participating CABs

Examples

- Information about internationally organised proficiency testing activities in some cases was forwarded to account managers, but it was not evident that a decision had been taken to invite relevant CABs to participate. E.g. TO76 and IMEP-28.

For one PT (IMEP-23) an RvA accredited laboratory had participated and the results had not been satisfactory. It was not possible in reports from later assessments to see that the laboratory or the assessment team was informed about the results and no follow-up was evident.

Status: Finding is corrected and solved. A flow-chart is drawn up (RvA-FS006). However implementation cannot be demonstrated yet.

CN4: the RvA has developed policies and procedures (T015) for the implementation of Flexible scopes for Laboratories in line with EA2/15. It was however noted that in a number of cases the documented provisions had not been fully implemented.

Examples:

For XXX there was no evidence of the receipt of the list of methods under the flexible scope to plan the assessments and there was no evidence in the reports that specific requirements for flexible scopes were included as part of the evaluation.

Status: Staff and assessors has been informed about the requirements and the template for the letter or email to the laboratory for announcing an assessment mentions the information to be provided about activities under the flexible scope. Samples demonstrated that the instructions were followed (XXXX) in most cases, but that still a number of assessments were conducted in which this was not the case. It was agreed in addition to the actions already implemented to record the information about the flexible scope also in the part A report.

CN5: Reporting. In the different accreditation fields Part A Reports (mainly Paragraphs in section 2) are not systematically completed resulting in critical information regarding the content of the assessment not being available for planning activities and demonstration of coverage of scopes and locations

In the different accreditation fields reports from technical experts and/or technical assessors are generally not fully making reference to the requirements which have been assessed for compliance. There is also no documented basis for the lead assessor's assumption of the requirements covered.

The lead assessor fills out a form of covered requirements assuming that all experts covered the same requirements.

Reports were seen from technical experts referring to a few specific requirements in ISO 17025 but leading to the assumption that all technical requirements had been assessed. Reports were also seen with no references to requirements.

Status: The instruction for the use of the part A report has been revised and the template has been improved. The unit manager and decision makers in the RvA have been reviewing these reports very thoroughly in 2011 and 2012. Now we conclude that no critical information is lacking in these reports anymore.

For the reporting from technical experts the RvA has taken the position that our reports are quite comprehensive and that from the report it is possible to judge which requirements were addressed. It is for the sake of safeguarding that all requirements will be addressed in a cycle that the overviews in the part A report are maintained and to provide information about structural findings over time. We consider

the accreditation standards to be the tool to assess competence but these tools are not the objectives of an assessment. So specifying each and every subclause from the standard does not add any value.

Team comments:

NC1: closed. New cross frontiers policy. Is running a survey to re-establish the key locations based on the new requirements in EA-2/13 and MD 12. However a new finding on this topic has been issued (see finding #4 on competence criteria).

In the product certification field, 3 CAB files having cross frontier activities were reviewed. It was observed that Part A of the report contained the detail information of the cross frontier activities and the planning and execution for the assessment of CFL's.

NC 2: closed. Now there is only one policy (inside and outside Europe).

NC3: closed. RVA is using NACE 2.

CN 1: closed (see in this report about impartiality). However 1 comment has been raised

CN2: closed. A large number (approx. 15) new or revised specific accreditation protocols are published

CN3: closed. Technical coordinator for ISO 17043 standard (JRJ) is in charge of collecting international proposal of ILC. A flow-chart Rv-FS006 "internal comparison handled by EA/ILAC" is available. Laboratories were invited by RvA to participate to international ILC. There is a list of international PT and ILC followed by the technical coordinator.

CN4: closed. The report of the last surveillance of the laboratories XXX shown that the lists of test concerned by the flexible scope were well received by RvA in advance before the assessment. The way of doing for flexible scope seems satisfactory for this point.

CN5: closed. working instructions W011 (working instruction preparing part B of the report) and W012 (working instruction preparing part A of the report) were examined with the illustration of some filled reports. The requirements assessed were now well identify in the report.

In product certification, the reviewed files during the witnessing and the office evaluation it was observed that the report were comprehensive. Part A of the report includes detailed information about the CAB and accreditation cycle. Part B of the report includes the specific information about the requirements of the standard and findings.

Cm1: cleared - the account managers now have technical background. Unit A and Unit B are responsible for the accreditation processes for testing & calibration laboratories, certification, inspection & verification bodies, PT-providers and RM-producers. RvA established nearly two identical units, both with a balance in types of accreditation, experience and back-ground of staff. The amount of the staff is suitable for the work load.

following the organisation of RvA in two units without speciality and to avoid the spread of expertise in units A and B, technical coordinators had been created. There was a coordinator for ISO 17025 testing, one for ISO 17025 calibration and some other for specific field (hydrobiology, non destructive tests, ...) and some technical expert group manager in contact with account manager. OK.

Cm2: cleared - Risk analysis of related bodies in the management review (that takes into consideration the relationship with the Ministry of Economic affairs). However a new finding on this topic has been issued.

Cm3: cleared - A "Supplementary application form" RvA-F004-1 is available for testing laboratories for a description of the internal calibrations + BR005 article 13.

Cm4: cleared - the testing laboratories scope gave the reference of the technical standards without a date. It means the last version is proposed to the client. If an old version was used the date followed the reference of the technical standard.

Cm5: cleared - The document RvA-T018 spoken about in the findings Cm5 was a direct translation of ILAC-P10:2002 note n° 3 § 2. The new version of the document RvA-T018 version 2february 2012 remove this reference.

3 Overview of evaluation activities

3.1 Witnessing

3.1.1 Overview witnessing

Activity (Level 2 and 3)	**Technical field, regulated field, EU directives and regulations** (Level 4 and 5)	**Type of assessment** (initial, surveillance, reassessment, scope extension)	**No. of days of assessment / no. of days witnessed**
Certification of management systems (ISO/IEC 17021)	QMS	3rd surveillance	1 day witnessed. The assessm. lasts 1,5 days
Certification of management systems (ISO/IEC 17021)	ISMS, QMS, ITsMS	2nd surveillance	1 day witnessed. The assessm. lasts 1 days
Calibration (ISO/IEC 17025)	Calibration in length, mass, volumic mass, weighing machine (automatical or not),temperature	surveillance	1,5 day of assessment / 1 day of witnessing
Testing (ISO/IEC 17025)	Testing in construction materials field	surveillance	1 day of assessment/1 day of witnessing
Calibration (ISO/IEC 17025)			
Testing (ISO/IEC 17025)	Food	surveillance	1 of 1
Medical Testing (ISO 15189)	Microbiology (Bacteriology, Infectiology, Moleculare Biology, Parasitology)	Reassessment (Transition CCKL to ISO 15189)	2 day assessment, witness on second day
Inspection (ISO/IEC 17020)	soil protection (liquid-tight features) E.g. type examination, product verification, MI-directive, NAWI-directive etc.	reassessment surveillance	2/1 1/1
Certification of persons (ISO/IEC 17024)	Welders; Electro technicians; Asbestos removal personnel	Reassessment	2/1
Verification of GHG (ISO 14065)	(EU) 600/2012 (AVR), 601/2012 (MRR)	Re-assessment ISO14065 and “up-dating” to AVR	2 days
Certification of products (EN 45011, ISO/IEC 17065)	Gaming	Re-assessment	1 day witnessed The duration of the assessment was 2 days.
Certification of products (EN 45011, ISO/IEC 17065)	Smoke detectors	surveillance	1 day witnessed. The assessment was a combined assessment with ISO/IEC 17021.

Activity (Level 2 and 3)	**Technical field, regulated field, EU directives and regulations** (Level 4 and 5)	**Type of assessment** (initial, surveillance, reassessment, scope extension)	**No. of days of assessment / no. of days witnessed**
			The duration of the assessment was 2 days.

3.1.2 Witnessing reports

Information on witnessed assessment	
Date(s) of assessment, team member participation:	26.11.2013 EA Team leader: XXX EA trainee assessor: XXX
Accreditation standard(s):	ISO 17021 (RvA assessed also ISO 17020, but this scheme was not witnessed by EA)
Scope of assessment:	QMS and EMS
Type of assessment	3rd surveillance - Office assessment
Composition of the assessment team of the accreditation body	Lead Assessor: XXX contracted (QMS) Assessor(s): XXX contracted (EMS) Expert(s): XXX contracted (INSP) Interpreter: XXX, internal staff RvA

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): Preparation was according to routine and gave a plan for the assessment to the assessor which was followed in a timely manner. During the opening meeting the EA assessors was presented, and the Certification Body gave a brief overview of the activities performed. The EA Assessor was accompanied by a translator (RvA own staff). However, in the morning it has been some overlapping, because the RvA assessors ware three, but the personnel of the certification (and computer available to have access to all the files) ware only two. The assessment team was equipped with a plan for the assessment and all background documentation was adequate.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): The 3rd surveillance MS assessment was scheduled for 1,5 day with a lead assessor, one assessor. During the first day also one assessor for Inspection was present (1st surveillance). In addition 2 witness assessments (QMS / EMS, and Inspection) has been performed before this assessment.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): The opening meeting was conducted by the lead assessor of RVA addressing details of the assessment procedure including especially the arrangements for the day program. The peer evaluation was explained and all participants introduced themselves. All staff members and the director of the certification body were present.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): The RVA assessor used an audit note. The team went through the standard clause by clause and asked for objective evidences.
2.3	Assessment of critical issues

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
	Management system certification: (competence management; man-days calculation; impartiality and independence; audit reports and decision making; witnessing): The team members gathered sufficient evidence to the assessment of competency management by CAB. Duration of the audit and Decision –making was satisfactory assessed. It has been shown that the competence of decision-making staff of CAB was covered. Team members sufficiently deeply analysed the impartiality and independence of the CAB, including risk analysis developed by CAB.
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): The team interviewed the staff members of the certification body, evaluated the corrective actions regarding the results from the witness audits and checked records of the certification body concerning applications, evaluation and decisions. Staff members were interviewed, their competence was evaluated by reviewing the personnel files and the records of the CAB were reviewed to get objective evidence regarding the effective implementation of the certification scheme.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): The assessment lasted two days. EA team attended only to the first one. So, a preliminary final meeting was conducted, to summarized the results of the first day. At this stage, 10 minor NCs raised by the Team Leader, and 6 minor NCs raised during the witness audits. The final number will be issued on the second day. NCs were properly formulated and substantiated. The findings were accepted by the certification body.. The team focused its attention to document control and to evaluate the competence of the CAB. The communication of the team members with the CAB was good.
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): ---
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): The CB is accredited in QMS for 4 IAF codes, and in EMS for 1 EMS code. In the accreditation cycle, RvA performed 3 witnesses for QMS and 1 for EMS. Last year assessment: 4 October 2012 and 10 January 2013 XXX – team Leader QMS and EMS XXX– Member QMS and EMS XXX – ISO 17020
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): The team had a good interaction, before the audit, and during the audit.
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): The lead assessor planned time for the preparation of the closing meeting (summary) on the first day of the assessment. He discussed the results of the day with the assessor and filled in the nonconformity forms.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): The assessment was very comprehensive. The findings were based on objective evidences and also the grading of the nonconformities was acceptable and justified.
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): The team conducted a professional assessment. However, some findings has been raised (see chapter 3.3 below). The interpreter was really professional and impartial.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
3.3	Other or general remarks: The RVA Audit team assessed if the certification body has arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations, but the RVA Audit team did not assess if the CB was able to demonstrate that it has evaluated the risks arising from its certification activities in each of its fields of activities and the geographic areas in which it operates, in order to justify the adequacy of the arrangements taken (coverage of the insurance). ISO 17021, 5.3.1 Insurance: the CB has one insurance (maximal coverage 2.500.000). The Audit team did not investigate on the justification of the adequacy of the coverage required to the insurance company, but limited its evaluation on the existing or not of this coverage. The RVA Audit team assessed if the certification body has arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations, but the RVA Audit team did not assessed if the CB was able to demonstrate that it has evaluated the risks arising from its certification activities in each of its fields of activities and the geographic areas in which it operates, in order to justify the adequacy of the coverage required to the insurance company. See finding #2

Information on witnessed assessment	
Date(s) of assessment, team member participation:	26.11.2013 XXX
Accreditation standard(s):	ISO/IEC 17065:2012
Scope of assessment:	Smoke detectors
Type of assessment	Surveillance
Composition of the assessment team of the accreditation body	Lead Assessor: own staff Assessor(s): Expert(s): fire safety (Smoke detectors)

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): The documents used for preparation were adequate. Documents included results of previous office assessment and witnessing. Lead assessor (LA) and Technical Expert (TE) had the detailed documentation of the previous assessment, including assessment report (Part A and Part B), NC's and corrective action plan. The time allocated was adequate for office assessment. Part A of the report was sent to the CAB for confirmation and an assessment plan was prepared in advance and sent to the CAB for information.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): The assessment was a combined assessment. The CAB was accredited based on both ISO/IEC 17021 and ISO Guide 65. The first day of the assessment (25.11.2013) was conducted based on ISO/IEC 17021 with the same LA but different TE's. The second day was conducted based on ISO/IEC 17065. It was 1 day surveillance assessment with two assessment team members (totally 2 mandays). Time allocated was sufficient and team composition was proper.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): During the opening meeting LA introduced the assessment team and the EA team member. LA explained the purpose of the EA evaluation together with confidentiality issues. Roles and responsibilities of the team were clarified. Assessment plan and scope of accreditation were verified. After the opening, a short team meeting was held and LA informed TE about the critical issues to be covered during the assessment.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): The assessment was conducted based on ISO/IEC 17065:2012. LA checked the plan for the implementation of ISO/IEC 17065:2012 and its results. Part A of the report was verified by the LA. Changes since the previous assessment, organisational structure, and changes in the management system including internal audits, management reviews, annual quality report, objectives, preventive and corrective actions, complaints, and appeals were evaluated by the LA.
2.3	Assessment of critical issues
	Calibration laboratories (traceability; uncertainty issues; competence of staff; method validation; data-processing; quality control; PT performance; reporting): NA
	Testing laboratories (contract review; traceability; method validation; quality control; PT performance; reporting; environmental conditions): NA
	Medical laboratories (pre-examination; post-examination; method validation; quality control; PT performance; reporting; environmental conditions): NA
	Inspection (independence type A, B or C (in particular type A); monitoring and harmonizing inspectors; selection and conduct of witnessing; quality assurance; calibration and traceability; testing and sampling): NA
	Management system certification: (competence management; man-days calculation; impartiality and independence; audit reports and decision making; witnessing): NA
	Product certification: (Impartiality and independence; subcontracting; certification schemes, surveillance regime; competence; evaluation and decision making; testing and inspection): The assessment was conducted according to previously prepared plan which was in line with ISO/IEC 17065. Training activities for ISO/IEC 17065 was checked by LA. Current structure of the CAB, subcontracting, use of mark and certificates, mechanisms for impartiality (objectives, meeting with stakeholders, and commitment of management), independence, internal audits, management reviews, preventive actions and corrective actions including those were done for the findings of the previous assessment, monitoring of auditors and decision making, complaints, and appeals were examined by the LA. Qualification, training and selection of auditors were verified by TE with sampling of auditor files. The certification scheme which was structured based on System 2 described in ISO/IEC 17067 was verified by team members using RvA T033 document.
	Person certification: (competence of CB to perform examination; impartiality; witnessing; certification schemes; surveillance and recertification): NA
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): Some files were sampled and a vertical assessment was conducted by TE. LA collected the copies of records and documents from the CAB as evidence. The assessment was done through interviewing, review of documents and reports. Techniques were appropriate.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): The team raised 5 Type B findings. One of those findings was “Type (B)”. “Type (B)” nonconformity was related with the transition to ISO/IEC 17065:2012. All findings were based on objective evidences and were communicated with CAB staff.
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): NA

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): Report from previous assessment was taken into account and corrective actions and use of mark were followed up. Plan of surveillance for the accreditation cycle was available and followed.
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): Team had an internal meeting before the closing meeting where they agreed on findings. LA formulated the findings. The team interaction during the assessment was good.
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): There was no formal closing meeting because witnessing activities were planned close to the office assessment and closing meeting would be done after the witnessing. LA confirmed the dates of witnessing and presented the findings of office assessment in detail. The team leader explained the RvA rules for closing "Type (B)" non-conformities. Approval of the manager of CAB was taken.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): Depth and width of the assessment was good and findings were relevant. Team used RvA T033 document for the review of the certification scheme. T033 document was prepared based on EA 1/22.
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): Competence of the team was good. Assessment team was professional and LA had a good experience and knowledge for RvA policies.
3.3	Other or general remarks: The assessment was conducted in line with the plan. Both team members were experienced and professional. No critical issue was observed.

