

### PUBLIC REPORT 2016



## Vision, mission and core values

## What is accreditation?

#### Vision

#### The RvA services:

- are provided in a professional, transparent and independent way with integrity;
- by deploying competent, motivated employees and external networks of experts;
- and according to national and international set requirements.

In addition, the interests of the Dutch market, the authorities and the people are taken into account.

#### **Mission**

The core activity of the RvA is to provide accreditation services. As a national accreditation body the RvA ensures that the confidence all the interested parties have in the certificates of conformity and assessment reports issued under its supervision is justified.

#### **Core values**

The RvA adheres to the following core values:

- competency
- impartiality and independence
- market orientation
- · people orientation
- integrity
- transparency

In Dutch the first letters of these words read as the acronym 'commit'. This is an abbreviation which means commitment, or involvement. It is precisely this involvement based on the core values that offers our clients actual guaranteed trust.

#### **Creating trust**

Accrediting really means: creating trust. Nationally and internationally buyers want to be able to trust blindly the quality and safety of products and services provided. If these are guaranteed, it not only benefits the buyer but also the supplier. This strengthens his position in the market. In order to be able to give an objective guarantee, the supplier can have his product or service assessed by an accredited organisation. This also applies to every area imaginable: health, environment, construction, energy, food, transport, finance etc.

#### Chain of trust

If a supplier meets the requirements he will receive a certificate of conformity in the form of a certificate or report. Assessing bodies are therefore called conformity assessment bodies. This statement has most value if the assessment body is professional, impartial and independent. The RvA has been appointed by the government as the national accreditation body with the aim of checking the expertise, impartiality and independence of conformity assessment bodies. If the result is positive an accreditation mark will be issued. Thereby the RvA forms the final link in the chain of trust.

## Foreword by the Board of Supervisors

It gives us great pleasure to bring this Dutch Accreditation Council RvA public report for 2016 to your attention. It is a report on a year in which for a change the RvA itself has been the subject of two assessment reports. The one was on its own instructions, an image survey. This shows the RvA as a reliable and good accreditation organisation with integrity. The other one was on the instructions of the Ministry of Economic Affairs, to evaluate the RvA in its capacity as an autonomous administrative authority ('ZBO') over the first five years of its ZBO existence.

This shows that the RvA is in general well-appreciated and that it operates effectively and efficiently. These are outcomes which also make us as the Board of Supervisors happy. There are obviously also recommendations for further improvements. They are mainly in the area of communication and client contact, efficient management and information. The present report deals with this concretely on the basis of the strategic themes which have been determined for the period 2015-2020.

As chairman of the day at the conference which the RvA organised in connection with World Accreditation Day (9 June) I saw with my own eyes that in 2016 a lot of work went into communication and information. It was a session that was very well attended and where I was able to meet many accreditation stakeholders.

Another highlight considered with regard to accreditation was the appearance of the renewed cabinet position with regard to conformity assessment and accreditation. It gives shape to the integral approach to the supervision of public interests, as this was advocated several years ago by the Netherlands Scientific Council for Government Policy. It encourages parties such as policy departments, State inspectorates, conformity assessment bodies and the RvA to

improve mutual information exchange. This is obviously without losing sight of each party's role and responsibility. The position taken by the RvA for many years, namely that accredited conformity assessment cannot or should not replace enforcement supervision, but that they could complement each other, is endorsed in the cabinet position.

The total system of quality assurance, supervision and enforcement should give society confidence that all is well with the products and services they can enjoy. As the Board of Supervisors we keep our finger on the pulse of how the RvA deals with all those interests, optimises its management, responds to signals from society and looks for the dialogue, without losing sight of its special role.

In 2016 we performed that duty in word and deed. You can read more about it in our report to the annual accounts

On behalf of the Board of Supervisors,

Drs. E.H.T.M. Nijpels Chairman



## Table of contents

Introduction	5		
PART 1 Giving confidence		PART 2 Annexes	
1 Strategic themes	9		
		Annex 1	
		Governance bodies and	
Interview with Jeroen Lammers and Peter van der Knaap		advisory committees	43
Confidence in self-regulation	16		
		Annex 2	
		Brief financial overview	44
2 Development and innovation	20	Arereari	
		Annex 3 Our work in figures	46
Interview with Peter Huijgens and Paul Robben		Our work in figures	40
Confidence in our healthcare	24		
	~ 1		
3 Supervision and advice: ensuring confidence	28		
Interview with Rian Brokx and Ger Egberts			
Confidence in our drinking water	30		
4 Quality leads to confidence	34		
Interview with Bernd Lehmann and André Barel			
Confidence in satellite systems			

## Introduction

Every year in our public report we shed light on the subject of *confidence*. This is not so strange if you think that this is what *accreditation* etymologically vouches for. On the basis of European harmonised standards the RvA assesses whether laboratories, certification bodies and inspection bodies carry out their work competently, impartially and independently. This is how we support the confidence that society has in the outcomes of that work. These standards are not formulated by ourselves but by all interested parties.

In our assessments we don't look directly at matters such as integrity or organisational culture. Neither are the standards we apply meant to determine whether organisations observe legislation and regulations; there are other bodies to keep an eye on this. However, we note that users of the outcomes of the work of accredited organisations often have the perception that all those subjects are covered by accreditation and certification. This presents a fine task for developers of standards and for players in the area of accreditation and certification. Because in a fast changing world it is crucial that the possibilities but also the limitations of our work are clear to everybody.

We wrote this last year. This position is again emphasised in several reports that were drawn up in 2016.

#### Looking back on 2016

Our primary task consists of conducting assessments in order to be able to take decisions about accreditation and maintaining accreditation of 686 RvA registrations and, in a transitional phase, another 141 CCKL registrations.

You will find the facts of this in the Annexes to this report. 2016 was the second year of the transition from CCKL registrations to RvA registrations. In the meantime 109 laboratories have been accredited against the international ISO 15189 standard. It is a transition that will be ongoing until sometime in 2019; because then the possibility of a CCKL registration will end.

However, more is required in order to be able to carry out the primary work in a way that justifies the changing needs of society. For instance in 2016 we paid a lot of attention to three reports by others which appeared about us or our work. These were reports each one of which also mapped for us the needs of the society. In chronological order these were an image survey on our instructions, an evaluation on the instructions of the Ministry of Economic Affairs ('EZ') and the renewed cabinet position on accreditation and conformity assessment.

#### Image survey

In 2015 on the basis of a SWOT analysis (*strengths*, *weaknesses*, *opportunities*, *threats*) we determined our strategic themes for the period 2015-2020. You will read more about this in Chapter 1. Subsequently, in 2016 we had an image survey carried out by an independent market research company. We asked this agency to examine the image the various stakeholders have of the RvA, and to determine whether this image contributes to confidence in the activities of the RvA.

It emerged from the survey (94% response) that the RvA scores good to excellent in respect of the core values such as *integrity* and *competence*. The RvA accreditation is well appreciated. As areas for improvement for the future the respondents recommended to us the following: fulfilling process agreements and more unequivocal, consistent procedures. In addition, it can be deduced from the results that the RvA cannot be 'transparent enough' about its activities and that it should proactively develop new services and activities.

## Evaluation on the instructions of the Ministry of EZ

Autonomous administrative bodies (ZBO) are evaluated every five years on the basis of legal requirements. Five years after the RvA had been appointed as the national accreditation body the Ministry of EZ instructed the KWINK agency to evaluate the operation of the RvA.

The following question was central in this respect: Did the RvA carry out its legal duties effectively and efficiently in the evaluation period? By means of an online questionnaire, interviews with accredited parties and other external stakeholders in the work of the RvA, analyses of documents and talks with the RvA, the KWINK agency came to the conclusion that the RvA has been operating effectively and efficiently. The general conclusion was that the RvA scored more than sufficient to good. We are obviously pleased by this. But it belongs pre-eminently to the nature of our work to aim at continuous improvement. The KWINK agency gave the following recommendations:

- Give information even more actively about the role of accreditation and then in particular about the role of accreditation in the system of supervision as a whole.
- Set up a low-threshold feedback system.
   Conformity assessment bodies want to be able to give feedback in a simple way.
- Make processing times more central. Making processing times shorter is important for the market position of accredited parties. Make this part of the work culture of the RvA.
- Make administrative burdens lighter and increase the transparency and predictability of costs for accredited parties. To this end develop the computerisation of accreditation processes.

## What do we do with the results of the image study and the evaluation?

Both reports provide clear and partly comparable areas of concern, which are moreover well covered by the strategic subjects we determined. They also gave us reason to set up this report differently than in previous years by dealing in the next Chapters particularly with the progress and developments involved in the four strategic themes.

## The renewed cabinet position on conformity assessment and accreditation

The third report is *The renewed cabinet position on conformity assessment and accreditation* as this has been drawn up under the responsibility of the Minister of Economic Affairs. Although the basic principles of the cabinet position in 2003 remained intact, this new point of view makes clearer the position of accredited conformity assessment in relation to European regulations.

The European Regulation for accreditation and market surveillance which came into force in 2010 made this necessary. The objectives of the report are supporting departments in applying conformity assessment as a policy instrument, subsequently doing this statewide and finally providing clarity to private parties about the way in which the authorities can deploy conformity assessment as a policy instrument. The report and the accompanying letter by the Minister clearly indicate that the accredited conformity assessment has not been designed and neither is it intended as a replacement for the work of the State inspectorates. But it can form a good basis for the confidence on companies and organisations by the State inspectorates.

We are pleased that the cabinet also sees opportunities, for instance for State inspectorates and the RvA to share more information with each other in the public interest. This is a subject we have been advocating for several years and which we are dealing with further in our regular contacts with various inspectorates. The cabinet clearly prefers the registration of conformity assessment bodies in connection with European regulations to be on the basis of expertise and independence which is demonstrated by means of accreditation. This is good for European harmonisation. It avoids the administrative burden as a result of separate assessment programmes which diverge from the international standard.

#### Other developments and activities

On 9 June 2016 (World Accreditation Day) the RvA organised a well attended conference on the theme of *accreditation: self-regulation and supervision.* The conference was initiated by the Advisory Panel of Interested Parties. Such a conference takes place every other year around 9 June.

We often consulted scheme owners about the changes in the RvA policy for evaluating schemes, in line with the European development. In cooperation with Fenelab we decided to carry out a two-year pilot scheme in which inspections of asbestos cleanups are attended by assessors of the RvA without prior notification.

This should improve the reliability of final inspections.

During the year under review the assessor capacity of the RvA has even been significantly extended. After training in 2016 and the beginning of 2017 the new assessors will be fully operational in the course of 2017 and contribute to smooth workload planning and better harmonisation.

#### Outlook for 2017

It remains a challenge to find good potential assessors. This applies to experts in the area of standards for accreditation as well as for substantive experts who can assess the various spheres of work of accredited parties. In 2017 we will pay extra attention to this so that we can expand our pool of qualified assessors. For instance we are going to use the opportunities offered by LinkedIn more, and a separate website will be set up: working for the RvA (www. werkenvoorderva.nl). Moreover, in 2017 we are concentrating on a continuously improving and efficiently operating primary process.