Information on witnessed assessment	
Date(s) of assessment, team member participation:	27.11.2013 (the second day of two days re-assessment) XXX
Accreditation standard(s):	ISO/IEC 17065
Scope of assessment:	Gaming machines
Type of assessment	Re-assessment
Composition of the assessment team of the accreditation body	Lead Assessor: contracted Assessor(s): Expert(s): gaming

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): Documents of CAB were sent to team members by e-mail. Lead assessor (LA) and Technical Expert (TE) had the detailed documentation of the previous assessment, including assessment report (Part A and Part B), NC's and corrective action plan. The time allocated was adequate for office assessment. Part A of the report was sent to the CAB for confirmation and an assessment plan was prepared in advance and sent to the CAB for information. The documents used for preparation were adequate including results of previous office assessment and witnessing.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): Time allocated was sufficient and team composition was proper. It was a 2 day re-assessment for two assessment team members (totally 4 man-days). The CAB had an accredited lab and an inspection body having scopes relevant to the product certification. No witnessing was done as due to RvA rules witnessing are planned separately from the office assessment.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): The official opening meeting was held on 26 November 2013. The meeting on 27.11.2013 was only to introduce EA evaluator and the purpose of the EA evaluation together with confidentiality issues. The summary of the previous day was presented by the team leader and the daily program was confirmed. The assessment was conducted in English as the CAB was owned by an International Company.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): The assessment was conducted based on ISO/IEC 17065:2012. LA checked the implementation of ISO/IEC 17065:2012. Changes since the previous assessment, organisational structure, and management system including internal audits, management reviews, preventive and corrective actions, complaints, and appeals were evaluated by the LA.
2.3	Assessment of critical issues
	Calibration laboratories (traceability; uncertainty issues; competence of staff; method validation; data-processing; quality control; PT performance; reporting): NA
	Testing laboratories (contract review; traceability; method validation; quality control; PT performance; reporting; environmental conditions): NA
	Medical laboratories (pre-examination; post-examination; method validation; quality control; PT performance; reporting; environmental conditions): NA
	Inspection (independence type A, B or C (in particular type A); monitoring and harmonizing inspectors; selection and conduct of witnessing; quality assurance; calibration and traceability; testing and sampling): NA
	Management system certification: (competence management; man-days calculation; impartiality and independence; audit reports and decision making; witnessing): NA
	Product certification: (Impartiality and independence; subcontracting; certification schemes, surveillance regime; competence; evaluation and decision making; testing and inspection): The assessment was conducted according to previously prepared plan which covered most of the clauses of the standard. Current structure of the CAB, use of mark and certificates, mechanisms for impartiality, independence, internal audits, management reviews, preventive actions and corrective actions including those were done for the findings of the previous assessment, complaints, and appeals were examined by the LA. Maintenance of the certification schemes, testing and inspection activities and certificates were evaluated by the TE. Records, confidentiality, security and use of mark were evaluated by both of the team members.
	Person certification: (competence of CB to perform examination; impartiality; witnessing; certification schemes; surveillance and recertification): NA
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): The assessment was done through interviewing, review of documents and reports. All finding were recorded on an electronic report format. Techniques were appropriate. Some files were sampled and a vertical assessment was conducted by TE. LA and TE collected the copies of records and documents from the CAB as evidence.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): Assessment team had 3 “Type B” findings. Two of them were “Type (B)” nonconformities which were related with the transition to ISO/IEC 17065:2012. All findings were based on objective evidences and were communicated with CAB representatives.
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): NA
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): Plan of surveillance for the accreditation cycle was available and followed. Report from previous assessment was taken into account and corrective actions and use of mark were followed up.
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): The team interaction during the assessment was good. Team had an internal meeting before the closing meeting where they agreed on findings. LA formulated findings. They agreed on roles and tasks for the closing meeting.
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): LA explained the findings in details and assessment team presented the findings. The team leader explained the RvA rules for closing “Type (B)” Approval of the manager of CAB was taken. LA explained the further process for the resolution of findings and the accreditation procedure.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): LA used the cross reference list prepared for the ISO/IEC 17065:2012. Depth and width of the assessment was good and findings were relevant.
3.2	Assessor performance (attitude and skills; consistency in following AB’s assessment policies): Competence of the team was good. Technical expert had a strong background in gaming machines. Assessment team was professional and especially LA had a good experience and knowledge for RvA policies.
3.3	Other or general remarks: The scheme was revised on 30 October 2013 and was put in the information file of the EA evaluator for witnessing. During the discussion with the team after the witnessing it was observed that the assessment team was not informed about the revised version. **(see finding 16)**

Information on witnessed assessment	
Date(s) of assessment, team member participation:	28.11.2013 EA Team leader: XXX EA trainee assessor: XXX
Accreditation standard(s):	ISO 17021
Scope of assessment:	ISMS, QMS (IAF 33), ITsMS
Type of assessment	2nd surveillance - Office assessment
Composition of the assessment team of the accreditation body	Lead Assessor: XXX contracted Expert(s): XXX contracted Interpreter: XXX internal staff RvA

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): Preparation was according to routine and gave a plan for the assessment to the assessor which was followed in a timely manner. During the opening meeting the EA assessors was presented, and the Certification Body gave a brief overview of the activities performed. The EA Assessor was accompanied by a translator (RvA own staff), however half of the assessment has been performed in English. The assessment team was equipped with a plan for the assessment and all background documentation was adequate.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): The 2nd surveillance MS assessment was scheduled for 1 day with a lead assessor, one technical expert. In addition 1 witness assessments (QMS) has been performed before this assessment.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): The opening meeting was conducted by the lead assessor of RVA addressing details of the assessment procedure including especially the arrangements for the day program. The peer evaluation was explained and all participants introduced themselves. Staff members and the director of the certification body were present.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): The RVA assessor used an audit note. The team went through the audit plan and asked for objective evidences.
2.3	Assessment of critical issues
	Management system certification: (competence management; man-days calculation; impartiality and independence; audit reports and decision making; witnessing): The team members gathered sufficient evidence to the assessment of competency management by CAB. Duration of the audit some certification files ware well assessed. It has been shown that the competence of the assessors and decision makers (present during the audit) of CAB was covered. Team members sufficiently deeply analysed the impartiality and independence of the CAB, including risk analysis developed by CAB. However, regarding impartiality has been issued a finding (see below).
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): The team interviewed the staff members of the certification body, evaluated the (2 minor nc) corrective actions regarding the results from the witness audits and checked records of the certification body concerning applications, evaluation and decisions. Staff members were interviewed, their competence was evaluated by reviewing the personnel files and the records of the CAB were reviewed to get objective evidence regarding the effective implementation of the certification scheme.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): The assessment lasted 1 day (the CB has 22 client considering all the accredited schemes). EA team attended the full audit. However, due the absence of the Quality Manger, the Team decided to ask for a follow up of 0,5 day to close the assessment. A preliminary final meeting was conducted, to summarized the results of the first day. At this stage, no finding has been raised by the Team Leader, considering that information are missing
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): ---
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): The CB is accredited in QMS for 1 IAF codes (IAF 33), and in ISMS and ITsMS. In the accreditation cycle, RvA has to perform 3 witnesses (1 QMS, 1 ISMS, 1 ITsMS) The QMS witness has been performed in May this year. Last year assessment: January 2013 by A.S.C.S with the same Technical expert
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): The team had a good interaction, before the audit, and during the audit.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): The lead assessor planned time for the preparation of the closing meeting (summary) on the first day of the assessment. He discussed the results of the day with the assessor and filled in the nonconformity forms.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): The assessment was very comprehensive. The findings were based on objective evidences and also the grading of the nonconformities was acceptable and justified.
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): The team conducted a professional assessment. However, some findings has been raised (see chapter 3.3 below). The interpreter was really professional and impartial.
3.3	Other or general remarks: See finding #2 1) The assessment team did not deeply investigate on the impartiality issue, raised by the new logo of the CAB (that is covering advisory and certification activities).The CB C466 is operating with the same logo and name of the group, that is perceived as an advisory and consultant company, also in managing IT risk. According ISO 17021, 5.2.9, The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides management system consultancy. The AB should have investigated more about that, in order to enhance the perception of impartiality. This company is part of a Group. However, it is fully independent regarding strategy, policy, decision-making and financially. However, the brand is the same, and they are sharing the web site and the location. 2) The assessment team did not anticipate the fact that one of the biggest client faced some problem for data security.

Information on witnessed assessment	
Date(s) of assessment, team member participation:	27 November 2013, EA team member XXX
Accreditation standard(s):	ISO/IEC 17020:1998 ISO/IEC 17020:2012
Scope of assessment:	Inspection: Soil protection, liquid-tight features (VDV)
Type of assessment	Re assessment (2 days office assessment, only second day was witnessed)
Composition of the assessment team of the accreditation body	Lead Assessor: internal Assessor(s): - Expert(s): one external

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): The team was well prepared by the material got from RvA according to the procedure of the accreditation body.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): The team consists of lead assessor and one technical expert. They were qualified and competent to assess inspection activities in case. The re-assessment process consists of two days office visit and besides that four separate witnessing visits. One witnessing has been already done. Three witnessing visits have been allocated to be done in December 2013 by technical expert. Comparing the scope and the type of the assessment the coverage of the assessment activities were sufficient.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): The office assessment visit was allocated to be two days. Only second day was witnessed by EA Team member. So there are no evaluation results from the first day. In the first day only lead assessor was involved with the assessment. In the second day also technical expert was involved. In the morning of the second day opening meeting was kept. Besides the assessment team there were director of the company and technical manager/quality manager in the opening meeting. The opening meeting was long enough to handle all relevant items. It took half hour. The lead assessor presented the assessment team, roles and responsibilities, program of the assessment visit, the meaning of the visit and accreditation criteria (new version of the ISO/IEC 17020) and also short summary from the first day. Technical expert shortly reported the conclusion of the already earlier made witnessing. The opening meeting was very effective and informative.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): The lead assessor had started assessment of management system issues on first day. He continued assessment (in the second day) of defined parts of the standard EN ISO/IEC 17020 e.g. management review, internal audits, corrective and preventive actions and contracts of personnel by looking at the records and by interviewing persons involved; director and quality manager. The deepness and the coverage of the assessment were very good.
2.3	Assessment of critical issues
	Inspection (independence type A, B or C (in particular type A); monitoring and harmonizing inspectors; selection and conduct of witnessing; quality assurance; calibration and traceability; testing and sampling): The inspection body is type A. According to the lead assessor impartiality was assessed in the first day. Second day e.g. monitoring procedure of inspectors was assessed carefully. Calibration and traceability items in the inspection methods in this case are not critical.
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): In general the methods of collecting evidence were systematically conducted. The amount of evidence in different items was sufficient. Interviews of the persons were used in efficient way. The questions made by assessor and technical expert were open and the answers gave all relevant information.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): During the assessment there was all the time clear focus on critical and relevant issues. The findings and observation that were risen out during the assessment were informed during the day. The lead assessor had a role when formulating non-conformities. They were addressed to the relevant clauses of the standard EN ISO/IEC 17020. Those non-conformities that were focused with the new version of the standard ISO/IEC 17020 were classified NC(B). They were given longer time for correction according RvA-procedures.
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): NA

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): There is a four years assessment plan for the assessed body. It covers all methods. The amount of the methods assessed and planned to be assessed during the re assessment process was in line with scope. So the whole scope will be assessed and witnessed during the accreditation period. The corrective actions and the effectiveness of the corrective actions from last visit were discussed by assessment team. Reference to accreditation was also assessed. There was an accreditation mark in the inspection report between the logos of other organisations so that it gives impression that RvA has accredited other organisation. Assessment of use of accreditation was not in line with RvA document RvA-VR003. The lead assessor looked at inspection reports but he did not notice the mentioned item. See finding #14
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): The interaction between the lead assessor and the technical expert was operating fine. The lead assessor lead the assessment in effective and systematic way and the lead assessor made relevant conclusions. There was also short meeting with the team in the middle of the day. Other team meeting for preparing closing meeting was kept before the closing meeting.
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): In the closing meeting there were same representatives of the inspection body as in the opening meeting. The observations, findings, non-conformities and conclusion of the assessment were presented clearly and in positive way by the assessment team. Lead assessor also informed that also results of the coming witnesses shall be taken account. The lead assessor had a good touch to lead the closing meeting. The time for the closing meeting was long enough so that there was no lack of the time to handle items.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): As the whole the depth and width of the assessment were satisfied. All planned relevant items including were analysed and assessed.
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): The attitude of team members towards to representatives of the inspection body was positive and constructive. The team made assessment according to the policies of the accreditation body and the team acted in effective and systematic way. Strength points and competence of the operation of the inspection body were sought, not only weakness or thing to be developed.
3.3	Other or general remarks: -

Second one

Information on witnessed assessment	
Date(s) of assessment, team member participation:	28 November 2013, EA team member XXX
Accreditation standard(s):	ISO/IEC 17020:1998 ISO/IEC 17020:2012 (+ ISO/IEC 17025:2005)
Scope of assessment:	Inspection: E.g. type examination, product verification, unit verification of defined equipment in the field of Measurement directive 2004/22/EC, Non-automatic weighing instrument directive 2009/23/EC, Automatic weighing instrument directive 2004/22/EC and specified national regulations
Type of assessment	Surveillance (1 day)
Composition of the assessment team of the accreditation body	Lead Assessor: internal Assessor(s): - Expert(s): 4 external (3 of them involved with the standard 17020)

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): Lead Assessor and technical experts have got all relevant documents from RvA by account manager before the assessment e.g. the schedule, the scopes, former assessment visit reports and up-dated report part A. Team members were well prepared to the assessment.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): The assessment consists of three different accreditations (inspection, testing and calibration). One day for the assessment in the office has been allocated. Besides that also one day witnessing (taximeters/inspection) has been made earlier this week by technical expert. Compared with the size of the inspection scope and assessment type (surveillance) the allocated time was long enough for the conducting sufficient assessment. Coverage of the scope in the assessment was in line with RvA's procedures.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): In the opening meeting there were four relevant representatives of the organisation in place. In the opening meeting the participants, roles and responsibilities of the assessment team were introduced by the lead assessor. The meaning of the visit, confidentiality matters, accreditation criteria, scopes and the schedule of the day were clearly discussed. There were no need for changes in the inspection scope. Technical expert who has made witnessing before this office assessment gave short summary of witnessed activities. The opening meeting was kept according to RvA's procedures.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): Assessment of management system (combination of ISO/IEC 17020 and ISO/IEC 17025) in this surveillance visit was mainly focused on internal audits, corrective and preventive actions and management reviews. Items were assessed carefully and deeply enough by lead assessor.
2.3	Assessment of critical issues

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
	Inspection (independence type A, B or C (in particular type A); monitoring and harmonizing inspectors; selection and conduct of witnessing; quality assurance; calibration and traceability; testing and sampling): By using reports of internal audits many relevant items in inspection area were assessed by the lead assessor. Calibration and traceability items were assessed mainly by technical experts. Assessment criteria of traceability of calibrations of critical equipment was in line with RvA's traceability policy and ILAC P10.
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): Lead Assessor and technical experts used different assessment techniques in an efficient way. They asked open questions and they also gave time enough for answering. They also wanted to get evidence not only looking documents.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): Team members focused assessment to relevant and important things. Relevant non-conformities were risen up during the day and they were discussed also with the team meetings. Non-conformities were formulated clearly and proper way. Also like in other witnessed assessment of inspection body longer time for corrective actions were given in the case of non-conformity focusing the new standard version ISO/IEC 17020:2012. Representatives of accredited bodies understood and agreed findings.
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): EA-2/17 was taken account during the assessment because there were three directives in the field of inspection activities.
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): There is combined assessment plan for accredited bodies (inspection, testing and calibration) items to be assessed for whole accreditation cycle made by RvA. The plan was taken account in this surveillance assessment. Findings from previous assessment were discussed. Use of accreditation mark was assessed e.g. from the website on the organisation. The assessment visit was conducted in competent way.
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): The team was rather big; five persons. Lead assessor managed whole team in a professional way. There were good interactions between the team members during the whole assessment. Lead assessor also followed/witnessed (max. 15 minutes/technical expert) all technical experts during the day. There were two team meetings; one during the lunch and other before the closing meeting. The discussion was relevant with the team members.
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): Closing meeting was kept under the lead of lead assessor. In closing meeting there were a director of company and other same representatives as in opening meeting. All team member report shortly what they have been assessed and they also gave their conclusion. Summary report and non-conformities were introduced.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): As the conclusion the surveillance assessment was made in line with the RvA's procedures. Assessment covered all relevant parts of management system and inspection activities; including also testing and calibration; that were relevant to assess in this surveillance assessment.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): The team members were competent, polite and calm and they acted both in systematic and professional way. Team was also familiar with the relevant procedures of RvA.
3.3	Other or general remarks: -

Information on witnessed assessment	
Date(s) of assessment, team member participation:	2013-11-26, 27 Team member: XXX (only witnessing on 2013-11-27)
Accreditation standard(s):	ISO/IEC 17024:2012
Scope of assessment:	Welders and Electro technicians (Stipel scheme)
Type of assessment	Reassessment
Composition of the assessment team of the accreditation body	Lead Assessor: 1 internal Assessor(s): 2 externals Expert(s): ---

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): The assessment was prepared on the basis of the documents of the previews assessment and also the documents from the CB management system. It was confirmed the team had the relevant documentation to conduct the assessment. An assessment plan was prepared referring the sections of ISO/IEC 17024 to be covered.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): The time allocated to this assessment was considered sufficient for the assessed scope; The team has worked separately covering different requirements; The accredited scope was partially covered (the scope shall be fully covered during the accreditation cycle). The management system was assessed during the first day (according to the plan but not witnessed) and some vertical audits performed. Two schemes have been deeply assessed by the team leader (both in welding). The Account Manager prepared a program for reaccreditation activities that includes 2 witnessing activities that shall take place during the beginning of 2014. For the previews cycle it was confirmed that RvA covered all the accredited scope both during office assessments and also by witnessing activities.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): The opening meeting was not witnessed. However the Team Leader conducted an opening meeting at the beginning of the second day where all team members (and also observers) were introduced. The plan for the second day was confirmed and it was also given the opportunity to the CB to introduce the members present in this opening meeting.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): Although the assessment plan covered these issues, it has not been witnessed.
2.3	Assessment of critical issues

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
	Person certification: (competence of CB to perform examination; impartiality; witnessing; certification schemes; surveillance and recertification): Competence of CB: The witnessed CB subcontracts all the certification work to external entities. The exams for certification are performed by examination centres. CB evaluates the competence of the examination centres through annual visits and witnessing of exams. Also for the certification schemes that require testing, this testing is subcontracted to accredited laboratories. See finding #12 CB maintains however the responsibility for the qualification of examiners. This qualification procedure and records were assessed by the team and one NC was raised because the CB could not demonstrate that it keep all the records to confirm the competence of the examiners. The certification decision is taken by the CB based on the conclusions/recommendations of the subcontracted parties. About this situations two NC were raised because the CB did not maintain all the documents needed for the review and decision making and because CB does not take any negative decision but always wait for the re-examination when a candidate fails to pass the exam. Impartiality: The assessment of impartiality issues has not been witnessed. Witnessing: The Account Manager prepared a program for reaccreditation activities that includes 2 witnessing activities that shall take place during the beginning of 2014. For the previews cycle it was confirmed that RvA covered all the accredited scope both during office assessments and also by witnessing activities. Certification schemes: During the witnessed assessment two schemes have been deeply assessed by the team leader (both in welding). The competence of the team on this aspect was confirmed and all the questions and conclusions were very relevant for the schemes and for the examination process. One NC has been raised by the team. Although the situations raised are considered important and relevant to confirm the competence of the CB in the application of the schemes, is raises the doubt if this is new due to introduced changes in the procedures or if it should have been identified before by RvA. See finding #12 Surveillance and recertification The surveillance and recertification process are described both in the certification standards and in the certification schemes.
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): The assessment team interviewed the key persons of the CB and records were investigated. The methods of collecting evidence were satisfactory. Witnessing of certification activities (exams) are performed separately from the office assessment.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): All requirements from the accreditation standard were included in the plan for the reassessment visit. Communication with the staff members of the CB was done in an open and friendly way. Relevant issues from ISO/IEC 17024 were properly addressed during the assessment and the relevant findings were raised by the team and presented to the CB at the closing meeting.
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): N.A.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): The programme for reaccreditation activities and for the accreditation cycle is prepared by the Account Manager. Every surveillance/reassessment is performed in the office of the CB and, as part of surveillance/reassessment, also practical exams are witnessed. During the previews assessment 10 (ten) NC were raised and it was possible to confirm the follow up of some of them during the witnessing. CB uses the accreditation mark in the certificates issued to certified persons. The correct use of mark was checked.
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): The interaction of the team members was good and they have properly communicated during the planned breaks. Before the closing meeting, the team performed an internal meeting to write the conclusions and the findings. During this meeting, the list of findings was prepared, to be presented to the CB at closing meeting.
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): A closing meeting was conducted at the end of the assessment to present the conclusions and the findings to the CB. This meeting was conducted by the Team Leader. Seven (7) non conformities (category B) were raised. Two NC were not accepted by the CB and there were some discussions between the team and the persons from the CB. Although the team tried to clarify these findings against the requirements of the accreditation standard, for one of them it was agreed to raise the question to RvA to decide on maintain or remove the finding (nr. NCB_PWE_01). The closing meeting was attended by 4 persons of the CAB including the Manager of Personnel Certification.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): The assessment plan for the second day was sufficiently covered, with appropriate depth. The competence of the CB was properly assessed (see clause 2.3). Seven non conformities were raised, based on evidences.
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): The performance of the assessment team was good, with good assessment skills and in compliance with AB's policies. The competence of the assessment team was confirmed.
3.3	Other or general remarks: None.

Information on witnessed assessment	
Date(s) of assessment, team member participation:	27.11.2013, XXX
Accreditation standard(s):	ISO 15189:2012
Type of assessment	Re-assessment (2 days), witness at second day
Composition of the assessment team of the accreditation body	Lead Assessor: internal Assessor(s): 1 TA (Moleculare Diagnostics), 1 TA (Mycology, Mycobacteriology, Bacteriology), 1 TA (Infection Serology), 1 TA (Parasitology) Expert(s): -

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information) Complete documents (Q-manual, instructions, scope, changes, PT-Lists, information of results of previous assessment etc.) were send to the assessors for preparation.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing) Team composition was suitable. All technical fields were covered by the assessors. The agenda was general, the roles were nevertheless clearly defined before the assessment. The information in report part A send to the team in advance (composition of the team) includes the information of the scopes of the specific TA. The witnessed TA (Mycology) covered the scope in the witnessed lab sufficiently. The covering of the scope in general was good.
1.3	(Preparation by individual assessors (studying of received documents; preparation of questions; focus on the CAB) All witnessed assessors were very well prepared. They received the relevant documents and some additional information from the AB.
1.4	(Competence and suitability of team nominated in relation to the particular assessment) The witness covered 1 of 2 days on 1 site of a multisite (2 sites) reassessment. For this part of the assessment, the team was competent and suitable.
2. Opening meeting	
2.1	(Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting) There was only a short opening meeting (LA, TA, key-staff of lab), because it was the second day of a 2-day assessment on this site. Because of this it was sufficient that not all criteria are mentioned. The meeting started with a representation of the participants, the clarification of their roles and responsibilities.
3. Conducting of the assessment	
3.1	(Sampling techniques; observed activities) The assessors tried to cover the key techniques of the whole scope. The Lead assessor focused on internal audits, complaints, document control and requirements to personnel during the witnessed time. Technical assessors covered a wide range of the scope, with good sampling.
3.2	(Adequacy of assessment in general: internal audits; corrective and preventive actions; management review; use of marks, scope of accreditation) All relevant requirements of the standards were assessed. Use of accreditation mark and the scope of accreditation were assessed, too.
3.3	Adequacy of assessment related to specific accreditations:
a	Laboratories: (traceability; uncertainty; validation; quality control; PT performance) All relevant requirements had been assessed. Assessors discussed the results for above mentioned points during the preparation for the closing meeting. They wrote 2 NCs according to PT.
3.4	(Methods of collecting evidence (interviews; observation of activities; investigation of documents and records; appropriateness of techniques) The assessors used different techniques to collect evidence. Usually they start with short interviews and changed than to investigation of documents and records or observation of activities. The use of theses assessment-techniques was very appropriate.
3.5	(Interviews of relevant personnel; adapted to the situation) The assessors interviewed the relevant personnel, both technical staff and executives.
3.6	(Coverage of the whole or planned part of the scope; means of deciding on focus points; dealing with extension or limitation of scope) The whole scope was covered (not during the day of the witness, but during the 2 days of the assessment). Discussions between the assessors and some NCs show the coverage of the relevant parts of the scope on the first day.The witnessed assessor was focused on critical points during the assessment on site, but in total the team covers the whole scope.
3.7	(Recording of non-conformities; formulating the NCs; objective evidence; identification of true problems of the body; communicating with appropriate representative of the body) All non-conformities were well formulated and based on objective evidence. They were communicated with appropriate representatives of the CAB during the assessment and identified the true problems of the CAB.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
3.8	(For surveillance and re-assessments: plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments) The witnessed assessment was a “formal” re-assessment. But the laboratory was accredited according the CCKL-Standard. And this was one of five pilot labs in the transition plan from CCKL to ISO 15189. So the team could not use information from previous reports and could not check the follow up of findings from previous assessments.
4. Closing meeting	
4.1	(Assessors interaction; preparation of closing meeting; agree on conclusions; agree on roles and tasks for meeting. The assessors interact very well, among other things in the preparation of the closing meeting. They agreed on the conclusions and on the roles and tasks for the meeting. The TA for Parasitology came for the preparation of closing meeting, after having assessed another location.
4.2	(Relevant representation of the CAB; participating in closing meeting) The relevant representations of the CAB (e.g. Lab-director, responsible people for assessed units, quality-manager) and a lot of technical staff participated in the closing meeting.
4.3	(Presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions) The presentation of findings and conclusions was very good. Assessor team and CAB had a good understanding and acknowledgement of these issues.
4.4	(Explanation of consequences of outcome for the accreditation process. Reporting procedures; positive and negative reporting; thoroughness of reports) As the CAB was not experienced in assessments according to ISO 15189 there was a good explanation of consequences of outcome for the accreditation process. Assessors and CAB agreed about the deadline for the corrective actions.
5. Conclusions	
5.1	(Depth and width of assessment; findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body Depth and range of the assessment were sufficient. The assessors reported the relevant findings. They focused on the critical and relevant points.
5.2	(The attitude and skill of assessors; consistency in following AB’s assessment policies) The witnessed assessors acted and behaved very well. They were aware of the AB´s assessment policies. But the technical assessors all performed their first assessment according to ISO 15189 (pilot lab in the transition period). RvA trained the assessors about 1 month ago. Lead assessor and representative of the RvA on-site support the technical assessor with formal help (e.g. how to handle RvA reporting tool, how to formulate NCs in detail) in a very sufficient way during the meetings of the team. So the team (LA, TAs, representative of RvA) worked very well together.
6. Critical issues observed during the witness (personal opinion)	
	/

Information on witnessed assessment	
Date(s) of assessment, team member participation:	26/11/13, XXX
Accreditation standard(s):	EN ISO/IEC 17025
Type of assessment	Surveillance (1 day)
Composition of the assessment team of the accreditation body	Lead Assessor: external Assessor(s): 1 TA (organic chemistry), 1 TA (inorganic chemistry), 1 TA (microbiology)

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)
1. Preparation by the accreditation body

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information) Full documentation was used for preparation (quality manual, operational instructions, internal audit reports, management review, list of staff and equipment, PT last results, information on the results of previous assessment, list of the changes since the previous assessment).
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing) One day surveillance covering the entire scope, on the request of the laboratory (no sampling). The time allocated was sufficient considering the composition of the team (3 technical assessors) and the few changes announced. The agenda was general. But the information in report part A sent to the team in advance (composition of the team) includes the information of the scopes of the specific TA..
1.3	(Preparation by individual assessors (studying of received documents; preparation of questions; focus on the CAB) Lead assessor as well as technical assessors are well prepared by having studied really deeply received documents, in order to focus on specific issues during the visit.
1.4	(Competence and suitability of team nominated in relation to the particular assessment) The nominated team demonstrated competence in this surveillance assessment. All of the assessors were very experienced and know the lab from the re-assessment one year before.
2. Opening meeting	
2.1	(Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting) There was a presentation of the team members and of the representatives of the laboratory. There was no presentation on confidentiality matters, on accreditation criteria or on the accreditation process (the laboratory is accredited for several years). The agenda was confirmed. The scope was discussed, the lab wants to withdraw one test (SO_2) because of quality problems. The changes (equipment, staff and LIMS) were discussed.
3. Conducting of the assessment	
3.1	(Sampling techniques; observed activities) The team was able to cover the whole scope, because there are not so many tests in the scope. Sampling was not covered during this surveillance because it was covered during the re-assessment one year ago.
3.2	(Adequacy of assessment in general: internal audits; corrective and preventive actions; management review; use of marks, scope of accreditation) The assessment covered all the management system issues with a focus on complaints, internal audits and management reviews. The use of marks was also addressed. PDCA-Cycle was assessed to. This lab has a fixed scope. Flexible scope is not necessary because of the very steady scope.
3.3	Adequacy of assessment related to specific accreditations:
a	Laboratories: (traceability; uncertainty; validation; quality control; PT performance) Critical issues as validation, quality control and PT performance were systematically assessed. Organic Chemical analyses (GC and HPLC) : - Validation aspects, internal quality control, PT performance, measurement uncertainty, reports Investigation was conducted in a professional way.
3.4	(Methods of collecting evidence (interviews; observation of activities; investigation of documents and records; appropriateness of techniques) The team appeared experienced in the different methods of collecting evidence. After having investigated thoroughly the documentation in preparation, they mainly used interviews and records. Considering the fact that the LA investigated the management review reports before the visit, a wide space was given to the interviews.
3.5	(Interviews of relevant personnel; adapted to the situation) The interviews were conducted with different persons in different positions in a friendly manner, by all the assessors. The lead assessor went also interviewing people in the lab.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
3.6	(Coverage of the whole or planned part of the scope; means of deciding on focus points; dealing with extension or limitation of scope) The scope was covered as planned. The time allocated to the different assessors was suitable.
3.7	(Recording of non-conformities; formulating the NCs; objective evidence; identification of true problems of the body; communicating with appropriate representative of the body) 6 non-conformities (grade B) were recorded, based on objective evidence. They were communicated with appropriate representatives of the CAB during the assessment and identified the true problems of the CAB.
3.8	(For surveillance and re-assessments: plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments) The plan of surveillance for the accreditation cycle was followed. The findings from the previous assessment were followed.
4. Closing meeting	
4.1	(Assessors interaction; preparation of closing meeting; agree on conclusions; agree on roles and tasks for meeting. There was a good interaction between the assessors during the preparation of closing meeting. After formulating the non-conformities, they agreed on conclusions.
4.2	(Relevant representation of the CAB; participating in closing meeting) Relevant representants of the laboratory were participating in the closing meeting, with the 4 assessors.
4.3	(Presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions) Findings and conclusions were presented by each assessor. There was no diverging opinion and the laboratory proposed an action plan. A summary report on assessment results and the NCs were issued to the lab.
4.4	(Explanation of consequences of outcome for the accreditation process. Reporting procedures; positive and negative reporting; thoroughness of reports) As the laboratory assessed was accredited for years, there was no explanation of consequences of outcome for the accreditation process or of the reporting procedures. The laboratory and the lead assessor agreed on the deadline to send corrective actions (in accordance with the AB procedures).
5. Conclusions	
5.1	(Depth and width of assessment; findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body The depth of the assessment was found to be adequate with the purpose of the surveillance assessment. The competence issues were duly addressed.
5.2	(The attitude and skill of assessors; consistency in following AB's assessment policies) The assessment was performed in an open and friendly manner, with professionalism. All assessors knows the assessment policies of RvA very well and followed them in an appropriate way.
6. Critical issues observed during the witness (personal opinion)	
	-

Information on witnessed assessment	
Date(s) of assessment, team member participation:	Tuesday 26th November 2013, XXX Testing team member
Accreditation standard(s):	ISO/CEI 17025

Scope of assessment:	Construction tests (construction aggregate, concrete aggregate, sand)
Type of assessment	Surveillance of an accredited testing laboratory
Composition of the assessment team of the accreditation body	Lead Assessor: own staff 1 XXX Assessor(s): 1 XXX Expert(s): /