One project that demands internally a lot of our time relates to the development of a digital reporting tool for assessments with an underlying database. This tool should increase the user-friendliness and the uniformity of reports for the assessor as well as the party assessed. In addition, the database provides opportunities to make analyses in the near future in order to organise our assessments more on a risk-basis. We are also examining whether we can organise our primary processes such that the communications with our accredited parties proceed more uniformly and quickly. Moreover, we also want to ensure that assessments take place according to the principle of 'what's sauce for the goose is sauce for the gander'. So this means harmonisation, with recognition of the difference in performances between accredited parties.

The legislative proposal of construction quality assurance will no doubt also cast its shadow on our sphere of work. New forms of conformity assessment can arise to make meeting the requirements of the Building Decree plausible. The relationship of our work with the new ZBO to be established for the assessment still has to be detailed.

The first accreditations are expected to be granted for providers of certification for Business Continuity Management Systems according to ISO 22301.

The RvA remains aware of the international nature of its work. We have been assessed by an evaluation team of the European Cooperation for Accreditation (EA) for the soon to be established European multilateral agreement for providers of ring tests on the basis of the ISO/IEC 17043 standard. The positive decision on this is expected to be taken in April 2017.

#### Structure of this public report

This public report consists of two parts. In the first part you will read how the RvA contributed in 2016 to the justified confidence of the people, authorities, companies and organisations. You will find the formal facts in the second part. Apart from these core texts you will find four interviews in this report in which parties shed their light on quality and confidence in their sphere of work. I hope you enjoy reading it!

Jan van der Poel Director/Chief Executive



## Part 1

## Giving confidence

## 1 Strategic themes

In 2013 and 2014 we conducted a comprehensive SWOT analysis (*strengths, weaknesses, opportunities, threats*). On the basis of this analysis the management of the RvA made several strategic choices which will determine the policy of the RvA from 2015 until 2020. We distinguish four main themes: human resources, operational excellence, harmonisation and accreditation as an instrument.

In this Chapter we would like to give an impression of the activities we undertake and the progress we are making with regard to the various themes.

#### **Human resources**

It is important that the need for and the availability of internal and external assessors are properly balanced. In the coming years we want to improve this balance further so that we can better respond to the needs of market parties - and manage to safeguard this for the future. This theme includes the activities by which we can further strengthen our professional networks. The aim of this is to gain better access to the experts necessary for the provision and development of our services and methods.

#### Internal assessors

We took a big step in 2016 on the strategic theme of human resources by creating six extra posts for assessors in the workforce of the RvA. This increases the number of (internal) assessors from 21 FTE in 2015 by 30% to 27 FTE in 2016. When these assessors have all been trained and settled in, we will have sufficient in-house capacity in 2018 to have at least two-thirds of all assessments guided by an employee employed by the RvA. We established this on the basis of a fouryear forecast of the capacity need on the basis of the number of assessments that can be expected under our rules. A flexible shell of freelance lead assessors is necessary for coping with capacity peaks and with any absence of our internal staff. It is important that we deploy the freelance lead assessors sufficiently so that they can maintain and keep their qualification and competence as assessors.

Our internal assessors also form our biggest knowledge base. Apart from assessments they have their own duties for instance in representing the RvA in international consultations, in providing interested parties with information about accreditation and its requirements, in developing new areas and implementing changes in the accreditation requirements as a result of international harmonisation. Therefore the team of assessors is highly important for the strategic themes of harmonisation and accreditation as an instrument.

Experts who know the spheres of work Apart from the assessors, who are particularly familiar with the standards on the basis of which accreditation takes place, we need technical experts for our assessments who know the spheres of work under accreditation like the back of their hand. These are people who are veterans in their trades and professions. They are often people who do not know that they can act as an expert for the RvA - and on top of that it is difficult for us to reach them. Originally we made contacts via networking, by our own employees as well as by our affiliated organisations. In order to gain better access to expertise we are going to make more use of social media such as the LinkedIn platform in order to contact potentially interested parties. This will be linked to a special website: working for the RvA (www.werkenvoorderva.nl), which is being developed as we write this and will be launched before the Summer of 2017.

#### Total staffing

That the strategic theme particularly deals with assessors, does not mean that the total staffing of the RvA would not be important. This is obviously important. The employees must ensure that the assessors can do their work properly and that their work is properly completed. This also means that we take our decisions with the necessary care, and also obviously that we operate as an autonomous administrative body (ZBO), as we ought to do.

In 2016 we did this with a total staffing of 96.6 FTE, of which at the end of the year 92.3 FTE was filled by 101

internal employees and 4.3 FTE by temporary workers. The average age was 48 years with an average employment of 8.3 years. With an outflow of 12 employees (of which 4 were due to retirement) this meant a higher outflow than is usual at the RvA. The HRM department was extra busy partly as a result of this.

In the year under review extra attention has been paid to the sustainable deployability of employees and guidance to employees who temporarily appeared to be non-deployable due to sickness or otherwise. The absence rate decreased in 2015 from 4.3% to 3.3% in 2016. We aim to reduce this to below 3%.

#### Employee satisfaction survey

Once again in 2016 an employee satisfaction survey was carried out. This showed that our employees are generally satisfied and that they feel highly involved in the RvA. Many employees are proud to work for the RvA. The following emerged as areas for improvement: the management communicating the organisational objectives of the RvA more clearly, the work pressure that is experienced and having the courage to address each other. In 2017 we are going to pay attention to these issues in consultation with our Works Council.

#### Operational excellence

We aim to professionalize our services further so that our client- and market-orientation increase. This not only applies to our assessments at clients but also to our procedures and communication. Part of this theme is the learning capacity of the RvA: we want to demonstrably improve whatever does not go well. Major pillars for this theme are not only making use of the motivation and involvement of our employees, but also formulating frameworks for behaviour and professionalism.

The importance of the theme of operational excellence emerged pointedly from the image survey and from the evaluation. This theme received a lot of attention in 2016.

#### Critical performance indicators

In 2015 we worked on streamlining and describing processes and defining benchmarks in this. In this way we determined critical performance indicators for 2016 in order to monitor performances. Through these performance indicators we can further improve our performances step by step.

#### Processing times are central

One major indicator is the *processing time*. For the 84 new accreditations the average processing time for certification, inspection and testing is currently between 7 and 9 months. This is an improvement of over 10% compared with 2015. No progress has (yet) been made particularly in medical laboratories which are in the transition phase. This is mainly caused by the laboratories not yet being used to the system of taking corrective measures, so that it takes longer before they are completed. In connection with transition assessments they are actually becoming familiar with this system for the first time. Where in 2015 16% of the new accreditations were still completed outside the legal period, in 2016 this dropped to 8%. There is a comparable improvement for the 276 extensions of accreditations. The average processing time has been reduced to below 6 months, this being the legal period. This does not yet apply to medical laboratories; see the previous statement. In 2015 8% of the applications for extension were completed outside the legal period; in 2016 this was 2%. You can find more detailed information in Annex 3 of

this report.

#### Low-threshold feedback mechanism

In 2016 the first module of a low-threshold feedback mechanism was also introduced: an online client satisfaction survey. At the end of every quarter we invite all the clients who have been involved with the RvA in that period to complete a survey by e-mail. In this we ask how they experienced the application process. We will be commissioning module 2 and 3 in the course of 2017. The three modules include:

- the application process (October 2016);
- the decision-making process (January 2017);
- the assessment visit (March 2017).

Our target figure for client satisfaction is 8.0. Until now we achieved a score of 7.2 for the first module of the client satisfaction survey.

#### Better planning

In order to be able to service clients faster and more flexibly with less planning frictions, we need a larger

our team of internally qualified assessors. We measure this by monitoring the percentage of the assessments carried out by permanent employees.

Our target figure for 2016 was 54%. We ended up with a percentage of 42%. This is caused on the one hand by new assessors entering employment later than anticipated and on the other hand by two assessors leaving employment. This had a particular negative effect on planning witness audits: these are visits in order to establish whether the expertise of the conformity assessment body is delivered in practice.

Because in the meantime we were able to contract the intended number of assessors, we expect in 2017 a clear improvement on this percentage.

pool of assessors. We will achieve this by expanding

Computerisation of accreditation processes

The following activities have been developed in the area of computerisation of accreditation processes:

- The invoicing has been fully digitised and implemented in December 2016. Bar one client everyone cooperates with this.
- In 2016 a project was started up to achieve a new digital reporting tool. It has the following starting points:
  - 1 We aim at a digital form of reporting in which the accredited party as well as the assessor is able to work.
  - 2 We want to restrict the extent and content of the report itself to what is necessary in order to reach sound decisions.
  - **3** It should be able to generate the report from a database.
  - 4 The database must be organised such that we can also carry out analyses per accredited party or group of accredited parties.
    An initial setup of requirements has been made. We discussed this setup with several

possible suppliers at the beginning of 2017.

The unity of thought with regard to the development of computerisation/digitalisation at the RvA has been promoted by the Digivision Project. In this we established that we will not switch in one 'big bang' to a completely new, fully integrated system. Instead we want to develop our system organically with systems using the same database, always based on commercially available software with no or hardly any tailored work.

Communication with the accredited party
In order to bring our communication with accredited parties more in line with the outcomes of the image survey and with the evaluation, we started the Line Organisation Project. In this Project we investigate how we can streamline and simplify the planning and administrative treatment of assessments in a process-oriented way. We also consider the best way to set up our office organisation technically. In order to create ideas for this, in 2016 we made a benchmark with five other accreditation bodies of various sizes. In this way we hope to improve the interaction with our clients.

#### Harmonisation

A level playing field for our clients and for the clients of our clients requires internal, European and international harmonisation of procedures and the use of standards. Firstly, one condition is internal harmonisation. This relates to the assessment processes as well as the interpretation of requirements. In addition, the harmonisation between national accreditation bodies is important. By benchmarking we obtain more insight into mutual differences. In this way we can avoid the Dutch market experiencing adverse competition as a result of choices made by the RvA. Actively influencing the decision-making processes in the European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF), and in the European Union via our Ministry of Economic Affairs, also forms part of the activities in this theme.

Harmonisation of methods and processes at clients in the Netherlands, in Europe and globally is important to our clients and other stakeholders, as is apparent from the image survey and from the evaluation.

Transparency of methods and processes are added to this. We certainly agree with this; transparency with regard to the content of assessments of a certain type of accreditation in itself already promotes harmonisation. In connection with transparency in 2016 the RvA published several new specific accreditation protocols (SAPs) on its website. These protocols indicate which international documents are applicable to assessments against the respective standard and

what is the intensity of our assessments in an accreditation cycle of four years.