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): Well detailed preparation in report part A, sent to the assessment team. Team leader is the same as the previous assessment. Previous report had been sent to the team. OK.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): 1 day surveillance assessment, Technical assessor (TA) covered all the scope, witness test decided in accordance with laboratory and TL at the beginning of the assessment. OK.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): Presentation of the participant, roles and responsibility was clear between TL and TA, formal validation of the scope of accreditation with a discussion about two lines under the same standards (this point had been discussed during the assessment with TL, TA and laboratory). OK.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): Assessment well done. The previous assessment was a re-assessment with a complete evaluation. It allowed some sampling for the TL (very few in facts). Internal audit, corrective action (including corrective actions from the previous RvA findings), management review checked in detail. OK
2.3	Assessment of critical issues
	Testing laboratories (contract review; traceability; method validation; quality control; PT performance; reporting; environmental conditions): Contract review well checked. Traceability to SI and PT performances well checked by TA. TA checked the calibration of critical instruments (weighing machine, sieves). TA, TL and laboratory had a discussion about the calibration of sieves and the periodicity used to send them to an accredited laboratory. The laboratory explained that, even if the period seems to be long, he used reference sand to check sieves inside the interval. Method validation checked (for example lines 3 and 4 of the scope in accordance with vs equivalent to). Reporting (including version of data on web site) and environmental conditions well checked. There was also a long discussion about 2 lines in the accredited scope concerning the same quantity under the same standard. Technical standard described two methods of measurement (2 lines in the scope), one for high value and one for low value of the quantity. It could be possible to merge these 2 lines. Unfortunately, method for high value was not used often by the laboratory and there was no interlaboratory comparison ring for this range of value. It was finally decided in agreement with assessment team, laboratory and RvA to remove the non-used line and propose to the laboratory to ask for an extension as soon he has performed a comparison in this domain. The treatment of this part of the scope was well done in a good collaboration inside the assessment team. OK.
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): Well done mix of assessment techniques, interviews; observation of activities by TA; investigation of documents and records). OK.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): Only one non conformity had been formalised, and well presented to the laboratory. Good communication with the staff of the CAB and inside the team. OK
2.6	~~Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap):~~

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): Plan of surveillance for the accreditation cycle was available in part A of the report. This assessment was a normal surveillance visit in the cycle. The assessors well followed the previous report taking into account the previous findings and specific aspect identified in the report. The TL spoke about these points and checked them during the assessment. The use of the mark was also checked (including check on web site). OK.
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): Communication inside the team during the assessment was very well done. There was a short meeting before lunch with the team. The closing meeting was also well prepared. The TM asked to the TA if he had some NCs. In fact he had only some remarks. TL checked with TA if these remarks were not NCs before the closing meeting. OK
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): All the staff of the CAB was present during the closing meeting. The conclusions from TL and TA were presented to the CAB. The only one NC was presented to the CAB and the understanding and acknowledgement were well done. There is no unresolved diverging opinion. Explanation of consequences including the delay to perform action to the finding was well done. OK.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): The assessment was done in an adapted depth and width. It was a small laboratory (around 5 people) and critical points (traceability, PT, witnessing some test, quality system including records) had been well checked.
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): This assessment was well done. The attitude and skills of the members of the team were effectiveness and they well followed the AB policies and advices (report part A). OK
3.3	Other or general remarks: I witness a surveillance assessment in a small test laboratory. This operation had been well done by the team leader and the technical assessor. I'm very confident with the positive conclusion of the assessment team.

Information on witnessed assessment	
Date(s) of assessment, team member participation:	2013-11-27--28 XXX
Accreditation standard(s):	ISO 14065 and (EU) 600/2012 (AVR)
Scope of assessment:	Re-assessment ISO 14065 and up-grading accreditation to AVR
Type of assessment	Re-assessment and RvA witnessing for the qualification of lead-assessor
Composition of the assessment team of the accreditation body	Lead Assessor: contracted Assessor(s): Expert(s): contracted

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)
1. Preparation by the accreditation body

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): The assessment was well prepared by the lead assessor. The preparation included a document review of the requirements in the AVR and ISO14065 on the implementation of the CAB.
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): Three man–days were allocated for the assessment of the CAB at the office on site. Two days on site for the lead-assessor (ISO 14065) and one day for the technical expert. The assessment was planned as a combined assessment on two accreditations ISO/IEC 17020 and ISO 14065 but with different assessments plans and done on separate days.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): The lead assessor held the opening meeting in an efficient and gentle way and all relevant issues for an open meeting was dealt with. The lead assessor presented the agenda for the assessment and the new and additional requirement and interpretation documents for the AVR. The administration and reporting procedures regarding any findings and confidentiality for the assessment team were presented to the representatives of the CAB. The participants in the opening meeting made short presentations on themselves and their tasks. The findings from the first day of the assessment were presented in a short meeting at the end of the first day. All the findings in all 21 were presented in writing at the closing meeting. The findings identified at the assessment and were all addressed to relevant paragraphs in ISO 14065 or the AVR.
	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): Internal audit and management review was assessed and the results discussed which resulted in findings on the CABs procedures on preventive action and on follow up on corrective actions. Other management system issues were addressed as e. g. the complaint and appeal process.
2.3	Assessment of critical issues
	Calibration laboratories (traceability; uncertainty issues; competence of staff; method validation; data-processing; quality control; PT performance; reporting): N.A.
	Testing laboratories (contract review; traceability; method validation; quality control; PT performance; reporting; environmental conditions): N.A.
	Medical laboratories (pre-examination; post-examination; method validation; quality control; PT performance; reporting; environmental conditions): N.A.
	Inspection (independence type A, B or C (in particular type A); monitoring and harmonizing inspectors; selection and conduct of witnessing; quality assurance; calibration and traceability; testing and sampling): N.A.
	Management system certification: (competence management; man-days calculation; impartiality and independence; audit reports and decision making; witnessing): N.A.
	Product certification: (Impartiality and independence; subcontracting; certification schemes, surveillance regime; competence; evaluation and decision making; testing and inspection): N.A.
	Person certification: (competence of CB to perform examination; impartiality; witnessing; certification schemes; surveillance and recertification): N.A

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): The assessment was planned with a document review in beforehand of the assessment on site. On site the assessment was done by interviewing the personnel and management of the CAB, checking procedures and records as records from management review, competence of the personnel involved in the verification process and records in files from verifications. The assessment followed the checklist developed by RvA on the requirements in ISO 14065 and AVR from the document review for clarification on missing documentation and procedures.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): The team focused on relevant issues for the accreditation ISO 14065 and AVR. The document review done on beforehand the assessment in the office had identified any missing or not clear issues in the CAB management system. These issues were addressed and focused on during the assessment (a re-assessment on ISO 14065 and an “up-grading” of the accreditation for the AVR). Finding presented the first day on procedures on corrective action and on the appeal processes caused a discussion which was handled in insistent but correct and good way by the assessor.
2.6	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap): The requirements in the AVR on the CAB and verification process were addressed by checking the CABs verification procedure and the managing of the CABs competence process as the identification of competence criteria, qualification and monitoring of verifiers. The competence process and the qualification of reviewer were checked in depth. Requirements on the preforming of the verification process was done by checking a file of an on-going verification process (third trading period) relevant for the AVR and also by checking files from verifications of 2012 years emissions. The files and the competence issues were checked by the technical assessor. Any communication and information from NCA (NEa) was asked for.
2.7	Surveillance and re-assessments (plan of surveillance for accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): Follow up on findings from the previous assessment as e.g on the risk analysis and on CABs records on any non-compliance with the MMR was done during the assessment. .
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): The lead assessor managed the assessment in a good and competent way. The technical expert was clearly instructed on the tasks and on what issues to assess as going deep into competence issues, the verification process and to check files from verification work. The team meet before the closing meeting and agreed on the findings which were presented to the CAB at the final meeting.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): The findings were relevant and referred to requirements in ISO 14065 and AVR and relevant documents was identified. EA6/03 was mentioned and the former issue had been used. (EA06/03:2013 was published 27th of November).
3.2	Assessor performance (attitude and skills; consistency in following AB’s assessment policies): Discussed, listened and give the representative time to response, followed the plan in content and in time. The assessment followed the plan with minor adjustments. The assessors were competent in assessing, asked for relevant information, listened and were observant on the responses from the representatives of the CAB. A discussion with the CAB on identification competence criteria the guideline KGN 11.7 was not mentioned though which could have given guidance to the CAB on relevant competence criteria for the qualification of their verifiers.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
3.3	Other or general remarks: The CAB has been accredited for verification for ISO /IEC 17020 with the use of EA06/03 in previous trading periods. Transfer of the accreditation to ISO 14065 has been done during 2013. The witnessed assessment was a re-assessment of the CAB and an assessment to fulfil the requirements of the AVR. The lead assessor was monitored by RvA during the assessment to be a qualified as lead assessor for ISO 14065 and AVR. The feed-back from the RvA to the assessor after the assessment was in line with the what was observed during the witnessing. The assessment was done in a competent way with the relevant issues addressed for accreditation on ISO 14065 and AVR (EU/ETS).

Information on witnessed assessment	
Date(s) of assessment, team member participation:	Tuesday 28th November 2013, XXX Calibration team member
Accreditation standard(s):	ISO/CEI 17025
Scope of assessment:	Calibration (length, mass, weighing instrument (automatic or not), volume mass, density, volume, temperature)
Type of assessment	Surveillance of an accredited calibration laboratory
Composition of the assessment team of the accreditation body	Lead Assessor: own staff 1 XXX Assessor(s): 3 XXX Expert(s): //

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information): Part A of the report available. It's the second time the TL performed the assessment of the laboratory. Two technical assessors performed witness calibration on location a week before (22/11/2013).
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing): For this surveillance assessment, TL had 1,5 day at the office. Two technical assessors (XXX) (mass and density, viscosity) performed witness calibration on location a week before (22/11/2013). The third technical assessor (XXX (mass) stay 0,5 day at the office partially with TL. Assessment plan is detailed for th1,5 day of assessment with the TL. For the witnessing on location we only had the date without more information. It was the usual way of doing for witness assessment, there was no specific plan for witness, the duration was usually half a day (4 hours) and the technical assessors took, each of them, specific arrangement with the company. Scope of accreditation was well covered (Mass in laboratory (XXX), dynamic weighing and filling machines (XXX), length and non-automatic weighing instruments (XXX)) The two assessors who performed witness calibration on location without TL have a qualification quoted 070 in RvA system. This qualification allowed them to make intervention alone. Unfortunately, laboratory is also accredited for Temperature calibration (in laboratory and on location). There was no qualify assessor in the field of temperature for the last 6 assessments (C08.2 (2009), C08.3 (2010), H09 (2011), C09.1 (2012), C09.2 (2013) and the witnessed one C09.3 (2013)). A temperature technical assessor is planned for the next assessment (H10 (2015)). In fact the temperature range in the scope was a very small one (15 °C to 25 °C with an uncertainty of 0,1 °C with a remark "concerning thermometer part of densitometer" (calibration of densitometer is another line of the scope)).
2. Conducting of the assessment	

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting of findings): During the opening meeting, only EA team member was asked for a presentation (TL made the previous assessment, TA arrived few minutes before TL in laboratory and RvA translator had already performed an assessment in this laboratory). The type of the assessment (surveillance), explanation about accreditation (historical aspect) and scope was presented was presented. A short presentation of the EA peer assessment was done by TL. Laboratory gave some precisions about the scope (possibility to stop accreditation for volume, activity on location planed 6 – 8 week in advance (inviting RvA to take this point in mind) and difficulty to plan witness for automatic weighing machine as an intervention on this instrument need a stop of the production of the client). RvA team recorded these data. OK.
2.2	Assessment of management system issues (Adequacy of assessment in general: internal audits; corrective and preventive actions; management review): TL well assessed management system issues including internal audit, corrective and preventive actions and management review. Some non- conformities had been formalised about this subjects. OK.
2.3	Assessment of critical issues
	Calibration laboratories (traceability; uncertainty issues; competence of staff; method validation; data-processing; quality control; PT performance; reporting): For the technical assessment observed, the assessment of the critical issues was correct even within ½ day. Traceability was checked in accordance with RvA policy. Uncertainty issues had been checked (a non-conformity had been formalised by the TA about the participation of the drift of the standards in the budget of uncertainty which was under evaluate (minor influence)). PT was also treated. Reporting was examined in detail by the TL. Skill of the operator in laboratory and technical procedure had been checked through a measurement assessment. TA, XXX) brought a mass for witnessed calibration during the assessment. OK.
2.4	Assessment techniques (interviews; observation/witnessing of activities; investigation of documents and records; sampling): Observed assessors used different way of assessment like interviews (quality manager but also personal manager for example), observation/witnessing of activities (measurement assessment in laboratory and witness calibration on location), investigation of documents and records (informatics records and paper records). Vertical audits were also used. OK.
2.5	Assessment capabilities (formulating and recording of NCs and other findings; identification of and focus on critical issues; communication with staff of CAB): The communication with staff of the laboratory was very good. The identification of critical issues was well done and well understood. The formulating of the NC was good and well done by the TL, with the laboratory for his own NCs, with the TA for the one she formalise. For the NC formalise by TA performing witness calibration on location the week before, one of them sent 2 NCs to the TL. The findings were well identified but the wording was not as good as necessary for a NC. TL rephrased these NCs. OK.
2.6	~~Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. EA-2/17, Directives, WADA, BRC, GlobalGap):~~
2.7	Surveillance and re-assessments (plan of surveillance for the accreditation cycle; following this plan for the particular surveillance visit; use of reports from previous assessment; follow up of findings from previous assessments; use of marks): The plan of surveillance for the accreditation cycle was available in the part A of the report. This table show a well cover of the scope (with an exception for temperature calibration). TL well used the previous report and paid attention with the follow up of the previous findings. The use of the mark was well done (for example TL made a remark to the laboratory when he saw the RvA logo on a personal document (certificate of qualification)). OK.
2.8	On-site management of the assessment team (assessor interaction during assessment; preparation of closing meeting; exchange views; agree on conclusions): There were good communication with TL and TA acting this day (XXX). TL had information from TA performing witness a week before. One of them (XXX) already sent his report with 2 NCs (which had been rephrased by the TL). The other one (XXX) did not sent his report yet but he did not formalise NC (the information had been given to the TL by XXX who is a colleague of XXX who gave XXX the message). TL had all information he need from the TA of the assessment team. OK.

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
2.9	Closing meeting (Relevant representation of the CAB; presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions; explanation of consequences): Formal closing meeting took place the 29th November (one day after the witness). No comment. A TA assessor had ½ day assessment. TL made a partial closing meeting with the TA before she left in a right way of doing with presentation of the technical finding and the conclusions of the TA. TL asked for comments. Quality manager made some comments about the evaluation done this day. OK.
3. Conclusions	
3.1	Depth and width of assessment (findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body, use of EA/IAF/ILAC documents): For the part I witnessed and taking into account the information I was able to pick up about the other part of this assessment, this surveillance assessment was well done in depth and width with skilled assessors. The points of focus relevant to a calibration laboratory were checked following RvA document which followed international recommendations. The findings were well linked with the referential standard (ISO 17025 for a calibration laboratory). OK.
3.2	Assessor performance (attitude and skills; consistency in following AB's assessment policies): The assessors I met had high skill. The TL had a lot of experience and the TA (XXX) worked at the XXX and was also high skilled. Their attitude was very fair and well constructive for the laboratory. There was no evidence for not following AB's assessment policy. OK.
3.3	Other or general remarks: I'm confident about the quality of this assessment and its capability to allow AB to take the right decision for this accreditation. RvA should pay attention about the covering of the accredited scope particularly for the following of the on location calibration taking into account information given by laboratory (for example during the opening meeting laboratory said to the RvA assessment team that an activity on site was planned 6-8 weeks in advance and RvA should take this information inconsideration. Moreover, an observation of a calibration of an automatic weighing machine could be difficult as this operation need a stop of the production of the client). On another hand the following of the specific line in temperature field in the scope should be more formalised even if it is a very small domain linked with another accredited line (densimeter). This long period without specific identified qualified assessor seems to be an isolated case (no observation in other observed files).

3.2 Overview office evaluation

In addition to the activities that have been witnessed the following activities have been addressed by the evaluation team during the evaluation.