#### Harmonisation in the Netherlands

The harmonisation of methods at clients in the Netherlands can be improved according to the report by the KWINK agency. The fact is that some of the accredited parties experience inconsistency in the depth of the assessments carried out. The RvA is working on improvement in this area in particular by allowing the assessors to conduct regular harmonisation consultations. In 2016 such consultations were held 9 times, spread over 5 different expertise/standard groups and once generally with all the assessors. This involved approx. 1.5 FTE man-days. A fixed part of these consultations is the settlement of interpretation issues and their outcome. See Annex 3 for more information. Assessors also receive training on specific subjects of the assessment. For instance they learn how they can clearly describe non-conformities so that the accredited party properly understands why something does not comply.

For substantive experts, of which we have over 800 in our pool, we organise an annual – depending on the size of the substantive area - harmonisation consultation. In 2016, 7 of such consultations took place.

Reviewing assessment reports is also a good source of further harmonisation. For instance we use observations of the Accreditation Committee and decision-makers, to achieve more consistency between the various assessors. In 2017 the assessors will start a pilot scheme to review each other's reports.

#### International harmonisation

International harmonisation between accreditation bodies takes place at European and global level. Harmonisation involves a lot of consultation. After all, no accreditation body likes to abandon its own way of working. Compromises are always required. Within Europe with about thirty members of the EA that is no picnic; globally it is even more difficult.

The RvA aims its first arrows at European harmonisation. This is important since the European regulation states that conformity assessment bodies must apply for accreditation in the country where the legal entity is established. Since in that sense there is no free movement of services, it is important that a level playing field for conformity assessment bodies is

strongly encouraged. The RvA does this by participating in all the substantive committees of the EA. For instance representatives of the RvA strongly encouraged:

- making the evaluation of conformity assessment schemes which are applied in multiple countries in the EA more uniform (EA Document 1/22);
- the validation of schemes (is the confidence of users of the certificates of conformity as it was intended?);
- the training of new members for peer evaluation teams;
- the principle that in principle an identical question must be answered equally by all EA members (read: substantively equally). This principle is now included in the EA strategy adopted in 2016 for the coming years;
- an unequivocal interpretation of the application of the concepts of *independence* and *impartiality* in the accreditation of inspection bodies according to ISO/IEC 17020.

The RvA plays a highly active role in the area of evaluation of internationally applied schemes. For several international food safety schemes the RvA is the so-called *home accreditation body,* the first contact with the scheme owner. The consequence of international harmonisation is also that if the EA policy does not correspond 100% with what was so far usual at the RvA, we must harmonise our way of dealing with the evaluation of schemes with what is common in Europe.

This was a major reason for reviewing our policy for evaluating schemes. We did this for the main part in 2016. We are going to apply the reviewed policy in 2017.

The RvA has actively provided input to the formation of the renewed EA Document 2/17, giving the preferred standards for accreditation of *notified bodies*. In the over 25 European directives for being allowed to market products the standard to be used for accreditation effecting a presumption of competence is often left open. This means in actual fact that different countries use different statements on the basis of which the conformity assessment body is notified. Because the EA has now set standards, the harmonisation is given direction. The RvA adopts the

preferred standards and actively promotes them in its contacts with notifying authorities in the Netherlands.

A more indirect form of harmonisation forms the participation by the RvA as a substantive expert in ISO committees which are managing the standards used for accreditation. In 2016 the RvA took part in the committees reviewing the ISO/IEC 17011 and the ISO/IEC 17025.

The uniformity of the description in the standards determines to a high degree how assessments are unequivocally made with them. That our input is appreciated is apparent from NEN awarding a special certificate to dr. Peter van de Leemput on the occasion of his farewell due to his retirement. He provided for instance a major contribution to the formation of the first version of the ISO/IEC 17025 for laboratories.



 $\ensuremath{\textit{Dr}}.$  Peter van de Leemput receives a special certificate from NEN

Participation in committees and work groups involves holding many meetings, by personal attendance as well as through web meetings and e-mail groups. This requires a lot of time and thereby human resources from the RvA. A stronger way to assure harmonisation is the peer evaluation in which colleagues take the measure of each other and assess whether they meet the criteria of the Multilateral Agreements (MLAs).

In 2016 the RvA contributed to evaluations of colleague bodies in Hungary, Portugal, Germany, the United Kingdom and Sweden.

On the basis of the membership of the EA-MLA for certification of persons based on ISO/IEC 17024 the RvA co-signed the IAF-MLA for that standard during the General Assembly of IAF in November 2016.



The RvA signs the IAF-MLA for certification of persons







#### Accreditation as an instrument

In the next few years the RvA will further detail the role which accreditation plays in public supervision and in private audit systems. The public and the business sector each have their own responsibility to protect the people. Accreditation can have a function in public supervision as well as in private audit systems, and we note more and more often that accreditation can also play a connecting role between both supervision systems. One major element in this theme is spreading knowledge about accreditation and conformity assessments by training and information.

In addition, stakeholders expect the RvA to take a proactively developing role, as is apparent from the image survey conducted in 2015. This also fits in with this theme.

#### Informative talks and consultation

We gave proactive development an impulse by expanding the capacity of the Strategy and Development department in 2015, so that it was wider and more intensively deployable in 2016. Development often starts with providing information. A discussion partner who wants to have confidence in accredited conformity assessments should first understand how his policy target can be supported by accreditation as an instrument and what he can expect from it. It is often necessary to discuss in informative talks exactly what a certificate of conformity should cover.

Many of these types of talks were held in 2016. To give an idea of the band width of the talks:

- On behalf of the Netherlands the notifying authorities are responsible for the notification of conformity assessment bodies that want to acquire the notified body status in Europe. In the consultation with these notifying authorities we have explained the meaning and consequences of the choice of harmonised standards for accreditation in relation to the required level of confidence and the subject of the conformity assessment. Accreditation forms sufficient presumption of conformity for such a notification. In this consultation the RvA also explained that the preferred standards which are defined in the EA form the most desirable basis for the accreditation of the conformity assessment bodies to be designated or to be notified.
- We consulted the Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit: 'NVWA') about requirements which ought to be imposed on certification schemes in the area of food safety, to guarantee a good alignment between the work that accreditation provides and the specific duties of the NVWA.
- We consulted the Ministry of Economic Affairs, the Netherlands Enterprise Agency and the NVWA about the application of accreditation to sampling in connection with the new regulations in the area of fertilisers.
- We explained the instrument of accreditation and conformity assessment to the Dutch Authority for Personal Data. The background to this is the new European General Data Protection Regulation.
- We have explained to the Ministry of Social Affairs and Employment the meaning of accredited personal certification and how and in which situations this tool can be properly deployed.
- We explained our role to the legislative proposal on quality assurance for the building sector to the quartermasters of the new Admissions Organisation ZBO to be established.
   It is important that the quartermasters have a
  - sound knowledge of the system of accreditation and conformity assessment and of the cabinet position in this respect. We want to avoid the creation of a parallel system of recognition of con-

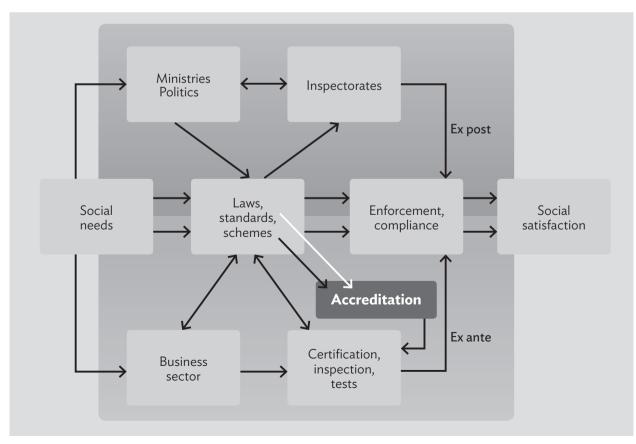
- formity assessment. The RvA made potential overlaps clear to the quartermasters.
- We consulted the Ministry of Education, Culture and Science about the intended implementation of an archaeology certification system. We also commenced consultations in this respect with the Dutch Cultural Heritage Inspectorate (*Erfgoedin-spectie*).
- We consulted representatives of technical inspection bodies about the possibilities of placing technical inspections under process certification without coming into conflict with the criteria for accredited inspection.
- We consulted the Air Quality Platform on which
  the Netherlands Emission Authority is also represented, about a pilot of unannounced witness
  audits at air emission measurements. Just as with
  final asbestos inspections the situation in which
  measurements are taken cannot be continued. In
  addition, the financial interests are often high
  here. The implementation of this project will commence in March 2017.
- We have consulted the Foundation Sustained
  Responsibility established in the Netherlands
  about the possibilities of accreditation of management system certification for the CSR Performance Ladder (MVO Prestatieladder), a management system that records 33 aspects of the
  performances of companies in the area of corporate social responsibility.

General information, lectures and conferences In addition we regularly gave general information to various groups and individuals, nationally as well as internationally. Internationally we showed a delegation from Montenegro how we deal with the accreditation of medical laboratories on the basis of ISO 15189. We also organised a lecture about the added value of laboratory accreditation at the sixth international congress of the European Customs Chemists in Amsterdam. Moreover, we talked at a congress in connection with the European Commission Initiative on Breast Cancer (ECIBC) about the application of accredited certification for the Europe-wide quality assurance of breast cancer care for women. Nationally the biggest activity was the conference organised by the RvA in connection with World Accreditation Day which was dominated by Accreditation, a Global Tool to support Public Policy. In the

Netherlands we detailed this event in close consultation with our advisory panel of stakeholders, with as its theme *accreditation*: *self-regulation* and *supervision*.

This continues the line we have taken in recent years. Our Chairman of the Board of Supervisors, drs. Ed Nijpels acted as the chairman for the day. After his general introduction and an introduction by Prof. dr. Philip Eijlander, Chairman of the Advisory Panel, we dealt further with the care, food and industry sectors in three sub-sessions. In a concluding session it emerged for instance as a clear conclusion that regulators, public supervisors and the parties involved in conformity assessments should communicate more with each other to make self regulation again something that everybody is proud of. The approx. 150 participants really appreciated the initiative for the conference by the RvA. They are looking forward to a repeat in two years.

On quite another scale the RvA participates in seminars and congresses. It does so as a speaker – for instance it contributed to the master course on Risk Management at the University of Twente and to the management course of the Federatie Medisch LaboratoriumSpecialismen – and on other occasions contacts are made and maintained particularly in the corridors.



The sphere of work of conformity assessment and accreditation (Source: RvA, 2016)

# Confidence in self-regulation

When does self-regulation form a suitable alternative to or a good addition to public sector regulation? We asked Jeroen Lammers (*left on the photograph*), director of Economic Affairs at VNO-NCW (Confederation of Netherlands Industry and Employers) and SME Netherlands, and Peter van der Knaap, Chairman of Vide – professional association of professionals in the area of supervision, inspection, enforcement and evaluation.



#### What does confidence mean?

JL: Self-regulation is often voluntary, but never without obligation. That rules are given shape in another way does not mean that you don't have to comply with them. Even more than that: without any further obligations all kinds of problems arise for instance with regard to the level playing field. So it is important that it runs smoothly - particularly also for the companies which subject themselves to self-regulation. A good practical example is the Energy Agreement. Although it sometimes goes jerkily, every year we manage to realise the agreed objectives again, without this being prompted by the law. That would have never succeeded without such an Agreement. Parliament is annually informed of the progress. Making sure it works and also being able to show this, leads in my view to justified confidence in self-regulation.

PK: You can explain self-regulation in various ways. On the one hand it is an instrument to serve public objectives, for instance when it involves making our energy management more sustainable; the interest to society. On the other hand it is an instrument for managing the quality of your own operations; the intrinsic interests. The closer you move to that intrinsic interest, the greater the chance that the confidence is already justified in essence. Apart from this, you obviously need audits. The sector can organise its own supervision, but it should then be transparent and be carried out on the basis of clear standards; so that an auditing party knows what happens and with what purpose. Moreover, it is important that you evaluate whether selfregulation leads to the required results. For instance the BOB campaign appeared to be effective but with regard to the self-regulation in connection with manipulating electric scooters after fifteen years we have to establish that it did not produce what we expected of it.

JL: I don't quite consider that big contradiction between both interests. You can say for instance anything about the energy-intensive industry, but a lot of work is focussed on sustainability. So this intrinsic movement is certainly there. I can imagine that self-regulation does not always work. Therefore you must always weigh up what the best instrument is in order to achieve the ultimate goal.

PK: I agree with you. The moment you consider self-regulation as an alternative to legislation and regulations and supervision by the public sector, you want to know for certain – and various inspectorates have pointed this out recently – that it proposes what you think it proposes. A certificate must have meaning; otherwise you erode confidence. Conformity assessment bodies and the RvA play a major role in this.

#### Self-regulation and supervision

JL: The government provides a lot of scope for self-regulation, but it is also looking for guarantees. Companies must submit a lot of paperwork to demonstrate that they are living up to what they state must be lived up to. This does not mean by definition that it also involves a lot of work. If data are in line with the business process, the administrative burden is low. It only becomes tedious if you have to record data which you would not normally record. We would not want that. What it is about is organising your self-regulation in such a way that it is a watertight system.

PK: I think there are two dimensions. You should be able to submit additional information because a regulator thinks it is interesting to examine these data or because the data you provided initially lead to new questions about the quality of your products, services or processes. In the second case it is obviously justified for a regulator to have additional questions. But unfortunately the first case also occurs. You then burden a party under supervision with an extra administrative burden and that is not always considered to be fair. Whereby you could also sometimes turn it around by saying:

'We are not assessing all the procedures which have been agreed in the sector, but only looking at the quality of the end product. And how you assure that quality, is up to you.'

JL: So long as regulators ask additional questions because they have insufficient information to be able to make a risk assessment, that is obviously fine. But what troubles me is that often a *mission creep* sneaks in, driven by social discussions. In that case regulators develop several objectives of their own on top of the instrument of self-regulation. Then the question of additional information arises from their own policy, not

from the instrument. I think we should continue to separate this clearly from each other.

PK: I agree with you: regulators should consider this more critically. At the same time I also understand that it can be very tempting to ask additional questions, certainly when great social interests or politically sensitive subjects are involved. As a regulator you must weigh the burden and risks, and this is not always simple.

JL: It is an eternal dilemma. The moment everything runs smoothly, as a regulator you will hear that something could be done a bit more or a bit less. But once things go wrong, immediately everything and everybody is at you. That is why many regulators exercise natural caution. But at the same time inherent in this caution is also the risk. That is why it is so important that at the commencement of each process clear arrangements are made as to how the progress is audited and what the role of a regulator is in it.

#### Taking responsibility

PK: Where is the responsibility when things go wrong? In politics the Minister is often pointed out – and thereby the regulator and the public system including the instrument of self-regulation that was opted for. I think that is right: if you deploy self-regulation to serve public interests, you should also account for this to Parliament and be able to demonstrate that it is effective. Supervision certainly plays a role in this.

JL: You obviously first have to establish whether it is about a one-off or a structural fault. What is often seen with incidents is that the regulator is blamed, that the instrument of self-regulation is vilified and that they immediately try to organise the public. In many cases this leads to new rules which have not or hardly been investigated, and which therefore do not offer any guarantee of improvement, but which do create an accumulation of obligations. Due to that 'activist' attitude it too often happens that good systems are unnecessarily scrapped and are replaced by something that is not by definition better. In short, a good analysis is absent.

PK: The primary responsibility for the quality of products and services obviously lies with the business sector itself. You should make sure that this responsibility is not moved externally. In supervision literature this is called *moral hazard*. So the first step is to be sparing with external supervision. Apart from this I agree with you that in the event of incidents a form of reflection should be built in. There can certainly be scope for moral outrage but then count from one to ten and think properly about the question of how you can better organise it.

JL: After all, it is not possible for society to banish all risks. We would not want that either. What it is about is that you consider together whether the instrument of self-regulation has failed or if it is something you could not have prevented in any other way. Is the first apparently true? You will then start the discussion about possible measures to reduce the chance of a repeat. And only when the system appears to fail do you start organising the public.

#### Regulators as knowledge partner

PK: Various State inspectorates recently gave a critical signal. In their regulatory duties they want to be able to build on certificates, but this does not always appear possible. That is why they developed a guideline, in the form of several criteria. In this way they can make agreements with private parties about adjusted supervision on the basis of certification, and assess whether the system offers sufficient guarantees to be able to trust them in their supervisory duties. I think there will be major opportunities for this in the coming years, for assessing existing as well as new forms of self-regulation and supervision.

JL: Following on from this I also see good opportunities in the area of transparency, for instance between regulators and the private sector but also between regulators and the RvA. A feedback loop comes to mind, where you not only look at where it goes wrong and where you therefore have to act, but also even more how you can make a learning process of it. This feedback from supervision can then be used again for the further development of standardisation.

In that way you will feed the justified confidence more than through a 'linear' process.

PK: The regulator as a knowledge partner: that is close to my heart! In addition, I think it is important – and that is also a positive aspect – that regulators contribute to the visibility of success factors: where does self-regulation actually bring public interests closer? Because the capacity is under pressure, regulators by nature often tend to focus on risks. But if they would use a part of their capacity to demonstrate where self-regulation is on the contrary working well, it can have a positive effect on the entire sector.

JL: They will then not only have the role of a referee but also of a partner in the process. If you enter the discussion with the part of the business sector where compliance plays a role proactively instead of repressively, you lift the entire system to a higher level. It makes it more robust. And this should be the ultimate goal of every regulator.

PK: I certainly see this as the future prospect, also for the RvA. The question of whether a certificate has been issued rightly is and obviously remains very important. But it also provides the opportunity to share knowledge intensively in order to learn from it as a sector. This is because it creates the basis for justified confidence.

Mr. J. (Jeroen) Lammers studied tax law at the University of Groningen. Since 2003 he has been working for the Confederation of Netherlands Industry and Employers VNO-NCW, initially as policy advisor in Tax Matters and later as manager of the policy team taxation matters, company law and corporate governance. In 2016 he was appointed as Director Economic Affairs in the joint policy bureau of VNO-NCW and SME Netherlands.

Since 2013 *Dr.* P. (Peter) van der Knaap has been Director and Board member for the Stichting Wetenschappelijk Onderzoek Verkeersveiligheid foundation (SWOV). Previously he had been department head at the Ministry of Finance, and director of Efficiency research for the Dutch Court of Audit. He is chairman of Vide, a professional organisation of professionals in the area of supervision, inspection, enforcement and evaluation, and a member of the Advisory Panel of the RvA.

## 2 Development and innovation

Our stakeholders expect the RvA to develop new methods and activities. We put a lot of energy into this. In 2016 we worked on several large, continuous development projects, namely the transition projects for the accreditation of medical laboratories on the basis of the CCKL Code of Practice towards ISO 15189 and the conversion of competence assessments for the benefit of the Ministry of Social Affairs and Employment ('SZW') towards an accreditation for the same sphere of work on which the Ministry can rely. Two other major developments were the review of the policy for the evaluation of schemes and the development of a method for unannounced witness audits at the accreditation of final inspections after asbestos cleanups.

You can read more about these projects in this Chapter. The Chapter ends with a summary of smaller projects in the area of development and innovation.

## How do we deal with development and innovation?

In order to develop new methods and activities, we extended the staffing of our Strategy and Development team. In addition, our assessors regularly cooperate on development projects. But the capacity available for development is not infinite; so we must deploy it sensibly. This means that we don't do everything, and certainly not everything at the same time. This is particularly because what has been developed must also subsequently be implemented.

Depending on how structural a development is we discuss a potential development project with the Board of Supervisors, the Advisory Panel of Interested Parties, industry associations of conformity assessment bodies – such as Fenelab, NVCi and the NEN policy commission on medical laboratories – and if there are arrangements for the benefit of the public sector, with the respective policy department. In this way we coordinate what we develop as much as possible with the wishes of the users of accredited conformity assessment.

#### Two major transitions

The European Regulation 765/2008 provides for instance that national accreditation bodies have the duty to assess conformity assessment bodies on the basis of harmonised standards. It was common in many countries that accreditation bodies also carried out other assessments; often with a slightly lighter regime than accreditation, but aimed at competence. This occurred for the private sector as well as for the public sector. In the years after 2010, the implementation date of the regulation, the European Commission came to the insight that it is undesirable for accreditation bodies to perform such other assessments. It undermines the authority of the 'real' accreditation on the basis of harmonised standards. In the Netherlands we also have two applications which are not completely based on harmonised standards. Transition processes have been agreed for these with the respective sectors. They both run from 2015 until the middle of 2019. We will briefly shed light on the state of affairs with regard to these transitions.

### Medical laboratories switch to the ISO 15189 accreditation

Before the transition project commenced on 1 January 2015, 18 medical laboratories were accredited according to ISO 15189.

After a project from which the first 4 transitions arose, in 2015 and 2016 a total of 91 new ISO accreditations were added, so that the counter was on 109. Of the then 242 laboratories with CCKL accreditation at year-end 2016 there are still 141 which have to complete the transition process in whole or in part. 10 laboratories with CCKL accreditation have been merged into a larger unit or do not consider that the demands of ISO accreditation are suitable for their needs.

The assessment frequency is higher with ISO accreditation than with CCKL accreditation. This requires a lot from the assessment capacity of the RvA and of external experts. In the past two years 250 technical

experts were re-trained in a two-day training session, so that they can conduct assessments against the requirements of ISO 15189. These technical experts were already qualified to carry out assessments against the CCKL Code of Practice. Every year the RvA trains about 30 to 40 new technical experts for the 15189 assessments.

Internally the RvA trained 3 new lead assessors. The number of external lead assessors has been extended to 8. In the light of harmonisation the internal lead assessors hold meetings four times a year. The entire 15189 lead assessors' group meets twice a year.