Activity (Level 2 and 3)	**Technical field, regulated field, EU directives and regulations** (Level 4 and 5)	**Type of evaluation activity** (file, interview, etc.)
Certification of management systems (ISO/IEC 17021)	XXX – QMS and Directive 97/23 (pressure equipment) XXX – cross frontier activity XXX – QMS – surveillance and extension XXX – audit ISMS – reassessment & Transition	File and Interview File, interview
Testing (ISO/IEC 17025)	Food, soil, compost, plants	5 (XXX 443) laboratory files were reviewed with the responsible

Activity (Level 2 and 3)	**Technical field, regulated field, EU directives and regulations** (Level 4 and 5)	**Type of evaluation activity** (file, interview, etc.)
	analysis and sampling, Forensic science, Water analyses, Construction material,	account managers, 6 technical assessor files were reviewed with responsible person for assessors. 2 Files of monitoring of lead assessors were checked with responsible person for lead assessors. Procedure for traceabilitiy (T018) was discussed with Lead assessor. Files of a lab with a “German Scheme (Fachmodule)” were checked with the account manager.
Medical Testing (ISO 15189)	Medical laboratory diagnosis (clinical chemistry, microbiology, virology, genetics, pathology)	2 (XXX) laboratory files were reviewed with account managers (focus on flexible scope, surveillance planning). Scoping (flexible, fixed) was discussed and checked in all of the 11 medical laboratories that have been accredited now according to ISO 15189. Transition plan from CCKL to 15189 was checked and discussed with head of unit medical labs. Project plan and some documents e.g. “mother-scopes” were reviewed and discussed.7 technical assessor files and 3 lead assessor files were reviewed with responsible persons for assessors for medical labs. 2 Files of monitoring of lead assessors were checked , PT programs and traceability in medical labs were discussed with lead assessor and head of Unit medical labs.
Inspection (ISO/IEC 17020)	solid protection (liquid-tight features) Installation NDT Type examination, product verification, unit verification, e.g. MI-directives NAWI-directives Automatic weighing instrument-directive Pressure equipment directive	files, interviews
Calibration (ISO/IEC 17025)	XXX (witnessed file) Length, mass, weighing machine (automatic or not),	File, interview, witness. All file records.

Activity (Level 2 and 3)	**Technical field, regulated field, EU directives and regulations** (Level 4 and 5)	**Type of evaluation activity** (file, interview, etc.)
	volume, temperature.	
Calibration (ISO/IEC 17025)	XXX reports recorded in DMF CA XXX	File and records XXX
Calibration (ISO/IEC 17025)	XXXmultiple quantities (U, I, R, capacity, HF quantities, time and frequency, pressure, temperature, humidity) and XXX (electrical quantities; high current, high voltage) Multiple accreditation (XXX) with six part A report (one per accreditation)	File, interview and records
Calibration (ISO/IEC 17025)	XXX multiple quantities (DC/LF, RF, time and frequency, optical quantities) Part A report well filled, very clear.	File, interview and records.
Calibration (ISO/IEC 17025)	XXX) small laboratory (one person, acoustic calibration)	File, interview and records. Complete file and deviation for the accreditation cycle
Testing (ISO/IEC 17025)	XXX (witnessed file) (Construction materials)	File, interview, witness. All file records
Testing (ISO/IEC 17025)	XXX (Construction materials) Testing laboratory on 3 sites.	File, interview and records Treatment of ILC in report
Testing (ISO/IEC 17025)	XXX Chemical laboratory water and mud analysis	File, interview and records Treatment of ILC in report
Testing (ISO/IEC 17025)	XXX (information technology)	File, interview and records Treatment of ILC in report. In this domain nothing was available, laboratory try to plan bilateral comparisons.
Testing (ISO/IEC 17025)	XXX (food analysis)	File, interview and records Treatment of ILC in report
Testing (ISO/IEC 17025)	XXX Water analysis)	File, interview and records Flexible scope
Testing (ISO/IEC 17025)	XXX (Animal feed analysis)	File, interview and records Flexible scope
Testing (ISO/IEC 17025)	XXX (fruit, vegetable and water analysis)	File, interview and records Flexible scope
Certification of persons (ISO/IEC 17024)	File 1: Initial assessment: Welders File 2: Surveillance and Reassessment: Welders; Electro technicians; Asbestos removal personnel	File review; Interview with RvA staff

Activity (Level 2 and 3)	**Technical field, regulated field, EU directives and regulations** (Level 4 and 5)	**Type of evaluation activity** (file, interview, etc.)
	File 3: Reassessment: Valuation of non-residential property for mortgage lending purposes	
Verification of GHG (ISO 14065)	Verification of GHG in the EU/ETS.	File review: XXX Transition of accreditation from ISO/IEC 17020 to ISO 14065 and AVR Interviewed: staff
Certification of products (EN 45011, ISO/IEC 17065)	Household equipment, lighting, IT and office equipment 2006/42/EC Machinery Directive (Cross frontier accreditation file)	File review, interview
Certification of products (EN 45011, ISO/IEC 17065)	Vegetable products, animal products, sustainable area management, feed materials	File review, interview
Certification of products (EN 45011, ISO/IEC 17065)	Fire equipment and safety (Cross frontier accreditation file)	File review, interview
Certification of products (EN 45011, ISO/IEC 17065)	Live or unprocessed agricultural products - Processed agricultural products for use as food - Feed - Vegetative propagation materials and seeds for cultivation - Aquaculture and seaweed Based on 834/2007 and 889/2008 Regulations for organic production GLOBALGAP (multisite and cross frontier accreditation)	File review, interview

4 List of findings

Number and Classification[1]			Response from AB	Team Comments/Conclusions
1.	CN	Requirement: ISO 17011, 4.3.7 Description of Finding: Related bodies: the risk analysis for related bodies does not take into considerations all the related bodies that are linked to RVA by a contractual arrangement (eg: Other ministries)	Analysis of root cause and extent: the RvA did consider other ministries in its analysis of related bodies. All ministries were considered, including the ones that do not have a contract with RvA, but only those were mentioned that have laboratory or other conformity assessment activities in its structure. RvA did not in particular consider the contracts with ministries in its analysis of related bodies also because it considered these contracts to be directly connected to the Law on accreditation that came into force on 1/1/2010. The only remaining contract is with the ministry of Social Affairs. Within this ministry no activities take place that conflict with accreditation, nor does the ministry has possibilities to influence the accreditation and decision making with RvA. Besides this contract RvA has contracts with parties that provide specific services (IT-support, website hosting, cleaning, archiving, housing, etc.). These parties however do not have activities that may pose a conflict of interest, nor do these parties influence the assessment or decision making process. Action plan: In the quality manual it is added that contractual arrangements will be considered in the context of impartiality (chapter 2 and chapter 3), and that during the management review the threats to impartiality will be	Seen the draft of the Quality manual and the compositions Agency Closed: Yes

[1] NC = Non-conformity; CN = Concern; Cm = Comment

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			analyzed (chapter 11), taking into account the related bodies. The Quality manual is revised. A risk analysis will be discussed with the stakeholder panel and the supervisory board in spring 2014. In October 2014 the management review will address related bodies.	
2.	CN	Requirement: ISO 17011, 7.8.1 ISO 17021, 5.3.1 Description of Finding: The team is concerned that the analysis by the assessment team are not always sufficient to determine the extent of competence and conformity of the CAB with the requirements for accreditation. 1) In one case The RVA Audit team assessed if the certification body has arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations, but the RVA Audit team did not assess if the CB was able to demonstrate that it has evaluated the risks arising from its certification activities in each of its fields of activities and the geographic areas in which it	Analysis of root cause and extent: 1) The subject of insurances/reserves has been discussed in several meetings of the RvA team leaders. The risk evaluation by the CAB has been highlighted as the way to assess the adequacy subject. We are convinced that the RvA team leaders are aware of the importance of the risk evaluation. In this particular case the TL did not consider it relevant to discuss the risk analyses because during the previous assessment (C01.2 in December 2012) the team had verified the analysis. The report of this previous assessment explicitly reflects this (see page 4 of the enclosed evidence). The question is whether the risk evaluation should be assessed again after it has been a subject in a previous assessment and the activities of the CAB have not changed. We do not think this is necessary. If there are no changes in the activities it does not make much sense to assess the (same) risk evaluation again. It is important however that in those cases the RvA assessor convinces himself/herself that the activities of the CAB have not changed (activities and geographic areas). This will be a subject for the upcoming team leader meetings for inspection and certification. 2) We agree that it would have been better to check whether the logo change had been a subject of the (ongoing) impartiality analyses. We will raise the subject during the upcoming team leader meetings and instruct our assessors that changes in structure and in	Seen the report of the previous assessment n the same CB, and example of project issue to log events in RADAR Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		operates, in order to justify the adequacy of the arrangements taken (coverage of the insurance). 2) The assessment team did not deeply investigate on the impartiality issue, raised by the new logo of the CAB (that is covering advisory and certification activities). The assessment team did not anticipate the fact that one of the biggest client faced some problem for data security.	establishing new brands are examples of changes that could require a review of the impartiality risk analysis. In the meantime we have reviewed the communication of this CB and have not identified a specific risk for impartiality due to the change in logo. 3) We agree that our assessors should have the political and social sensibility that enables them to judge whether signals from outside needs to be taken into account in their assessments. Also from our account managers we expect this type of sensibility. In our database RADAR we have the possibility in record specific issues that may be relevant for a body. Account managers are instructed to use this feature for logging issues that could be relevant for the assessment teams (see enclosed example of issue log in Radar). <u>Action plan:</u> 1) During the upcoming team leader meetings the importance of the risk evaluation regarding insurances/reserves will be stressed again. Furthermore the conditions for the need to re-assess the risk evaluation will be discussed. 2) During the upcoming team leader meetings the team leaders will discuss the events that should be a reason for a CB to redo or review the impartiality analyses. 3) During the upcoming team leader meetings the team leaders will discuss how to improve the sensibility for issues that could have an impact on the confident that RvA may have in the competence of a body. 4) Account managers will be reminded to use the project issues for relevant signals (see example). Subjects 1), 2) and 3) above will be addressed during the upcoming team leader meetings. For certification this will be on March 24 and for inspection this will be on April 28,	

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			2014.	
3.	CN	Requirement: ISO/IEC 17011 §7.1.2 Description of Finding: The team is concerned that RvA does not always timely publishes and updates information on the of accreditation criteria and processes. No transition policy has been issued to ISO 27001:2011 IAF Resolution 2013–13	Analysis of root cause and extent: This particular IAF resolution was identified by RvA in-time and was analyzed by means of the F946 form according to our procedures. Because the internal specialist was ill the analysis was conducted by an external expert and he reported his analysis in December 2013. Due to this the establishment of the transition arrangement has been delayed. In the meantime however the accounts managers had been informed about the revised standard to enable them to answer questions from their CABs and to inform them about the IAF resolution. Also RvA publishes the IAF (and ILAC) resolutions on the website to inform the CABs. We have analyzed the implementation of all EA, IAF and ILAC resolutions in 2012 and 2013. Out of the total of 28 resolutions that needed some actions from the ABs we failed to timely fully implement 1 resolution. This was the EA resolution R2013(31)27 on ILAC-P10. The impact of this resolution was analyzed by means of form F946, but actions were not implemented before 1/1/2014 as was planned. Since the policy of RvA described in RvA-T18 on traceability was already in-line with P10 RvA did not consider this a priority issue. The internal audit in 2013 however showed that, although almost all resolutions are implemented timely, too much time is needed to agree on and to publish the results of the impact assessments. This process should be improved. In February RvA decided to extend its staff with a full time Quality manager. To ensure the follow-up of quality plans and the quality project and to improve the process of	Seen contribution from experts on 27.12.2013 for ISO 27001, proposal for transition period, the CAB has been informed. Seen the list of actions taken by RVA to cover all the coming International resolution (including ILAC-P10, that was missing) Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			document control. Action plan: The coordination of the impact assessments and the control of implementation of actions resulting from these will be a returning agenda item for the relevant management committee and the Steering Committee for developments (SATO). In the SATO meeting in February 2014 the progress in impact assessments with F946 will be reviewed. The new quality manager will start on 15 March. In the Quality manual (chapter 4) the revised procedure for controlling the implementation of results of impact analysis is described. The management of the implementation of action resulting from impact analysis will be supported by P2F software in our Vivaldi software, before July 2014.	
4.	CN	Requirement: ISO/IEC 17011 § 7.5.2 Description of Finding: ISO 17021 - The competence criteria for all QMS assessment performed out of Netherlands is not requiring legal competence, even if the standard is referring to legal aspects of the client's operation, or performance as regards legal compliance.	Analysis of root cause and extent: We do recognize that QMS auditors of CB's should have knowledge of "statutory and regulatory requirements" (text in ISO 9001 ad 17021-3) applicable to the clients that they audit. We however never considered it a requirement that assessors from AB's should have the same level of knowledge. It is the task of AB to assess whether the CB has a process of certification and auditing that results in trustworthy certificates for the QMS system in relation to ISO 9001 and it is not the job of the AB to assess the competence of the CB in auditing compliance with regulations. The AB assessor shall assess the mechanisms that the CB has in place to identify the relevant legal requirements and to include these in its competence management system.	Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			We do not intend to change our view in this. Our main considerations are: - A certified company can provide its services/products to any place in the world - Because of this in theory each AB should have competence in the legal aspects of all the countries in which the CB's accredited by them operate and of all the countries the clients of these CBs are providing their services or products and this is impossible. - For ISO 14001 and other MS the situation is different because for those it doesn't really matter where the products or services are provided and local legislation is very important for the contents of the management system (that is why EA published EA-7/04). Although we will not change our policy we will however instruct our lead assessors to take care in particular of clauses 9.2.3.1.1.d) and 9.2.3.2 c) and g) in 17021 and clause 5.6 of 17021-3. For other management system certification (EMS, FSMS and OHSAS) the finding is not applicable as RvA has already documented in its procedure for team composition (P017) that for these schemes local experts will be included in the team. Action plan: To discuss the issues mentioned above with our lead assessors during the next meeting on 24 March 2014.	
5.	CN	Requirement: ISO 17011, 7.9.2 Description of Finding:	Analysis of root cause and extent: All decisions concerning the accredited status of the CAB's are communicated formally by means of a letter	Seen change in W067 on page 1