The transition assessments are generally successful. Most of the clients are properly prepared and the period for the decision (one year after having received the complete application) has been realised in almost all cases. The RvA collaborates closely with the 15189 NEN Advisory Committee. This Committee, consisting of delegates from the various medical disciplines, is involved in various subjects, including the formulation of explanatory documents, recruitment of technical experts and advising on interpretation issues.

The second part of the transition is expected to proceed according to plan. This means that the last transition assessments will take place in November 2018 so that all clients previously accredited against CCKL will have been accredited against the requirements of ISO 15189 before 1 July 2019.

Increasingly more medical laboratories are merging and are forming larger organisations with many branch locations. This makes the assessments (more) complex: a wide scope and a large number of locations require a larger assessment team. These complex assessments with quite a large team present a challenge for the lead assessor(s) and for the office organisation.

## The Ministry of SZW will designate and notify on the basis of accreditation

After many years of preparation the Ministry of SZW began in 2008 with a system change with regard to the certification of working conditions. Parts of this system formed documents in which the work of certification and inspection bodies ('CKIs') was described and documents with requirements imposed on these CKIs. The assessments by the RvA did not lead to

accreditation but they did form the basis for demonstrating independence and competence for the benefit of being designated pursuant to national legislation or notification pursuant to European directives for the Ministry of SZW.

In this context the RvA and the Ministry opened a dialogue on the question of how it would be possible to switch to 'regular' accreditation. This was given shape as the project that commenced in 2015 for the transition of Assessment (*Beoordeling*) to Accreditation (from 'B to A'). This project should result in the RvA having accredited all CKIs for the respective areas of work by 1 July 2019 at the latest.

Several dates have been fixed for this project. On 1 July 2016 for the various areas of work the Ministry of SZW had to make a choice between notification and designation of the CKIs on the basis of accreditation or on the basis of that other way, without the RvA's involvement. The Ministry chose the first option. For each area of work for which accreditation will be used, the schemes for carrying out the conformity assessments must be ready by 1 July 2017. The RvA will assess them against the accreditation requirements. The accreditation applications of the CKIs must thereafter be received by the RvA at the latest by 1 July 2018, so that the RvA can decide on these applications at the latest by 1 July 2019.

For the areas of work to which European legislation is applicable, the switch to designation and notification was already made in 2016. For the product areas of explosion-proof equipment, lifts, machinery, pressure equipment and personal protective equipment, in the meantime accreditation for the *trade phase*, forms the basis for notification as a *notified body* and for the *user phase* the possibility is open for designation on the basis of a suitable accreditation. For all other spheres of work legislation has opted for designation on the basis of accreditation. This relates to:

certification of persons on the basis of ISO/IEC
17024 of higher safety experts, labour hygienists
and labour and organizational experts, divers,
asbestos experts and supervisors for asbestos
cleanups. Contrary to this for crane drivers and
firework experts the Ministry of SZW chose a
system of registration of persons instead of
accredited certification of persons;

- management system certification on the basis of ISO/ IEC 17021-1 of occupational health and safety services and detection of conventional explosives;
- process certification on the basis of ISO/IEC
   17065 of asbestos survey and asbestos cleanups.

### Review of the policy for the evaluation of schemes

In 2016 we reviewed our policy for the evaluation of schemes. This review had two purposes. On the one hand we realised in our assessments that when conformity assessment bodies used a scheme that was not their own they felt less responsibility for correcting and preventing non-conformities that were established in applying the scheme in practice. On the other hand we wanted to come into line with the policy for evaluation of schemes established in the European Co-operation for Accreditation (EA). After intensive talks with interested parties, including primarily scheme owners and representatives of policy departments, in the summer of 2016 we submitted the draft of the new policy for consultation to interested parties. After having incorporated all the responses, the new policy rule and the adjusted explanatory document were finalized at the end of 2016 and published at the beginning of 2017. In the meantime the implementation is underway.

## Asbestos cleanups and reliable final inspection

Asbestos cleanups must be completed with a final inspection of a released area or object by an accredited inspection body. This usually involves in any event a visual inspection, and an air measurement. Every year about 65,000 to 90,000 of these final inspections are carried out. They are carried out by approx. 20 accredited inspection bodies, which jointly employ over 200 inspectors.

Accreditation assessments concentrate on the management and independence of the inspections as well as on the competence of the inspectors. We determine this competence by assessing qualification files of inspectors in combination with their performance in practice. We assess this performance in practice during a so-called *witness audit*. The RvA attends

about 70 inspections every year in order to determine the expertise of inspection bodies. In normal accreditation practice such witness audits are always announced in advance. For this specific sphere of work there was reason to change this policy and to conduct a trial with unannounced witness audits:

- 1 The RvA receives many reports and signals that the work of this group of inspection bodies does not meet the requirements. In connection with many of these reports and signals it is impossible to verify afterwards whether the work of the body did not in actual fact meet the requirements.
- 2 The RvA receives signals that the percentage of asbestos cleanups rejected by the inspection bodies is higher with final inspections which are attended by the RvA than those not attended by it. The announced witness audit of the RvA apparently influences the results of the inspection.
- 3 The RvA has ascertained a relatively high number of substantive non-conformities at these witness audits.
- 4 Reliable final inspections are of high social importance. Our regular way of assessment does not always yield sufficient confidence in the quality of these final inspections.

A major condition for the success of this new form of assessment is that the RvA is informed about the final inspections which are planned by the accredited bodies. That is why from 1 September 2016 onwards the bodies are obliged to inform us continuously about the inspections they are carrying out. On the basis of this information the RvA selects the inspections which will be observed. The question can obviously be asked whether by doing this the RvA is taking over the role of the regulators. The SZW Inspectorate and the Regional Implementation Departments in particular supervise asbestos cleanups, including the final inspection. In the opinion of the RvA we are not taking over the work of these regulators.

Accreditation and public sector supervision are separate responsibilities. But the public sector supervision can take into account the results of private conformity assessment systems such as the accredited final inspections. The public sector can make use of a good accreditation system that ensures that only competent and reliable parties conduct final inspec-

tions, to concentrate in particular on situations in which confidence in conformity with the requirements is absent. This may result in smarter and more effective supervision. The effectiveness of the system of self-regulation of the chain of asbestos survey up to and including the final audit must be apparent from the public sector supervision.

The RvA gives itself and the sector two years to raise confidence in the quality of final inspections back to an acceptable level by means of these unannounced witness audits. If after this period it appears that confidence has not improved, the RvA will have to consider other options which guarantee confidence in accreditation.

In order to enable this new form of witnessing, we consulted intensively with the Asbestos Committee of Fenelab. We also formulated a specific accreditation protocol, developed a computerisation tool for mapping final audits (date, time and place), harmonised and simplified scopes, trained and instructed technical experts and informed the bodies involved in an information event.

#### Other innovations

Apart from these big transitions and development projects the RvA was active in 2016 with various innovations on a smaller scale.

Regulations for sampling solid fertiliser

In the area of sampling solid fertiliser the government included new requirements in the regulations, including requirements for accreditation (APO6). In consultation with the interested parties the RvA coordinated the method for accreditation and recorded it in a specific accreditation protocol. New technical experts have also been trained for this programme. The assessment bodies, which will be sampling, have been informed of the specific requirements of the scheme, particularly in the area of independence. The first accreditation assessments will take place in 2017.

Accreditation pilot of new spheres of work
In 2016 we commenced a pilot scheme with accreditation for two new spheres of work. This is the certification of asset management (ISO 55001) and business continuity management (ISO 22301). In consultation with the Dutch notifying authorities we worked hard

on the so-called *new legal framework* (the adjustment of European Directives to the European Regulation 765/2008 and the associated EU decision 768/2008). With due observance of the renewed EU *blue guide* and harmonisation document EA 1-22, for the respective directives specific accreditation protocols were developed, scopes were harmonised and accreditations were granted.

## Answering questions about changing standards

Our Strategy and Development team and the expertise groups were regularly engaged in answering questions with regard to changing the standards. This related to the standards for accreditation as well as to the standards for which accreditation is granted. In the International Accreditation Forum (IAF) transition periods were determined for these standards. They will end on the following dates:

- ISO/IEC 17021-1: completed at the latest by 15 June 2017:
- ISO 9001:2015: completed at the latest by 12 January 2018;
- ISO 14001:2015: completed at the latest by 27 February 2018.

#### Amended ISO documents

The publication of new and amended ISO documents in the 17021 series (such as ISO/IEC 17021-2 with competence requirements for auditing environmental management systems) also meant extra work for the RvA and the certification bodies.

#### New IAF mandatory documents

The introduction of various new *IAF mandatory documents*, including more requirements in the area of witness audits and the competence of assessors, also caused extra work. The higher aim is harmonisation, but in the meantime a lot has first to be recorded and explained. After all the rules only work if the ideas behind it have become second nature to the assessors.

## Confidence in our healthcare

How can the perspective of patients be more actively involved in quality improvement and supervision? When does variation in practice cause a problem and what attitude does this require from the various players in the field? A talk with Peter Huijgens (*left on the photograph*), director of the Dutch Association of Comprehensive Cancer Centres, and Paul Robben, advisor of the Dutch Health Care Inspectorate, about quality and safety in health care.



#### What does confidence mean?

PR: As a patient you want to be properly cared for. There are many aspects to this. For instance I have a congenital hip defect. When I was ten years old I was treated for this. It went well for a long time but I was expected to have trouble with it again in later life; and in the end that happened. At such a moment you have a choice: which hospital do you choose? I decided to choose the hospital where I went as a child. That was not the most obvious choice since I had to travel a long way. Moreover, we have excellent care here in Utrecht as well. But apparently, due to my history, I had a certain idea of that hospital. I thought it was curious that it was particularly an intuitive choice. I think this has everything to do with confidence.

PH: And with hindsight was it a good decision?

PR: Definitely. What I think personally very important is that they listen to what the patient himself wants; and that an expert opinion is given on the other hand. From both perspectives the best treatment plan will be achieved. And this also happened. My medical specialist first proposed to see whether rehabilitation day treatment would help. I thought that a good idea, because it could still be possible to operate. He then advised following this day treatment in Utrecht so that I did not have to travel backwards and forwards all the time. That was also a good idea. In other words self-interest did not play a big role. Arrangements were adhered to. These are all matters which contribute to the feeling that you are in good hands.

PH: There are obviously many protocols which you should observe as the healthcare provider. But what is particularly important is that an exception is made if the situation requires it and that the first thought is not: yes, but the rule is ... I have worked for more than forty years as a haematologist at the VU MC. This is a strictly protocolled discipline. Patients are involved who can require immediate help at any moment of the day. So I am used to respond immediately to an alarm bell even if it is in the middle of the night. Safety 24/7. This is in sharp contrast with what I myself recently experienced when I needed a medical specialist immediately. It was half past four in the afternoon and my wife took me to the A&E of a small hospital nearby. First I had to wait. Then I had an intake interview. I

then received a waiting ticket. And in the meantime I was racked with pain.