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		The AB should formally inform the CAB about the decision taken by the Accreditation Committee if the committee does not consider the assessment or report to be suitable to give a recommendation for decision.	containing the individual accreditation decision. In case there are no scope changes as outcome of an assessment, the account manager sends a letter to confirm the continuation of the accreditation. Because no decision is taken about the accreditation in case the Accreditation Committee does not give a recommendation, there was no clear internal procedure concerning the communication to the CAB. Action plan: Work Instruction W067 (withholding after Accreditation Committee) will be adjusted. The communication with the client in case of withholding the report by the Accreditation Committee will now described in this instruction. After publication of the new version of the instruction, the involved employees will get a notification of publication. Next to this, relevant changes in documentation are always discussed during the monthly work meetings of the units A, B and Z. Work instruction W067-NL Aanhouding na CA (Postponement by CA) revision 2 was published on 27 January 2014.	Closed: Yes
6.	NC	Requirement ISO 17011 § 7.5.4. The accreditation body shall inform the CAB of the names of the members of the assessment team and the organization they belong to, sufficiently in advance to allow the CAB to object to the appointment of any particular assessor or expert. The accreditation body shall have a policy for dealing with such	Analysis of root cause and extent: In the past, the people who worked for the RvA considered as RvA employees. There was no need to present the organization they work for. Remedial and corrective actions: For the medical laboratory field a correction was implemented immediately because the information about the assessors and the organization they belong to is already in the database used by this department. For the rest of the RvA the short term action will be to establish a list (and up-date this every 3 months) with the RvA	Seen the Copy of webpage in which the list of the assessors and their company is published. Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		objections. Description of Finding The proposal of the assessment team sent to the CAB gives no information about the company members of the team belong to. RADAR system does not give this information in the document sent to CAB.	external assessors/experts and specifying for each person the organization her or she belongs to. This list will be made available to all CABs. On the long term we will modify our IT system RADAR in such a way that the information will be in the letter that confirms the assessment team to the CAB. The change in the IT system for this long term solution is expected to be initiated in 2015. At this moment another major modification is implemented and the next up-date is planned for 2015. Objective evidence of implementation: 1. The list of external assessors that is made available for the CABs. 2. Copy of webpage in which the list is shown.	
7.	NC	Requirement: ILAC P9 § 4.3 (any requirements regarding the minimum level and frequency of participation in PT by accredited laboratories, including the need for a PT participation plan which has been formulated by the laboratory or inspection body (if relevant) and is regularly reviewed in response to changes in staffing, methodology, instrumentation etc;); § 7.15.3 (ISO 17011) Description of Finding	Analysis of root cause and extent: For ILAC P9 an impact analysis (recorded on form F946) has been done on 19-01-2011. Unfortunately the analyses has not been profound enough to recognize the need for a PT plan mentioned in clause 4.3 and thus not all assessors are aware of this requirement. Most labs however have plans for PT as they need to make a budget in which costs for participation is included. Remedial and corrective actions: We modified RvA-T30 to include explicitly the need for a plan. With the publication of T30 revision we inform the labs, inspection bodies and our staff (including the external assessors and experts). RvA team leaders will be informed by email when the T30	Seen the Revised RvA-T30 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		Document RvA T030 version 2 asked for a check of the participation to ILC and PT during the accreditation cycle and the assessment team checked this participation and the covering of the scope in the previous cycle during assessment (seen on different reports including the findings if the situation was not correct). Nevertheless there is no requirement for a PT Participation plan.	is published before 1 March and during the team leader meetings on April 7 (Testing & Calibration) and April 28 (Inspection) we will explain the requirement. Objective evidence of implementation: Revised RvA-T30 (see in particular 4.2).	
8.	CN	Requirement: ISO 17011, 5.3 & 7.1.2 Description of Finding Although not all ISO/IEC 17024 accredited CB are established in Netherlands (RvA has one accreditation granted in Italy), it was found that RvA only provides the Dutch versions of the following documents: SAP-C014 "Accreditation of certification of persons (general)" and T036 "Implementation of ISO/IEC 17024:2012".	Analysis of root cause and extent: After publication of the Dutch version of the SAP and the T36 translations were prepared. The fact that we have only one accreditation outside the Netherlands caused that processing and approval of these documents did not have a high priority. Also the lack of capacity in the QA department caused delay of the publications. Action Plan: The documents RvA-T036 and SAP-C014 have been translated and published. On 15 March the new quality manager will effectively starts his job.	Seen the translation into English, it will be published in two weeks Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
9.	NC	Requirement: ISO 17011, 6.2 Description of Finding During ISO/IEC 17024 file review it was found that RvA performed witnessing assessments using technical experts not holding the sufficient qualification to perform witnessing, without the presence of a qualified assessor, which is not in line with Procedure RvA-P011 (version 4 of 27-10-2009). It was further found that some witnessing assessments are planned for 2013/2014 with the appointment of technical experts not holding the sufficient qualification. Additionally, the procedure document P011 (version 4) gives no clear indication about the use of technical expert during witnessing in inspection (without Lead assessor)	Analysis of root cause and extent: For the 17024 the analyses of witnessing files for the accredited CBs in 2012 and 2013 learned that in total during 4 witnessing the technical experts had been working without the proper qualification (level 070 instead of 090 as is required by P011). Three of the examinations that were witnessed were in technical areas (welding and asbestos removal) and the examinations were practical exams, an expert in the field of examination should have been present also (according to our procedure P017). Review of the report of these three cases learned that there is not a need to disregard the results of these witnessing, also because the expert in examination had been involved in the office assessment that followed the witnessed examinations. In the other case the examination was witnessed by an expert that was already nominated as an assessor level 100, but this qualification was not recorded in RADAR. Analysis of witnessing in the field of 17021 and 45011 (10 files sampled) learned that in these fields no witnessing occurred by non-qualified persons. In the field of inspection the problem is caused by failing to up-date the database with qualification levels in Radar. The requirement in P011 to become a level 070 expert (witnessing) is at least 10 assessments experience and positive evaluation of performance. The experts that have been witnessing on their own having a level 060 qualification have been checked. From this we concluded that all comply with these requirements and should have been assigned level 070. The requirements for our assessment teams for witnessing were not clearly described in P011 and P017, and due to the differences between inspection/testing and certification not applied in a consistent manner.	Seen Revised P011 and P17 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			Remedial and corrective actions: P011 and P017 have been revised to make even more clear which qualification levels exist and which are the activities that can be performed (independently) by the various qualification levels. Also the complete database with experts for inspection level 060 was reviewed and in the qualification committee meeting on 10 February 2014 decisions on qualification of experts for level 070 were taken (more than 20 experts were qualified on level 070 for inspection). Instruction to the staff will be given on 6 March for the use of this P011 and P017 and the qualifications in RADAR. The planning for 2014 was checked to see if any unqualified persons were scheduled for assessment, which appeared not to be the case. Objective evidence of implementation: 1. Revised P011 and P17; 2. Report on review of witnessing files.	
10.	CN	Requirement: ISO 17011, 6.2 Description of Finding The team is concerned that RvA staff will not always be competent to deal with accreditations in the field of ISO/IEC 17024:2012. It has not been demonstrated that all personnel involved in the	Analysis of root cause and extent: At this moment RvA is dealing with the transition of the accreditation standards 17065, 17020, 17024 and introduction of the new standard 14065. Normally the account managers are informed about the differences between the new and the old version and the transition process in the monthly account managers meeting. In the meeting of 19 March 2013 17020:2012 and T035 were discussed. In the meeting of 21 January 2014 17065:2012 and T037 are discussed. Because RvA holds only a few accreditations for 17024 en 14065 a small part of the	Seen the planning of the meeting for the account manager regarding Transition Policy for ISO 17024 and ISO 17065 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		accreditation process have received relevant training in the new standard ISO/IEC 17024:2012. It was confirmed that Account Managers did not participated in training sessions performed by RvA.	account managers is involved. The coordinator of these standards therefore chooses to plan a separate meeting. Action plan: The meeting concerning 17024: 2012 is planned on 28 January and the meeting concerning 14065 is planned on 31 January. Objective evidence of implementation: Minutes and of meeting of account managers 2013-03-19 Outlook invitation: meeting 17024 Outlook invitation: meeting 14065 EU-ETS	
11.	CN	Requirement: ISO/IEC 17011 §7.1.2 Description of Finding The team is concerned that RvA's practices in transition to the new standards may not be consistent with the international policies. RvA issued a transition plan for ISO/IEC 17024:2012 that is written in RvA-T036 document. The 2 last paragraphs of 2.3 seem to be in contradiction and it is not clear what is RvA's policy to deal with a CAB that could not give evidence of the implementation of all the requirements of the new standard before 1st of July 2015.	Analysis of root cause and extent: RvA has chosen to apply the normal escalation route consisting of suspension followed by withdrawal for situations where a CAB is not able to demonstrate that it complies with the requirements. The reason for this is that when RvA would withdraw an existing accreditation without first having suspended the accreditation there is a risk that in an appeal this would be considered out of proportion. A CAB from which the accreditation is withdrawn will in most cases be out of business soon. We will not be able to justify such a decision as nobody will understand that the CAB is no longer considered competent only because the standard changed. To convince a judge that RvA is acting transparent and that our sanctions are proportional we will first suspend and then withdraw. We are of the opinion that the result is the same as what is meant in the IAF and ILAC transition resolutions. The accreditation based on the old standard is suspended and because of this no longer valid. The CAB is no longer allowed to use the mark, or to claim that it is accredited. As the ILAC nor the IAF states that accreditation shall be withdrawn on the date the transition	Seen the revised T036 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			period ends, we consider our arrangement to comply with the respective resolutions. If a body is suspended on the date the transition period ends, this body is no longer allowed to use the accreditation mark. The only difference with withdrawing the accreditation is that the CAB should in the latter case with draw its accredited certificates. This would mean that the certified clients of the CAB will be faced with an immediate withdrawal of their certificates without any warning before that time as is the case when we first suspend. Also for this reason we first suspend for three months and then withdrawn. All four transition plans in 2013 have the same wording except for the 17024 plan in which one sentence caused the ambiguity. <u>Action plan:</u> The sentence in the 17024 transition document (T036) is removed and the revised T036 (together with the English translation for finding #8) is published.	
12.	CN	<u>Requirement</u>: ISO 17011, 7.8 <u>Description of Finding</u> During the ISO/IEC 17024 witness on the reassessment of XXX, the following situations were observed: a) The assessment team raised some nonconformities against the accreditation standard. Concerning the findings NCB_XXX (fairness and validity of the exams) and NCB_XXX (decision making	<u>Analysis of root cause and extent</u>: a) XXX is part of a multi-accreditation CAB with many critical CF locations for management system certification. As a result of a NC during the previous EA peer evaluation in 2010 (NC1) in the field of CF accreditation a lot of attention was needed from the account manager regarding the CF issue. As a result, the subject of personnel certification did not get sufficient attention to make sure that all schemes on the scope were assessed at least once during the accreditation cycle (which is the RvA policy). Regarding NCB_XXX and NCB_XXX: The scheme for welding coordinator had not been assessed for several years prior to the witnessed assessment.	Seen the screen print from the RADAR issue log for project XXX which is the next project for this accreditation. Seen the four year accreditation program for XXX Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		process) it is questionable whether those are new situations, due to changes in the CB procedures, or situations that should have been detected in an earlier stage of the accreditation process. b) During file review on certified persons (welders), it was confirmed that the CB outsourced the testing of working pieces produced during the practical exam. According to the CB's policy the tests shall be done in accredited laboratories. Although the above policy exists, it was not always demonstrated that the tests were conducted by an accredited laboratory. This situation has not been questioned by the assessment team (ex. XXX).	Furthermore there has been a relatively large amount of changes at C124 during the past years (in the position of personnel certification department in the company structure, in the quality system and in the workforce). Especially the QMS of XXX required a lot of attention of the RvA assessors, leaving less time to assess the various schemes during the office assessments. b) The file review has been carried out by a new technical expert, who carried out a first time assessment accompanied by a qualified team leader. The absence of an accreditation mark on the reports issued by the testing laboratories should have been noticed. Both testing organization mentioned in the finding however are accredited NDT inspection bodies and in the field of inspection it is well known that these laboratories have accreditation. However the expert should have verified whether this specific assignment was conducted under accreditation. This finding will be discussed with the experts in this field and the team leaders to prevent reoccurrence. The finding will also be input for the next assessment of the CAB. As this was the first assessment of this expert (after having participated as observer in other assessments) no other assessments were influenced by this. Verification of reports of the other 17024 CB in the field of welding learned that this issue had been assessed properly (a finding was raised for subcontracting at the initial assessment in 2013 at XXX). <u>Action plan:</u> a) In order to be able to actively monitor the assessment activities for the various schemes on the accreditation scopes, RvA decided some time ago to include a four year accreditation program in the report part A. The four year program contains for this CAB is revised and now shows an overview of all schemes on the scope and the planning for the assessments for each scheme.	

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			b) The finding will be discussed with the technical expert, her monitor during the assessment and the other examination and technical experts, who will all be present during the next personnel certification assessor meeting. This meeting was scheduled for March 3, but will have to be rescheduled due to the absence of some of the participants. The finding will be entered into the Radar system as an issue for the next assessment of XXX. Objective evidence of implementation: a) The four year accreditation program for XXX, showing a planned assessment for welding coordinator scheme in 2013 and 2016: b) project issue regarding the finding in the project file for the next assessment logged in Radar.	
13.	Cm	Requirement: 17011, 4.4 Description of Finding Confidentiality: The accreditation body has confidentiality policy (BR-002) to handle client's material in confidential way. Anyway sometimes client's documents are sent to technical experts by e-mail without encryption. It is not clear how the accreditation body assures the confidentiality of client's documents in case mentioned. No strategic plan is in place to	RvA has in the past taken some precaution in its IT systems to support the confidentiality policy (e.g. secured VPN connection for persons working from home, encryption of the laptops, mandatory use and periodically changes of passwords, penetration tests for the secured part of the RvA website). Due to a number of changes in IT-management in RvA a consistent policy on securing information however was not developed. It is already planned for 2014 to analyze all information and forms of archiving (because of changes in the Dutch law for governmental archives). The result of this analysis will be used as input for the strategic plan for our digital data, taking into account the issues raised by the team.	Noted

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		minimize the risk to lose confidential data (eg: penetration test, security audit to the internal IT department and to the external datacentre, plan the maintenance on IT devices and keep the relevant records)		
14.	CN	Requirement: 17011, 8.3.2.a Description of Finding In one case, during the witnessing visit, lead assessor looked at inspection reports and did not detected a wrong use of accreditation logo.	Analysis of root cause and extent: We have reviewed the inspection reports of this inspection body with respect to the use f the accreditation mark. Also we reviewed the wording in our regulation (RvA-VR003) for the use of the mark. Showing the report to a sample of our lead assessors showed that interpretation of our rules is not harmonized on this issue. The wording in VR003 (article 12 clause 1) is: "The accreditation mark must be used in combination with the mark, logo and/or name of the accredited body. Use in combination with marks, logos or names of other organizations may not in any way create the impression that the owners of these organizations have been accredited by the RvA.". The situation with these types of inspection bodies is that they have to use a number of marks on their reports. For example one mark is mandatory because the owner of the installation that was inspected need a report with that logo because of legislation. Another logo is of a branch organization that requires its members to use the logo. The question however is whether the use of the other logo's in combination with the RvA mark will give the impression that the other organizations are accredited. Considering that the other marks are not of conformity assessment bodies we have concluded that this is not the	Seen RvA-VR003-UK Version 2, 28 February 2014 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			case. Because we learned that our lead assessors do not always use this rule in VR003 in the same way we have changed the wording in article 12 to: “The accreditation mark shall not be used in combination with the mark, logo and/or name of other conformity assessment bodies”. Action plan: Publish the revised VR003 before 1 March 2014 and inform the CABs. Instruction of the lead assessors of RvA during the scheduled meetings on 24 March and 7 April	
15.	NC	Requirement ISO 17011 6.3.1 Description of Finding There is no procedure/policy for monitoring the performance and competence of personnel involved in the accreditation decision-making process.	Analysis of root cause and extent: The monitoring of decision making is part of RvA’s standard procedures that ensure that the work of the Accreditation Committee is observed by a senior staff member on a regular base and by a member of the Supervisory Board at least every two years. RvA never had the need to document these procedures for monitoring of the decision making process. Remedial and corrective actions: The procedure is documented in the revised RvA quality manual (chapter 6). Objective evidence of implementation: The revised manual.	Seen the quality manual, chapter 6, with the explanation of the monitoring rules Closed: Yes
16.	CN	Requirement ISO 17011, 7.5.5 Description of Finding • In one case RvA did not inform	Analysis of root cause and extent: The RvA procedure for control of accepted schemes explains that the version number of a scheme is specified in the scope of the acceptance of the scheme owner.	Seen the new Template for the part A

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		the assessment team about the new revision of the applicable certification scheme • In another case RvA didn't record the information about the applicable version of the certification scheme	When the scheme is owned by an accredited body, RvA records the applicable version of the scheme in the part A report. The part A report is updated by the CAB's before the yearly RvA assessment. Part of this update is a check of the version numbers of the schemes. The RvA team leader receives the updated part A report for preparing the assessment. This procedure makes sure that the team leader is informed about the applicable version of the own schemes of the CAB's. This procedure is recently introduced and therefore not all part A reports are already modified. Remedial and corrective actions: The new template for the part A report is published on 15 January 2014. Objective evidence of implementation: Template part A report F101-UK part A report 15-01-2014.	Closed: Yes
17.	CN	Requirement ISO 17011, 7.11.3 Description of Finding The team is concerned that RvA may not always follow its own policy on coverage of scope of accreditation in the accreditation cycle. For product certification, in one case it is not traceable that all schemes have been assessed at least once in the accreditation cycle. There is no clear explanation in	Analysis of root cause and extent: Analysis of the root cause learned that although RvA has established general policies for coverage of scopes in document BR005, these general policies are not sufficient to ensure an harmonized approach within RvA and are not sufficiently transparent. For a number of schemes we have detailed policies in specific accreditation protocols (SAP) but for example for the scheme relating to the CB where this finding was done (SMK scheme) a SAP has never been considered necessary. In particular the finding is relevant for schemes in which a more detailed description of working areas (product groups, sectors etc.) is applied and where the scheme does not give guidance for sampling within the scheme during accreditation	Seen the inventory of SAPs needed to define the sampling strategy for sub-scopes Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		section 2.3 of Report part A and in the assessment program.	assessments. RvA will reconsider its general policy in BR005 and where relevant develop SAPs for schemes in which a subdivision of areas (product groups, sectors, etc.) is used in defining the scope for accreditation. The SAPs will be developed with input from scheme-owners. <u>Action plan:</u> Before April 2014 the BR005 will be revised. Before May 2014 the SAP for the SMK scheme will be published. Before March 2014 we will make an inventory of schemes for which a SAP is necessary for sampling of (sub-) scopes. Before January 2015 the SAPs will be implemented.	
18.	CM	<u>Requirement</u> ISO 17011: 4.2.6 <u>Description of Finding</u> Medical steering committee is not mentioned in RvA documents.	This committee is not a RvA committee. This committee is a group of representatives of the medical labs that was formed by these representatives and not by the RvA. We had several meetings with this group to discuss the transition from CCKL accreditation to ISO 15189 accreditation. In December 2013 this committee was transformed to a subcommittee in the Dutch standardization body to continue its harmonization work on quality of medical laboratories. Also this committee will appoint the members that will represent the medical laboratories in the RvA User Council. RvA will also in future have regular meetings with this committee in the same way RvA has regular meetings with the federation of accredited laboratories (Fenelab), the association of accredited certification bodies (VOC) and a group of RvA accepted scheme-owners. The Quality manual could not	Seen quality manual – chapter 11 – client feedback Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			yet reflect this. In the quality manual the NEN-IVD committee will be formally mentioned as one of the parties that RvA uses to receive feedback.	
19.	NC	Requirement EA 2/15, 5.2.1 Description of Finding Medical laboratories have flexible scope, but RvA has no procedure with definitions for the flexible scope of medical laboratories.	Analysis of root cause and extent: The rules for scopes definitions are stated in policy rules for scopes (BR003). The current 15189 scopes were drafted as flexible scopes according to the rules in BR003 that are derived from EA-4/17. At that time with the limited number of medical laboratories this was considered appropriate. Remedial and corrective actions: In the transition project from the CCKL accreditation to the 15189 accreditation that we started in 2012, we identified that more harmonization was required and therefore we launched a project to establish the scope structure for all the different medical fields. In good cooperation with representatives from the different medical fields we have designed the draft templates for the scopes in October 2013. In the pilot assessments in November-December 2013 we tested most of the drafts and we will decide on the templates after the evaluation of the pilots in January-February 2014. In the meeting of 12 February we managed to establish the template for the scopes for the different fields. The templates will be the basis for each application for accreditation. Also the existing accreditations for 15189 will be transformed to the new templates, unless the laboratory wants a fixed scope. Objective evidence of implementation:	Seen the excel sheets that contain the templates for the medical laboratories. Closed: yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			The excel sheets enclosed contain the templates for the medical laboratories.	
20.	Cm	Requirement ISO/ IEC 17011 - 7.9.5 (EA 2/15): Description of Finding The limits of the flexible scope in the accreditation scope of testing labs are not clearly described. The degree of flexibility covered by the accreditation, need to be clarified in the scope.	We do not agree that 17011 7.9.5 requires the AB to clarify the degree of flexibility in the scope. The scope description shall be such that the degree is understood. We will review RvA-T025 and see whether it is possible to state in our policy how the limits of the flexible scopes may be described.	Noted
21.	Cm	Requirement ISO 17011, 7.11.3 Description of Finding After first re-assessment it is possible to extend the time between 2 assessments if the lab fulfils defined criteria (good performer). But the maximum time between 2 assessments is not defined.	RvA never considered documenting the requirement that the maximum time between 2 on-site assessments will not exceed 2 year because we never considered to reduce the number of on-site surveillances in a cycle of 4 years to less than 2 surveillances. We agree that this is however not formally documented in our rules. In our new policy rules for Surveillances and Reassessments BR005 we will include article 20 saying that the time between 2 on/site assessments for a CAB will never be less than 24 months. The new RvA-BR005 that will be published before 1 July 2014 (a major revision with other modifications is in process at this moment).	Seen art 20 in BR005, that explains that the maximum period between 2 surveillance assessment at the HQ is 24 months Closed: Yes
22.	NC	Requirement ISO 17011, 6.3.2	Analysis of root cause and extent: The NC is caused by some inconsistency in the	The finding was based on a