PR: I hear from what you are saying where this will lead to ...

PH: In the end I was told that I first had to go to my general practitioner. By chance my own general practitioner was on call. A gem of a woman, who took me in with open arms as should happen. She concluded within a couple of minutes that I immediately needed specialist care and called the respective hospital. When I arrived there I was submitted to the same intake interview by the same nurse who had sent me away previously. No apology, nothing. I did not blame her but the hospital. This is because it is apparently not in order.

#### Differences in perspective

PR: Healthcare providers themselves are responsible for the quality they provide. There are parties who provide training, perform examinations and supervise but the primary responsibility lies with the provider itself.

However, it appears from a survey that patients think about this quite differently (Bouwman 2016). They think that the Inspectorate is primary responsible. This difference in perspective is a problem. Patients only approach us when they have already come up against a brick wall somewhere else. They then hear that we do not deal with individual complaints. This results in disappointments. So it is very important that we can explain properly what our role is. You can also see other aspects of differences in perspective. For instance we have been trying for several years to involve patients more intensively in issues in the area of quality improvement and supervision. But it emerged from the survey referred to above that they prefer not to play an active role in this.

PH: This is indeed complicated. You try to involve patients for instance in developing guidelines, study protocols or treatment methods, but experience shows that in general there is very little interest in this. And those who do want to become involved in this are originally often physicians or nurses. The rest think – and that is perhaps also right – it should be in order and if

this is not the case I will act. The comments are then made afterwards.

PR: Obviously patients should not be involved in everything. They are not trained for this and they have no time for it or don't like it. But at certain moments you could propose something to them. For instance you could ask in advance which components they would like to see in a guideline. You will then receive partly different information than if you would ask the physicians or nurses.

PH: For patients organisational and communicative aspects are highly important. Is there a tram stop in the area? Am I received in a friendly way? Is the outpatients clinic pleasantly set up? Does a physician take the time to listen to me? These aspects do not directly contribute to the results of a treatment but they do affect the quality of care experienced. Therefore they are crucial, certainly when long-term treatment processes are involved. So apart from the responsibility for a treatment group there is a component that you should manage to realise in consultation with a patient group. This is not easy because patients differ greatly. So there is a great diversity in input which you should manage to match with the quality of care. There is not one single way to do this. You will have to experience gradually what works and what doesn't.

PR: You can also see this person-oriented approach slowly but surely in the supervision. In the past we concentrated particularly on preconditions in the area of quality and safety. The procedure was central. Now we increasingly include how care providers deal with their patients. Does a physician for instance listen to his patient? Does he consult with them? Is he not continuously staring at his screen? That type of thing. There are people who think that this is not our duty, that it is all much too soft. But I think that this is quite possible. But you must obviously be able to objectify it all. It should not be a gut feeling.

#### Guidelines: inching and pinching

PH: In practice you see big differences in the observance of guidelines. This does not have to be a problem. There are oncologists who never stop treatments and there are oncologists who deal with this more

leniently. This all has to do with the physician's nature, after all they are also ordinary people. And for a patient it is pleasant if such choice is available from a team of practitioners. It will be different if big differences depend on hospitals. If the rate of stomach cancer patients given chemotherapy after an operation is 30% in the one hospital and 70% in the other hospital, it will be important to consider this properly.

PR: That's crucial in my view. The fact is that such differences are allowed and that you cannot prevent them. That is a good thing because otherwise it would all become rather mechanical. I consider variety of practice as an important instrument for discussing things with each other and seeing what can be done better. It becomes more problematical if medical health insurers are going to use variety of practice to aim at uniformity. It is not meant for that.

PH: Every year 120,000 people will get cancer in the Netherlands. These are all individuals, and one should hope that within a certain context there is an individual approach. Even more than that: where this never happens, patients themselves are often going to look for this. I was recently called by one of my pupils. She had a patient – a woman aged fifty with a slowly growing Hodgkin's lymphoma – who wanted a slightly different therapy so that she would not shock her grand-children immediately with a bald head. She thought herself that there was room for this but would like my opinion. I indicated that she was right and how she would be able to tackle it.

She then said: "If I say in this hospital that I concluded the consultation in this way, I will be penalised.

Because it is not in compliance with the guidelines." I think that is the ultimate form of poor medical practice. A very acute clinical picture makes it clear: you either intervene, and you do that in a certain way, or you don't intervene. But in other cases it is inching and pinching. This is how those guidelines were intended.

PR: NIVEL recently conducted a survey amongst general practitioners about variety of practice. The same thing happens there. For instance the one issues a lot of prescriptions for anti-depressants, but the other only a few. This is a strange signal that should be properly considered, preferably by the general practitioners themselves. It does not help if an insurer is going to say that it will cease or penalise the insurance payment

when a certain quantity of prescriptions has been reached. That does not work. It is about learning from those signals; not that we settle our accounts with each other.

PH: This also plays a role in indicator settings: you must do so much percentage of this, so much percentage of that. This can have far-reaching consequences. It is important that physicians can again be courageous, that they venture to adjust their conduct to the patient who is sitting in front of him.

This showed he had backbone. I think we should move more towards this.

#### A good system

PR: You can see that there is a lot of distrust. This already starts in actual fact in the Lower House, in which the care sector is still sometimes considered with suspicion. The result is that we all swoop down on it when an incident occurs.

PH: It is a complicated discipline, and so it sometimes goes wrong. I think that at those moments you should look properly at what is really going on. In connection with leukaemia patients you know for instance that a substantial proportion will die during the treatment. You run that risk. But it can also be the case that in a split second somewhere a wrong appraisal was made and that you decide together that the next time this should be different; or that you must adjust a protocol. Sometimes someone appears to have gone through the red light on purpose. You then see that society immediately demands a second, third and fourth traffic light. But that is nonsense. We organised it properly in the Netherlands. When someone ignores a red light, that person must be penalised. But don't try to make the system 100% watertight, because after all it is and remains just a profession.

PR: This reminds me of one of the most courageous performances I witnessed in politics. A violent incident was caused by a prisoner under a hospital order who was released on parole and the then Minister Piet Hein Donner was strongly attacked. But he kept a cool head. He said in Parliament that we in the Netherlands have an excellent system at our disposal, probably the best in the world and that he was not going to adjust that system due to one individual incident.

Prof. dr. P.C. (Peter) Huijgens, emeritus professor of Haematology has been a director of IKNL (Dutch Association of Comprehensive Cancer Centres) since 2014. Previous to that he worked as a haematologist at the VU MC for over forty years. In 2016 he received from KWF Dutch Cancer Society the prof. dr. P Muntendamprijs award due to his enormous dedication to organisational and social changes in oncological healthcare.

Prof. dr. P.B.M. (Paul) Robben has been working since 2002 for the Dutch Healthcare Inspectorate (IGZ). As advisor of the Research and Innovation department he is responsible for the supervision evaluation programme. In addition he is professor by special appointment in Effectiveness of the supervision of the healthcare quality at the Healthcare Policy & Management institute at Erasmus University Rotterdam.

## 3 Supervision and advice: ensuring confidence

The RvA is allowed to operate with a high degree of independence but the forms of supervising the work and advice in the accreditation decision-making process are of major importance in this connection. They guarantee the expertise, impartiality and independence of the RvA and provide a critical evaluation of our activities and business operations.

Supervision and advice also contribute to a major extent to the trust of the public sector, society and our customers in performing our activities. Various bodies and committees are active in the RvA to this end. In the organisational chart in Annex 1 you can see their relation to each other and their composition. In this chapter we will outline the role and activities of the different bodies and committees.

#### **Board of Supervisors**

The Board of Supervisors of the RvA is comparable to the supervisory board of a commercial organisation. The Board of Supervisors ensures that the Board of Directors realises the objectives of the RvA. Selection of members takes place on the basis of expertise and competencies. It is preferable for the following competence areas to be represented on the Board of Supervisors:

- · business sector
- public sector
- · research/technology
- care/medical
- food and goods
- quality

It is important that the members of the Board of Supervisors:

- have wide knowledge and experience of professional organisations;
- are properly able to advise and encourage;
- · apply an objective, detached approach;
- · have integrity and a sense of responsibility;
- · have an independent and critical attitude;
- · can formulate a balanced assessment.

The members of the Board of Supervisors are appointed for a period of three years and can be reappointed twice.

In 2016 the third period in office of dr. Simone Hertzberger came to an end. With her many years of experience in quality assurance systems as a supervisor and as a sounding board she made a major contribution to our work. We are very grateful to her for that.

The Board of Supervisors will subsequently appoint the members of the Accreditation Committee and the Chairmen Committee for Objection according to the Articles. These two committees operate independently of the Board of Directors.

#### Accreditation Committee

This Accreditation Committee consists of four members appointed on the basis of their expertise in accreditation, their integrity and independence. The Committee meets once a month. Its duty is to advise the Board of Directors on granting accreditations. In addition the committee has the power to advise on the suspension or withdrawal of accreditations. It receives information from the Board of Directors about measures and sanctions taken against organisations.

The Accreditation Committee does not take decisions. The decision-making is entrusted to the Board of Directors. If the view of the Board is different from the advice of this Committee, the Board of Supervisors will be heard. The Committee reports annually on its activities to the Board of Supervisors.

#### Chairmen Committee for Objection

In the event of objections to a decision by the RvA a member of this Committee will be engaged. The Committee consists of at least one and not more than five legally trained members. With regard to each notice of objection received, the Board of Directors will appoint a member of the Committee to form an advisory committee for the respective objection. The members of this Committee are strictly independent.

They will never be members of the Board of the RvA and do not carry out any activities under the responsibility of the Board. This guarantees impartial treatment of objections.

#### **Ministry of Economic Affairs**

The RvA must comply with the relevant provisions of the Dutch Autonomous Administrative Authorities Framework Act (Kaderwet zelfstandige bestuursorganen) and European Regulation 765/2008. The Ministry of Economic Affairs ('EZ') supervises this. In accordance with the communication protocol we are in contact at least twice a year with the Competition and Consumers directorate. The ownership role of the Ministry is detailed in an annual talk with the deputy secretary general in the Business Management, Finance and ICT consultations and through the approval of the fees, budget and annual accounts. With regard to the substantive accreditation aspect, attendance at *peer* evaluations by the European co-operation for Accreditation (EA) is generally considered sufficient according to the Regulation.

#### EA Multilateral Agreement Committee

In order to remain a signatory of the Multilateral Agreement ('MLA') of EA the RvA must satisfy the requirements of the European Regulation 765/2008 and the international ISO/IEC 17011 standard. Every four years the RvA is assessed by a team of about eight 'peers' in the form of a *peer* evaluation.

#### **Board of Directors and Executive Board**

The Managing Director/Chief Executive is responsible for the realisation of the RvA's objectives, its strategy and policy, and the developments resulting from these. He accounts for this to the Board of Supervisors. In this connection he is assisted in his management by the Operational Director.