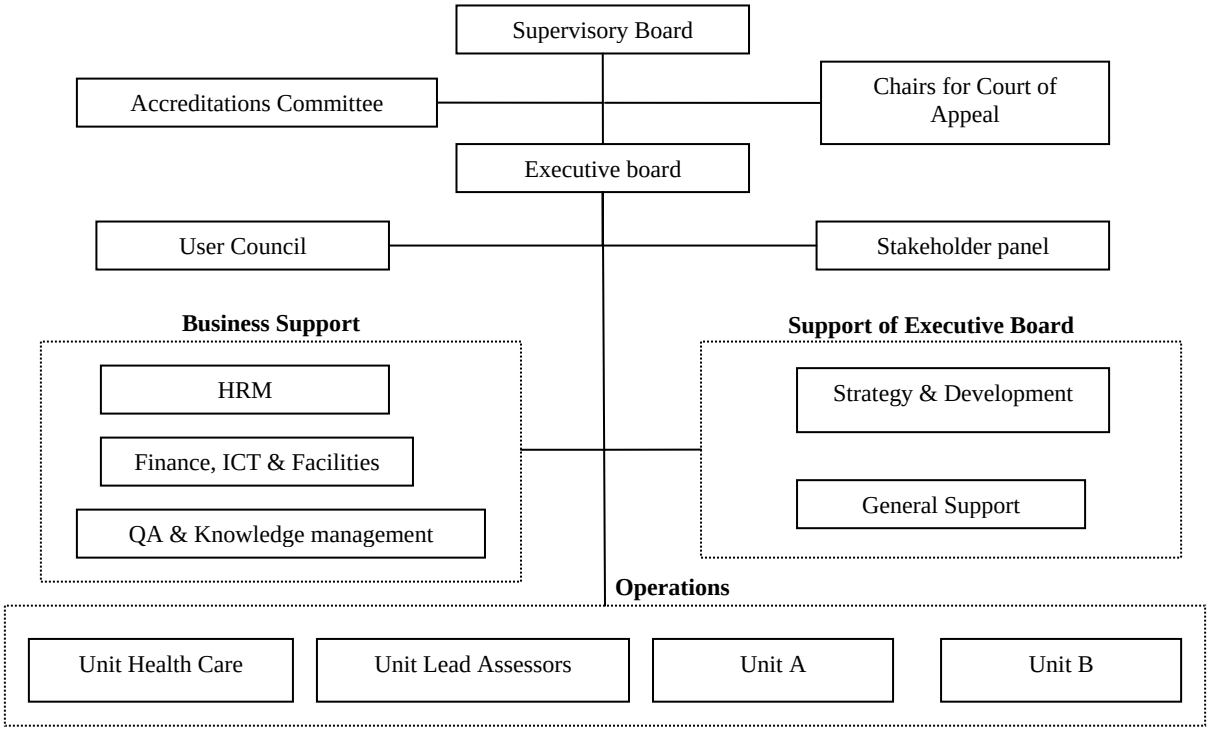
Number and Classification[1]			Response from AB	Team Comments/Conclusions
		Description of Finding Not always monitoring of lead assessors does follow RvA P011.	procedures of RvA. Our procedures distinguish supervised assessments during a qualification route (P011, Recruitment, selection and qualification) and regular periodic monitoring (P007, Monitoring). For supervised assessments of a team leader under training (a team leader to be qualified for surveillance assessments) RvA-P011 states a minimum level of 120 for the supervisor. P007 contains 3 possible "qualifications" for RvA observers during monitoring. These possibilities are: *The following persons are allowed to perform observation activities:* *• A RvA team leader who has acted for more than 4 years for the RvA on a regular basis.* *• RvA employees who also act as EA team leaders are preferred.* *• RvA employees with qualification level 150 in Radar.* *Knowledge of the relevant assessment criteria and the interpretations is a requirement.* The ambiguity is also caused by the use of the term "monitor" in P011 as a qualification level. This level is in fact not used to indicate that a person van do monitoring but to indicate that a person is qualified as peer evaluator or has specific experience in EA committees. We have verified all the two types of monitoring in the last years and did not found any monitoring that was not conducted by person with the qualifications as stated in P007. Also all supervised assessments were supervised by person with qualification of at least 120. What we however found that P007 states that all persons that do monitoring shall be assigned as such by the RvA director. In 2010 this authority however was changed to the manager of the unit lead assessors, therefore P007 was amended.	misinterpretation of the procedures. However, seen RvA-P007 new version 3 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			Remedial and corrective actions: As an improvement RvA will add an additional requirement to the first possibility for the qualification for monitoring: "A RvA team leader who has acted for more than 4 years for the RvA on a regular basis, having at least the same qualification level as the team leader to be monitored."	
23.	NC	Requirement ISO 17011, 4.6.1 Description of Finding Accreditation of verification and validation bodies according ISO 14065 rules are not fully addressed in the relevant approved policies and procedures 1. The Policy rule BR003 Scope of Accreditation, P017 (Composition of RvA assessment team), P011 (Recruitment, selection and qualification) are not including the accreditation for ISO 14065 and (EU) 600/2012. Updated versions of P017 and P011 but not approved were sent for document review for the exemption rules	Analysis of root cause and extent: Most of these requirements (1, 3, 4) had already been identified and the relevant procedures had been adapted and used in practice; however the formal approval process and introduction into the RvA had not been completed yet. For finding 2, RvA had not recognized that it required an extension to its Cross Frontier process to cover the formal requirements of the AVR. Finding is specific and limited to ISO 14065 (EU ETS) accreditation, due to additional requirement of AVR. Remedial and corrective actions: Adapt SAP-V001 to include additional process for handling feedback to foreign NAB (sub 2). Complete approval process in Vivaldi (RvA document control system). Instruction to staff on issue sub 2. To prevent the re-occurrence in delay in approval processes in RvA we have appointed a new quality manager. This person will start his job om 15 March 2014.	Seen the new documents: SAP-V001, BR003, P017, P011, VR003, SAP-V001, F035, F018 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
		2. No available a written procedure that explains how RvA gives feedback to a foreign NAB about handling of the Corrective Actions 3. the version of SAP V001, version 4 (Validation and Verification of Greenhouse Gases – GHG - in the EU/ETS) is in use but it is not approved 4. The Regulation for the use of Accreditation marks does not include marks to be used for accreditation of verification bodies according to ISO 14065 for the verification bodies	Objective evidence of implementation: Adapted SAP-V001 (v2) and published. The updated documents (BR003, P017, P011, VR003, SAP-V001, F035, F018) are approved in Vivaldi and published.	
24.	NC	Requirement ISO 17011, 6.2.1 Description of Finding Required competence in (EU) 600/2012 Article 58.3 regarding the review and decision on accreditation is not applied in the accreditation process of verification bodies.	Analysis of root cause and extent: With all focus on the AVR requirements on the implementation and planning of the EU ETS assessments, RvA underestimated the requirement related to competence required in the review and decision making process. It was thought that the regular RvA decision making process could be used. Finding is specific and limited to ISO 14065 (EU ETS) accreditation, due to additional requirement of AVR. Remedial and corrective actions: Add process step in RvA-V001 to ensure a review of all assessment reports by a qualified RvA assessor for EU	Seen the new documents: SAP-V001, BR003, P017, P011, VR003, SAP-V001, F035, F018 Closed: Yes

Number and Classification[1]			Response from AB	Team Comments/Conclusions
			ETS verifications. Include the review as a mandatory item on form F035 which is the overall form to check the content the decision making file. Instruction of staff and decision makers involved in these assessment processes. <u>Objective evidence of implementation:</u> The above described additional process step has been implemented with the transition process to the AVR requirements (example of decision making form and of review by assessor XXX Adapted RvA SAP-V001 (v2) and F035 (see finding #23).	

Appendix 1: Organization chart and key personnel



Internal committees are not indicated in this chart.

Management:
Chief executive: Mr. J.C. van der Poel
Director Operations: Mr. J.A.W.M. de Haas
Manager Unit A: Mrs. M.A.J. Pijnenburg
Manager Unit B: Mrs. P. de Borst
Manager Unit Health care: Mrs. B.H.E. Greven
Manager Unit Lead Assessors: Mr. J.E. Grefhorst
Manager HRM: Mrs. L.J. Manko
Manager Finance, ICT & Facilities: Mrs. K.A. Schipper, ICT temporarily under Unit B, Facilities temporaily under HRM
Manager Strategy & Development: Mr. M.J.E. Wieles
Quality Manager: Mr. R.F. Geenen

Expertise holders:
ISO/IEC 17020: XXX
ISO/IEC 17021: XXX
ISO/IEC 17024: XXX
ISO/IEC 17025: XXX
ISO/IEC 17065: XXX
ISO 15189: XXX
ISO 14065: XXX

Appendix 2: Report on participation in international PT/ILC's

This appendix contains an overview of the international PT's/ILC's in which the laboratories accredited by the AB have participated in the last 4 years, including the performance of the labs.

Participation of RvA labs in international PT's

PT code	Organiser	PT scope	Start date mm/yy	nbr of NL labs	Participation
APLAC T063	TAF	safety test for Creepage and Clearance distance	04-2008	0	No accredited labs
APLAC T065	HKAS	Determination of Cadmium and Lead in Herbal Sample	08-2008	0	No accredited labs
APLAC T066	CNAS	total heavy elements in soil	09-2008	0	No accredited labs
0802/0803-EMS 2008	IfEP	Emission spectrometry low / high alloyed steel	10-2008	0	No accredited labs
0801-HRC 2008	IfEP	Hardness testing Rockwell C, ISO 6508	10-2008	0	No accredited labs
APLAC T067	CNAS	Chemical analysis of the components in stainless steel	11-2008	1	Potential: L150, L208: No participation, deadline was 10-11-2008
IMEP 27	IRMM	analysis of total Cd, Pb and As and extractable Cd and Pb in mineral feed	11-2008	-	no invitation received
APLAC T068	HKAS	Polycyclic Aromatic Hydrocarbons in Sediment	12-2008	0	No accredited labs
IMEP 24	IRMM	analysis of heavy metals in toys	04-2009	>1	forwarded to RB, no confirmation
APLAC T069	HKAS	Melamine in Fish Feed	05-2009	0	No accredited labs
IMEP 28	IRMM	analysis of total Cd, Pb, As and Hg in food supplements	05-2009	>1	Internally forwarded, no response
IMEP 25b	IRMM	determination of bromate in drinking water	05-2009	>1	Potential L049, L151, no confirmation
APLAC T071	HKAS	Melamine in Milk	06-2009	1	L027: good performance
IMEP 29	IRMM	Heavy metals in feed of plant origin	11-2009	>1	L053, L172 no information on results
IMEP 107	IRMM	determination of total and inorganic As in rice	11-2009	1	L312, no confirmation on participation
APLAC T072	CNAS	Food Synthetic Dyestuff	12-2009	>1	Internally forwarded, no response
IMEP 30	IRMM	Determination of total arsenic, cadmium, lead, and mercury, and methylmercury in seafood	05-2010	>1	L092, no information on results
APLAC T078	HKAS	Polycyclic Aromatic Hydrocarbons (PAHs) in Sediment	08-2010	>1	Deadline 29-8-2010: No further actions.
APLAC T076	CNAS/ NIL	Determination of TFe, Fe(II), SiO_2, CaO, MgO, P, S, Al2O3, Mn, Ti, K2O, Na2O contents in iron ore	09-2010	>1	Internally forwarded, no response, deadline 24-9-2010
Roughness	DTU Mechanik	Proficiency Testing for European Accredited Laboratories: Roughness	02-2012	2	No participation due to high fees
APLAC T084	BQSF	Organochlorine pesticide residues in chicken fat	12-2012	4	L234, no information on results
IMEP 39	IRMM	Determination of total Cd, Pb, As, Hg and inorganic As in mushrooms	04-2013	4	L053, L059 no information on results
DRRR	DRRR	Sensory-WATER QUALITY acc. to EN 1622	05-2013	>1	No participation due to high fees
APLAC T088	CNAS	Photometric Measurement on Solid State Lighting Products	05-2013	0	No accredited labs
IMEP 38	IRMM	Total As, Cd, Pb and Hg in Compound Feed	06-2013	>1	No participation, deadline on short notice
APLAC T087	CNAS	Cause and manner of death	07-2013	1	No participation, deadline on short notice
IMEP 37	IRMM	Pesticides in Grapes	08-2013	4	L201, L335 nominated

Appendix 3 Statistical information AB

Name of AB: Dutch Accreditation Council RvA, The Netherlands **Date of completion: 9 September 2013**

Table 1: General statistical information

Scope MLA following EA-2/02			**Accredited Bodies (4)**	**Lead assessors (5)**	**Technical assessors (6)**	**Technical experts (7)**	**Major Fields (8)**
Level 2 activity (1)	**Level 3 standard (2)**	**Level 4+5 CA-scheme and normative document (3)**		**Internal External**	**Internal External**		
Calibration	ISO/IEC 17025	Not applicable; specify major fields in column 8.	58	11 6	3 0	49	1. DC/LF Electricity 2. Temperature 3. Pressure and Vacuum 4. Time and Frequency 5. Dimensional quantities
Testing	ISO/IEC 17025	Not applicable; specify major fields in column 8.	242	12 6	-- --	217	1. Environment-Water 2. Food 3. Fuels/Oils 4. Microbiology 5. Chemistry
	ISO 15189	Not applicable; specify major fields in column 8.	11	5 2	-- --	22	1. Clinical Chemistry 2. Haematology 3. Clinical Genetics 4. Medical Microbiology 5. Clinical Pathology
Inspection	ISO/IEC 17020	Not applicable; specify major fields in column 8.	135	14 9	5 8	112	1. Soil protection 2. Environment 3. Asbestos 4. Food Oils & Fats Logistics 5. Pressure
Management system certification	ISO/IEC 17021	QMS (ISO 9001)	66	9 9	13 13	78	

Table 1: General statistical information

Scope MLA following EA-2/02			**Accredited Bodies (4)**	**Lead assessors (5)**	**Technical assessors (6)**	**Technical experts (7)**	**Major Fields (8)**
Level 2 activity (1)	**Level 3 standard (2)**	**Level 4+5 CA-scheme and normative document (3)**		**Internal External**	**Internal External**		
		EMS (ISO 14001)	39		5 5	26	
		FSMS (ISO 22000) / ISO 22003	12		3 3	19	
		ISMS (ISO/IEC 27001) / ISO/IEC 27006	10		1 2	4	
		ISO 13485	6		--	5	
		Identify other MS as applicable					
		VCA	24		2 6	2	
		OHSAS 18001	18				
		ISO/IEC 20000-1	3				
		ISO 50001	1				
Product certification	EN 45011	Not applicable; specify major fields in column 8.	55	7 6	7 12	72	1. Food technology 2. Agriculture 3. Construction materials and building 4. Environment and health protection. Safety.
Certification of persons	ISO/IEC 17024	Not applicable; specify major fields in column 8.	6	3 2	-- 1	28	1. Examination 2. Electrotechnology 3. Real Estate 4. Asbestos

Table 2: Accreditation in the field of European Legislation (Directives, Regulations)

Directive / Regulation [total no. accr. Bodies]	**Accreditation standard**	**Accredited Bodies**	**Technical assessors**	**Technical experts**

Table 2: Accreditation in the field of European Legislation (Directives, Regulations)

Directive / Regulation [total no. accr. Bodies]	**Accreditation standard**	**Accredited Bodies**	**Technical assessors**	**Technical experts**
89/106/EEC CPD [2]	45011 17025	1 1		4
89/686/EEC Personal protective equipment (PPE) [1]	45011 17020	0 1		1
92/42/EEC Hot-water boilers [1]	45011 17021	1 1		2 2
94/25/EC Recreational craft [3]	45011	3		2
94/9/EC Equipment & protective systems/explosive atmospheres [1]	45011 17021	1 1		2
95/16/EC Lifts [4]	17020 45011	4 1		2 2
96/98/EC Marine equipment [3]	17021 17020 45011	1 1 1		1 2 2
97/23/EC Pressure equipment [8]	17021 17020	5 8		2 5
2000/14/EC Noise emission [1]	17020	1		3
2004/108/EC Electromagnetic compatibility (EMC) [5]	45011 17025	5 1		3 3
2004/22/EC Measuring instruments Directive [4]	17021 17020 17025	1 4 2		1 3 3
2006/42/EC Machinery [7]	17020 45011	5 3		2
2006/95/EC Low Voltage [2]	45011	2		3
2008/57/EC Interoperability of the rail system [1]	17020	1		1
2009/142/EC (90/396/EEC) Gas appliances [2]	45011 17021	1 1		2 2
2009/23/EC (90/384/EEC) Non-automatic weighing instruments [2]	17021 17020 17025	1 2 1		1 3 3
2010/35/EU Transportable pressure equipment [1]	17020	1		

Table 2: Accreditation in the field of European Legislation (Directives, Regulations)

Directive / Regulation [total no. accr. Bodies]	**Accreditation standard**	**Accredited Bodies**	**Technical assessors**	**Technical experts**
Regulation (EC) 305/2011 Construction Products and Repealing (CPR) [1]	45011 17025	1 1		
Regulation (EC) No 834/2007 and No 889/2008 on organic production [2]	45011	2		2
Regulation (EC) No 178/2002, No 853/2004 and others on food safety and food hygiene [2]	17020	2		2

Table 3: Accreditation in the field of European or international sector schemes

Sector Scheme	**Accreditation standard**	**Accredited Bodies**	**Technical assessors**	**Technical experts**
GlobalGAP	EN 45011	5		4
BRC	EN 45011	4		3
PEFC	EN 45011	2		2
KeyMark	EN 45011	1		2

Table 4: Accreditation outside the EA-MLA

Conformity assessment activity	**Accreditation standard**	**Accredited Bodies**	**Lead assessors**	**Technical experts**
Reference Materials	ILAC-G34	2		
Proficiency Testing	ISO17043	15		
EMAS	EMAS Regulation EC 1221/2009	1		
Medical Laboratories	CCKL Praktijkrichtlijn	247		
GHG Verification	ISO 14065 (EU ETS)	4	2	4

Table 5: Overall statistics on EA-MLA activities

Name of AB:	**Dutch Accreditation Council RvA, The Netherlands**
Total number of valid accreditation certificates within the EA-MLA:	587
Total number of lead assessors available to the AB for the activities related to the EA-MLA scope:	37
Total number of technical assessors available to the AB for the activities related to the EA-MLA scope:	40
Total number of technical experts available to the AB for the activities related to the EA-MLA scope:	508

Table 6: Information on international activities

Are you signatory of IAF-MLA?	**~~No~~ / Yes for :** **Management systems:** ☒ **ISO 9001** ☒ **ISO 14001** ☐ **ISO 22000** ☐ **ISO 27001** ☐ **ISO 13485** **Products** **Persons**
If yes do you have a licensing agreement for the use of the IAF-MLA mark?	**~~No~~ / Yes**

Table 6: Information on international activities

Are you signatory of ILAC-MRA?	**~~No~~ / Yes for** **Calibration** **Testing** **Medical laboratories** **Inspection**
If yes do you have a licensing agreement for the use of the ILAC-MRA mark?	**~~No~~ / Yes**

Appendix 4: Evaluation plan

Sunday 24	Monday 25	Tuesday 26	Wednesday 27	Thursday 28	Friday 29	Team Member & Expertise
17:00-19:00 Team meeting Hotel	08:30 Team meets at the hotel reception to be guided to RvA 9:00-10:30 Opening meeting with key personnel and team • RVA General presentation • General questions • Changes from last visit • Structure, *RvA Observers:* *XXX* *XXX* *XXX)* 10:30-17:00 Vertical audits, file check (each team member check files independently)	Accreditation criteria and information (RS) Technical committees (RS) Monitoring of assessors, experts and decision makers Surveillance and reassessment Check previous findings: CN 5, Cm 1	WITNESS 2 day reassessment XXX XXX XXX *to witness second day*	Extension of the AB scope Extension of NATs activities (GB) Transition to new version of accreditation standards. Obligations of AB Sector Schemes, Directives	Final Office Check + Team meeting Closing meeting with RVA key personnel *Observers:* *XXX* *XXX*	XXX Persons Certification 17024 RvA interlocutor:
		WITNESS 1 day surveillance XXX XXX XXX	WITNESS 2 day reassessment XXX XXX XXX *to witness second day*	Monitoring of assessors, experts and decision makers (FS) Transition to new version of accreditation standards. Surveillance and Re-assessment Sector schemes, Directives Accreditation of foreign CABs, Accreditation of local CAB with key activities in foreign countries, Participation in accreditation of Dutch CAB by foreign NAB Extension of NATs activities (AG) Check previous findings: NC 1, CN 5, Cm 1 *RvA Observer: XXX*		XXX Product Certification 45011 RvA interlocutor:
		Accreditation criteria and information (AG) Technical committees (AG) Policy on traceability Surveillance and Re-assessment Sector schemes, Directives Notified bodies Check previous findings: CN 5, Cm 1	WITNESS 2 day reassessment XXX XXX XXX *to witness second day* *RvA Observer: XXX*	WITNESS 1 day surveillance XXX XXX XXX		XXX Inspection and Notified Bodies Directives/ Regulations 17020 RvA Interlocutor:
		WITNESS Testing 1 day surveillance XXX	Proficiency testing and other comparisons for laboratories, Policy on traceability, Reference Materials Monitoring of assessors, experts and decision makers Surveillance and Re-assessment Flexible scopes Attendance to Accreditation Committee Check previous findings: CN 2, CN 3, CN 4, CN 5, Cm 1, Cm 3, Cm 4, Cm 5	WITNESS Calibration 1 day surveillance XXX XXX XXX		XXX Testing and calibration laboratories 17025 RvA interlocutor:
	13:00-17:00 XXX: (EU) 600/2012 (AVR) EU/ETS *RvA Observer:* *XXX*	Extension of NATs activities. Transition to new version of accreditation standards. Sector Schemes, Directives Monitoring of assessors and experts Comittees and working groups Check previous findings: CN 5, Cm 1	WITNESS 2 day reassessment XXX EU ETS Directive 2003/87/EC, pressure equipment (European Directive 97/23/EG) XXX			XXX GHG verification 14065 Directives/regulations RvA interlocutor:

		WITNESS ISO 17025 1 day surveillance XXX XXX XXX	WITNESS ISO 15189 2 day reassessment XXX XXX XXX XXX *to witness second day*	Proficiency testing and other comparisons for laboratories, Policy on traceability, Reference Materials Extension of AB scope. Transition to new version of accreditation standards. Surveillance and Reassessment Monitoring of assessors, experts and decision makers Flexible scopes Check previous findings: NC 3, CN 2, CN 3, CN 4, CN 5, Cm 1, Cm 3, Cm 4, Cm 5		X Testing 17025+15189 RvA interlocutor:
	~~10:30-12:30~~ ~~Accreditation law, Legal responsibility, impartiality, confidentiality, liability and financing~~ ~~Check previous findings: NC 2, CN 1, Cm 2~~	~~Management reviews, internal audits, complaints, appeals, Non conformities and corrective action, preventive action, client feedback.~~ ~~Management system document control and records~~ ~~Pending issues~~ ~~Preparing Report~~	~~Attendance to Accreditation Committee~~ ~~Procedures for recruiting, qualifying assessors and experts.~~ ~~Internal personnel training and records~~ ~~Committees, working groups~~ ~~Pending issues~~ ~~Preparing report~~ ~~Check previous findings: NC 2~~	~~Pending issues~~ ~~Preparing Report~~ ~~Check previous findings: NC 3, Cm 1~~		XXX XXX XXX
	9:00-11:00 Opening meeting with key personnel and team • RVA General presentation • General questions • Changes from last visit • Structure, 10:30-12:30 Accreditation law, Legal responsibility, impartiality, confidentiality, liability and financing Check previous findings: NC 2, CN 1, Cm 2 12:30-17:00 Vertical audits, file check	WITNESS 1,5 day assessment XXX XXX XXX *To witness first day*	Cross frontier activities, Accreditation of foreign CABs, Accreditation of local CAB with key activities in foreign countries, Participation in accreditation of Dutch CAB by foreign NAB Extension of NATs activities. Transition to new version of accreditation standards. Sector Schemes, Directives ISMS Check previous findings: NC 1, NC 2, NC 3, CN 5, Cm 1	WITNESS 1 day surveillance XXX XXX XXX		XXX Deputy TL XXX Trainee MS Certification 17021 Directives/ Regulations RvA interlocutor:

There are crucial aspects not mentioned in the programme. Those aspects will need to be check by every team member, preferably as part of vertical audits.

- ✓ **Human resources**
- ✓ **Personnel involved in the accreditation process**
- ✓ **Accreditation process**
- ✓ **Extending, suspending, withdrawing or reducing accreditations**
- ✓ **Records on CABs**
- ✓ **Reference and use of accreditation mark and symbols.**

LOGISTICS - 2013

- Approx working hours Monday to Thursday (RVA premises) from 09:00 to 17:00
- Daily internal Team meeting from Monday to Thursday, at hotel: 19:00 to 20:00
- Lunch break should not last longer than 45 minutes, approx.
- Team members may leave RvA HQ separately when finishing the planned work for the day. No need to waste time waiting for each other. (Each TM to decide when to have dinner, before or after meeting, depending on Mediterranean or Nordic preference ;-)! No obligation to have dinner all together)
- Many aspects may be evaluated by two TM from different backgrounds, coordinating at the same time, if possible.

- Trainees will always be with trainers (not necessarily looking at the same files!).
- Monday morning we will all be together at the opening meeting, afterwards each team member will start with the vertical audits (check case files), except Emanuele and me, that will do a joint evaluation.

- RvA should prepare a dossier of each of the witnessed CABs with relevant information for each team member to take to the witness visit. Preferably sent by mail before the evaluation.

LOGISTICS - 2014

TL: XXX

Tuesday 21 January 2014	Wednesday 22 January 2014	Thursday 23 January 2014
9:00-17.00 Opening meeting with RVA Management Procedures for recruiting, qualifying, monitoring assessors and experts. Internal personnel training and records Management system document control and records Check findings issued on November Check findings issued in the last peer evaluation	9:00-17.00 Management reviews, internal audits, complaints, appeals, Non conformities and corrective action, preventive action, client feedback Confidentiality Committees, working groups Check findings issued on November Check findings issued in the last peer evaluation	9:00-13.30 Pending issues Check findings issued on November Writing report 13.30 Closing meeting with RVA key personnel

Appendix 4: Checklist EU-ETS requirements

Here below the EU-ETS checklist which was delivered to MAC in September as a part of the application review.
In this new revision you can find in italic some supplementary notes references to the findings.

Clause in AVR Reg and related 17011 requirements	Requirement (Keywords or phrases)	Reference to AB's documen-tation	AB Comments	Findings/ Comments from the evaluation
Article 53 and 71 17011, 7.13	Procedure for administrative measures on suspension, withdrawal or reduction of scope, Information exchange	RvA-BR002, art. 30 SAP-V001	The rules for suspension and withdrawal of accreditation are contained in the policy rule RvA-BR002. This also includes the suspension or withdrawal of part of the scope (reducing the scope). This document specifies conditions and reasons for these sanctions, including publication thereof through the RvA website. Currently, BR002 is being updated, bringing the text even more in line with the AVR texts,	The rules for suspension in RvA- BR002 are general and in line with (EU) 600/2012. Information exchange as required by (EU) 600/2012 is reflected in SAP-V001. *No available written procedure that explains how RvA gives feedback to a foreign NAB about handling of Corrective actions, Finding #23*
Article 57 17011, 7.5.2	Competence - Assessment team	RvA-P11 and RvA-P17	The requirements for the team composition are contained in procedure RvA-P17. The requirements for assessors and experts are documented in RvA-P11. Revisions of both documents are expected to be published before November 2012 taking into account the requirements in the AVR.	The documents RvA-P17 and RvA-P11 were available only in Dutch for the review. RvA-P17 address competence requirements for the team on ISO

			Procedures to develop the required competence for the reviewers and decision takers (in line with AVR, art. 58, sub 3) are still under development. Initial training of the RvA Accreditation Committee and Director has started.	14065 and EU-ETS regulation
Article 58 and 59 17011, 6.2	Competence – assessors and experts			For experts the RvA-P11 define competence criteria for qualification as e g knowledge of data-auditing *Required competence in article 58.3 regarding review and decision on accreditation is not applied in the accreditation process of verification bodies, Finding#24*
Article 67 and 72 17011, 5.9	Complaints	RvA-BR002 RvA-BR008 SAP-V001	The general rules for dealing with complaints are stated in BR002 and BR008. The specifics for GHG verification have been included in SAP-V001.	Handling of complaints as required by (EU) 600/2012 is reflected in SAP-V001.
Article 70 and 74	Accreditation work programme	SAP V001	Refer to Annex A, 4.5 latest additions highlighted	Accreditation work programme required by (EU) 600/2012 is reflected in SAP-V001
Article 70 and 74	Management report			Management report required by (EU) 600/2012 is reflected in SAP-V001
Article 73	Information exchange on surveillance Cross border verification			Information exchange on surveillance and cross border verification as required by (EU) 600/2012 is reflected in SAP-V001
Article 75	Register - Database	RvA	The RvA website contains most of the data	Accredited verification

17011, 8.2.1		website	mentioned in article 75. Not included are the 'the Member States in which the verifier is carrying out verification' and 'the date on which the accreditation was granted'. RvA will include this information on the scope statements, when these will be updated for the AVR format (to be implemented end of 2013, early 2014).	bodies was found and identified on RvAs web site. *Information on which countries the verifiers are preforming verification is now included in the accreditation certificates and the information is publically available at the web-site.* *The accessibility for the pubic and interested parties on the information regarding verification bodies can though be improved.*
Article 76 17011, 7.2	Provision -Information for the work programme	SAP-V001	Refer to Annex A, 4.5	Provision -Information for the work programme is addresses in SAP-V001

From the Finding #23:

1. *The Policy rule BR003 Scope of Accreditation, P017 (Composition of RvA assessment team), P011 (Recruitment, selection and qualification) are not including the accreditation for ISO 14065 and (EU) 600/2012. Updated versions of P017 and P011 but not approved were sent for document review for the exemption rules*
2. *The version of SAP V001, version 4 (Validation and Verification of Greenhouse Gases – GHG - in the EU/ETS) is in use but it is not approved*