The Board of Directors and the Executive Board are furthermore served by two advisory panels: the Advisory Panel of Interested Parties and the User Council. Advisory Panel of Interested Parties

The stakeholders in the work of the RvA in the broadest sense are represented on this Panel: the public sector, direct clients of the RvA, direct clients of the conformity assessment bodies, scheme owners and scientific institutes. The Panel operates at a strategic and tactical level. The aim of the Panel is twofold:

- to advise the Board and the Executive Board on general policy matters whether or not requested;
- to guarantee the impartiality of the RvA in policy matters.

The Panel meets twice a year to discuss (for instance) relevant developments, the added value of the RvA and the long-term vision. In 2016 for instance the following matters came up for discussion: the programme and content of the conference on 9 June 2016, which is organised once every two years under the auspices of the advisory panel, a new approach to the evaluation of schemes, unannounced witness audits at final inspections of asbestos removal, the (un)desirability of accreditation activities in which auditors/decision-makers must meet religious requirements, the outcomes of the image survey of the RvA, the outcomes of the evaluation of the RvA on the instructions of the Ministry of EZ, and the renewed cabinet position on conformity assessment and accreditation. Once every two years the Panel initiates a conference for its supporters. The Board of Supervisors receives the minutes of the meetings and the decisions of the Panel are published on our website.

#### **User Council**

The User Council consists of representatives of direct clients of the RvA and meets twice a year to advise the RvA about the budget and rates and about the service level of the RvA. The Board of Supervisors receives the minutes of the meetings, so that it can include the opinions of users in its deliberations.

The forms of supervision and advice outlined in this chapter make a big contribution to our clients, the society and the public sector being able to continue to have confidence in our work. Therefore this is the place to thank all those active in the bodies and committees referred to above for their input in 2016.

# Confidence in our drinking water

The drinking water in the Netherlands has a consistent quality and is highly appreciated. As consumers we think it quite normal that we can trust the quality of the water that flows from our taps every day. But how matter of course is that actually? A talk between Rian Brokx, director of Het Waterlaboratorium, and Ger Egberts, lead assessor at the RvA.



#### What does confidence mean?

RB: Like most Dutch people I drink tap water every day. I have never become ill from this. This is I think the reason why I have so much confidence in the quality of our drinking water. I obviously know due to my background that this is not without reason; but what it is really about is that I have had no negative experience with it. If you never betray the confidence, it remains intact. A recent survey by Vewin, the association of water companies shows that 95% of the Dutch people have much confidence in the water they are drinking every day. The experiences abroad are often different.

GE: The tap water there often smells of chlorine, which really puts you off. But you wonder why that is in it.....

Do I understand that in the Netherlands we don't have to add anything at all because we have such good purification techniques?

RB: That's right. A nice example is the talk my colleagues and me had recently with a large building company. This company wants to have an office building certified on the basis of the WELL Building Standard; a new certificate that has been developed in America and which puts health and wellbeing of people in buildings first and foremost. This means that all materials are tested for harmful substances: the flooring laid, the sealants used etc. It is the first Dutch office building that will be granted a WELL Certificate. They asked us in that talk to look with them at the package of parameters and the associated standards in the area of water supply. To our surprise the colony count appeared to be absent. This is a measurement of the general hygiene of drinking water and in the Netherlands this is a major parameter to determine whether the water is of good quality. Suddenly the penny dropped: in America they use so much chlorine that all bacteria are killed. That is why they don't have to measure colony counts. So there the hygiene of drinking water is guaranteed in another way.

GE: It is something that consumers do not realise. They think it is a matter of fact that at any time of the day we can have clean and clear drinking water at our disposal. In holiday periods you can sometimes read that it is recommended on arriving home to open the taps for a minute. You then realise once again that

water remains somewhat vulnerable. But you really don't think about it; you just trust that it is OK. It is obviously really good that this is possible in our country. At the same time I think that more awareness is required. If you realise all that is flushed down kitchen sinks in the Netherlands: drug residues, turpentine, pesticides, and many more. I myself often visit water laboratories and therefore I know how complicated it is to purify surface waters. Whereas so much time and money could be saved if consumers would deal with this more consciously. But then they should know how.

RB: You can often easily take this into account, for instance by taking old medicine to the pharmacy instead of flushing it down the sink. More campaigns should be conducted for this. It all starts with good communication and the right facilities so that it can be easily realised by the consumers. I think this is a clear task for the Dutch authorities.

#### Cooperation in the chain

GE: Quality assurance obviously goes much further than good analyses. For instance it also requires scientific research and knowledge of relevant public health risks. But above all it is a matter of effective cooperation, both nationally as well as internationally.

RB: In that respect the Netherlands has already made significant progress; although it can always be even better. We have an excellent water sector. There is proactive investment in innovative techniques, in maintenance of pipes and installations etc. If you compare that with England: there the water companies are private enterprises which have to realise a certain return. The pressure there is much higher. It makes a big difference. You see for instance that companies opt for saving on maintenance of pipes so that a shortage can occur because 10 to 20% of water might leak away in some areas. In the Netherlands the percentage of leaks is only a few percent.

GE: Is cooperation easier because the Dutch water companies are in the hands of the authorities?

RB: Certainly. In England but also in many other countries water laboratories are each others competitors.

Contracts are outsourced. If a competitor bids below the price, the contract will simply be lost. That obviously does not encourage cooperation. In the Netherlands this is quite different. There the four water laboratories all have their own demarcated area. This makes it much easier to work together; and our quality assurance system benefits from it. There are over one hundred samplers who every day hit the road to monitor and sample the entire water production, from source to tap. That takes place under the auspices of the quality system. There are over five hundred laboratory assistants who conduct daily - partly legally required - quality checks and investigate new or better techniques. In other words the quality of our drinking water is very well monitored. That is why the chance of negative experiences is minimal. So the public sector must always wonder: how can we best guarantee the quality? What do we want or not want to leave to the private sector? And what requirements do we demand from businesses when we outsource?

#### Innovative techniques

GE: We are now talking about cooperation in a larger whole. But what I also see is that Dutch water laboratories cooperate intensively with each other. For instance they audit each other and share non-compliances which we note as the RvA assessment team so that colleagues of other laboratories can learn again from it.

RB: It is true that they interact a lot with each other, also in the area of new techniques which have not yet been incorporated into the standard, but which are already applied and which we want to see embedded in the law. You can obviously try to demonstrate on your own that those techniques are at least as reliable, but it is much more effective if you sit around the table with the Inspectorate.

GE: And does accreditation play a role in this?

RB: Yes, but there is some frustration in this respect. For Dutch water laboratories new techniques for some analyses – particularly microbiological analyses – must be legally recognised. This is very difficult because the legislation is based on international standards which have come about with consensus. Embedding new

techniques into these standards always lags behind. Take the MALDI-TOF, a technique for quickly and accurately identifying micro-organisms (bacteria, yeasts and fungi). The entire medical sector has been using this technique already for dozens of years. We want to use the MALDI-TOF now also for drinking water and have it embedded in the law, but in this respect we hit a brick wall.

The Inspectorate has indicated that this is not possible just like that, because the standard says nothing about it. That the RvA subsequently held that this technique has been properly validated and thereby makes a confidence statement, does not change anything. So that is not properly organised in the Netherlands. In England the Inspectorate expresses its confidence on the basis of an accreditation. It is a matter of a proper distribution of roles and having the courage to take responsibility.

GE: So in this way you run the risk that you obstruct innovation.

RB: Exactly! Our country has a progressive approach and has a lot of expertise in the area of water technology. We like to maintain and extend this headstart. But in this way you put the cart before the horse. We ought to develop a framework for this, so that we can properly guarantee and apply new techniques. In that way we can also inspire other countries.

#### Challenge for the coming years

GE: The primary purpose of the assessments which are the responsibility of the RvA is that a positive final assessment leads to confidence in the quality of products and services. In doing this we support confidence in the chain. For the coming years I particularly see major opportunities with regard to acknowledgement of each others results, nationally as well as internationally Because if you work according to the same system and speak the same language, it greatly promotes cooperation. As the RvA we are trying to contribute to this through European and global inter-institutional cooperations such as the EA (European cooperation for Accreditation) and ILAC (International Laboratory Accreditation Cooperation).

RB: The future particularly requires more cooperation between all the parties in the chain: the water boards, the drinking water sector, the Department of Waterways and Public Works, the Dutch Association of River Water Supply ... We will be facing new threats. A good example is the increasing concentration of drug residues in the surface water, a consequence of the aging population. Every year 140,000 kg of drug residues end up in our surface waters through urine and faeces. If you compare this with residues of crop protection products, it is an enormous difference. Because this results in 17,000 kg per annum. In addition to that the water level of our rivers drops periodically, so that the pollution thickens. That is why water companies recently sounded the alarm: they want this problem to be addressed at source. In the water world we all face the same problem. The art lies in connecting each other's expertise in the chain and in sharing information. Because if we succeed in this, it would yield great profits!

Drs. A.E.M. (Rian) Brokx was appointed at the beginning of 2016 as the director of Het Water-laboratorium; an organisation specialising in high-quality water research. Before that she held various management positions in the world of laboratories. For instance she was for ten years the general director of Alcontrol and performed various interim assignments, including the merger of Aqualab Zuid.

Ir. G.T.C. (Ger) Egberts was originally a chemist. As a lead assessor at RvA he directs assessment teams with (external) technical experts. He is qualified for various major standards, including the ISO 17025 (laboratories) and the ISO 17020 (inspection). Before that he worked for Heineken for instance as a microbiologist, quality manager and department head of Knowledge Management.

## 4 Quality leads to confidence

The RvA has its own management system in order to guarantee the carrying out of its mission and objectives. To monitor and optimise the proper operation of this system we for instance use observations during internal audits, complaints we receive and feedback which users of accredited services provide.

Every year a management review will determine whether the management system guarantees that we continue to meet our own wishes, the requirements of ISO/IEC 17011, the European Regulation 765/2008, the Dutch National Accreditation Body Appointment Act (Wet aanwijzing nationale accreditatie-instantie) and the Dutch Autonomous Administrative Authorities Framework Act (Kaderwet zelfstandige bestuursorganen).

#### Internal quality care

The year 2016 at the RvA was characterised by several initiatives for change in the area of quality and process management. The improvement measures which emerged from previous audits and peer reviews were completed and new initiatives were started. For instance we followed a quality dialogue cycle, in which all employees participated. In this the core values of the RvA and the implementation of quality and process management aspects came up for discussion. In this way all employees remain informed of the internal instruments for quality and process management and the involvement in and the awareness of quality care is maintained in our organisation.

The management review is discussed with the Board of Supervisors. The processing of complaints, objections and appeals is a permanent agenda item in the meetings of the Board of Supervisors and in the Executives meetings.

#### Peer evaluations

A limited peer evaluation was carried out in 2016 for the expansion of the scope of our Multilateral Agreement with the accreditation of providers of ring tests. Several points to consider emerged from this from which we have taken corrective measures. The decision on this being granted will be taken in the EA-MAC meeting in April 2017. Another full peer evaluation is planned for January 2018.

#### **Processing complaints**

In accordance with the Dutch General Administrative Law Act (*Algemene bestuurswet*) the RvA has a complaints policy in place for any complaints about the RvA as an administrative body.

This policy, which is currently adjusted, has been published as Policy Rule BR-008 and is directly accessible via our website.

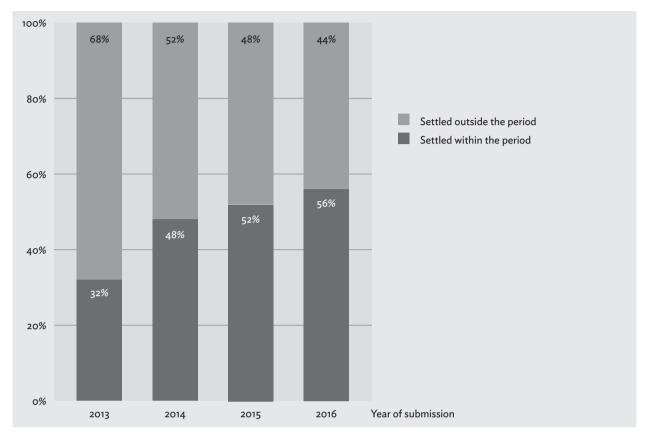
In previous years the statutory and/or agreed periods for processing complaints were exceeded too often. That is why in mid 2015 a measure was taken. Before this measure was implemented structurally less than half of the complaints were dealt with on time. After the measure was implemented in 2015 an improvement was already visible, which also continued in 2016. In the meantime 56% of the complaints have been dealt with within the period. It is our aim to improve the processing time even further in 2017.

In 2016, 26 complaints were submitted which were all declared admissible. ¹ The complaints came from the following types of institutions:

Accreditation category	Complaints
General & other	8
Certification bodies	8
Laboratories	8
Inspection bodies	2

1 In 2015 this was 29.

In 2016 25 complaints were processed. Of these 10 were considered justified, 7 as partly justified and 6 as



Processing period of complaints about the RvA

unjustified. Two complaints were held to be expired. These were complaints which were withdrawn by the complainant himself during the complaints processing. One complaint is still being processed.

The seventeen (partly) justified complaints related in particular to:

- the performance of the assessment(s) and/or the conduct of (*lead*-)assessors;
- $\bullet \quad \text{the communication with the RvA;} \\$
- the administrative processing of projects, or the project management.

Interpretation of standard texts particularly at certification bodies sometimes leads to an almost legal discussion. In some cases the assessor is blamed for this and a complaint then results. In order not to obfuscate the complaints policy, a dispute settlement policy has been set up. Should there be an important specific difference of opinion about the interpretation of the standard, the assessed body can submit this to the RvA by reporting an interpretation dispute.

#### **Notifications and alerts**

In the event of dissatisfaction or doubt about the work of an accredited body a notification or an alert can be submitted to the RvA. The RvA will investigate the notification or the alert at the accredited body. The respective submitter will receive feedback from a notification. No feedback will be given on an alert.

In 2016 the RvA received 59 notifications and 35 alerts. In both cases 35 of these were declared admissible. The notifications and alerts declared admissible related in particular to the following aspects:

- the performance of the assessors;
- an unjustified accreditation claim;
- the complaint settlement by the accredited bodies;

The notifications and alerts declared admissible related particularly to bodies accredited for certification or for inspection.

In connection with a notification or alert the Executive Board of the RvA can decide to carry out an extra assessment if the content of what has been detected is such that doubts are raised about the reliability of

the work of the accredited conformity assessment body. An extra assessment was decided on nine times in 2016. In two cases the doubts appeared justified and the respective organisation had to take measures to avoid a future recurrence.

In two cases we did not ascertain any non-conformities and in five cases the extra assessment at the end of 2016 had not yet been fully completed.

# Processing objections, appeals and WOB applications

In 2016 five WOB applications were submitted.<sup>2</sup> One application was about the activities and acts of the RvA itself, two applications related to the processing of notifications with regard to organisations accredited by the RvA and two applications related to an organisation accredited by the RvA.

In 2016 three objections were lodged against a decision of the RvA.<sup>3</sup> The decisions objected to involved:

- · an accreditation subject to conditions;
- · an incomplete accreditation decision;
- a suspension of the accreditation of an institution.

One notice of objection has been declared inadmissible because it was directed against a letter which was not a decision within the sense of the Dutch General Administrative Law Act (*Algemene wet bestuursrecht*).

One notice of objection was withdrawn after consultation with the submitter with the promise of the RvA that the decision would be adjusted. One notice of objection was still pending at the end of 2016 and was concluded in February 2017. The Committee for Objection advised that the notice of objection be declared well-founded. The RvA decided not to follow this advice and declared the respective notice of objection unfounded.

In 2014 an appeal was lodged with the District Court of Limburg with regard to a decision by the RvA about two associated WOB applications. In July 2016 the District Court held that there was misuse of the WOB and misuse of the law of procedure. That is why the appeal was declared inadmissible.

<sup>2~</sup> In 2015 this was 8.

<sup>3</sup> In 2015 objections were lodged 4 times.



# Confidence in satellite systems

Satellites play a major role in our society. They not only create more prosperity but also provide crucial information in a wide variety of areas. They contribute for instance to a better climate and safer traffic. What does innovation in the space industry – a sector in which top technology is the essence – require from quality systems? Bernd Lehmann (*right on the photograph*), engineer at ESTEC (European Space Research and Technology Centre), and André Barel, lead assessor at the Dutch Accreditation Council ('RvA'), give their vision.



#### What does confidence mean?

BL: The quality systems for the construction of satellites are at such a high level that one can almost always expect a longer lifespan from them than that for which the satellite was originally designed. Take an example: at the beginning of my career with the ESA (European Space Agency) I cooperated on the Cluster II Project. This was a mission in which four satellites were launched into orbit around the earth in 2000 in order to take measurements of the magnetosphere. The innovative aspect of this mission was that instead of a two-dimensional image it yielded a three-dimensional image because the satellites orbited in formation. These four satellites which were originally designed to have a lifespan of 4.5 years, will be in operation until 2018. Due to that extended period the Cluster II Proiect has delivered an enormous scientific return. It shows that these satellites are extremely reliable and are of high quality.

AB: How is that high quality level achieved?

BL: It starts with a good selection of materials and components, such as transistors and condensers. Everything is comprehensively tested in advance. ESA maintains a list of all types of materials and components which comply with the set requirements and also assesses whether they have been manufactured according to those requirements. When the various parts have been fitted and we can actually speak of a satellite, more extensive checks are carried out. In a test environment the satellite is exposed to environmental conditions occurring in space. For instance we can imitate temperatures and sunlight. It is also verified whether subsystems communicate properly with each other and whether the exact results are obtained which you would expect in space. You will obviously only achieve final verification after the satellite has been launched and put into orbit around the earth. Only then will it be possible to actually assess the quality.

AB: If you act for a higher interest, as you do, you obviously want the entire process from the start to be a well-oiled machine. After satellites are launched you cannot bring them back to earth for maintenance, as for instance is done with cars. So here it particularly applies: "trying by doing it right first time". And as you

already outlined: I think that it is very important that you apply a structured approach in which quality control is given continuous priority. You do this by splitting projects into sub-projects and ensuring that all the sub-parts are equally reliable.

#### High quality, high costs

BL: The downside of a high level of quality is that the development costs are also high. You have to weigh these all the time. The CubeSats are interesting in this respect. These are nano-satellites of exactly 10 x 10 x 10 centimetres, which are so to speak ready and available on the shelf. Universities can also afford these CubeSats. This is already important in one respect because it ensures a new generation of enthusiastic aerospace engineers. In this way we can adjust the CubeSats according to need and only have to carry out limited tests in order to then launch them. These small, relatively cheap satellites are still operating very well at three, four months and even after several years. In comparison with large satellites the quality level obviously plays a much less important role. Something can be said for both approaches.

CubeSats are quickly ready for use and therefore produce a quick return. For small or medium-sized missions you could also opt for a higher risk in selecting materials and components. It is all how the balance turns out, with a view to the available budget. There are for instance parties who apply much more the concept of 'high risk, low costs'. When something goes wrong after the launch they say there: 'It was an exciting day, and we will continue.'

AB: Although you could learn a lot from this ... But if you launch a system in space that a large population has to rely on, obviously the reliability factor must be high. Let alone if you start to work with people in orbit around the earth.

# The increasing importance of precision measurement

BL: The growth in the number of satellite formations and the importance of precision measurement in that connection means that the resolutions in connection with calibration methods must increase. Verification at

a higher resolution is only possible in a very stable test environment. For instance temperature differences are relevant: thermal expansion influences the alignment of an optical test setup for a telescope. A wrong alignment will cause quality loss in the data obtained. So the precision measurement not only depends on the instrument itself but also on the conditions in which the instrument is used. In addition, the location is important – if an instrument is first calibrated at one location it should also be possible to calibrate it afterwards at another location. So what you need are reliable calibration data and a clear image of their accuracy limits. ISO 17025 is a very useful standard for this.

AB: Can you give me a good example of this?

BL: At the moment ESA is involved in the construction of the James Webb space telescope, a star gazer of over six tons which will be able to look into the farthest corners of the universe. Here the accuracy of focus is very important. This telescope is assembled at room temperature. But the performance must be verified in a test environment at temperatures around minus 200 degrees Celsius so that you know exactly how the materials will behave at operating temperatures in space. It is only under those circumstances that you can achieve the exact required focus. Because once that telescope is in space it is not possible or hardly possible to adjust something.

AB: I think that ESA is one of the top users of metrology and of the standards of national metrology institutions derived from it which are provided, nationally and internationally. Obviously the accuracy of measurement units does not appeal so much to the imagination when manufacturing bicycles or some car parts, but I think that it demonstrates par excellence here that the utmost should be done, as ESA does. The ISO 17025 standard provides together with several underlying documents a very good tool for approaching that challenge in a structural way, by building an uncertainty budget with the various interference components which play a role. Taking the step from conditions on earth to those in space in a laboratory environment helps you to verify whether a measurement value still indeed has the accuracy which you calculated.

#### Measurements under accreditation

AB: You have highly specialised in house knowledge. What for you is the reason to carry out certain activities under accreditation?

BL: This choice was partly made by the circumstance that the various laboratories in our departments work slightly differently. In addition, if I am asked personally, you cannot expect your subcontractors to work according to a certain standard if you don't adhere to that standard yourself. This applies particularly to measurements. It is important that you can demonstrate what your accuracy entails. This is because the outcome of a measurement is worth nothing if you cannot indicate how accurate that measurement is. Apart from this, accreditation also contributes to the general improvement of your own internal processes, because you place all your measurements in a certain structure. So you don't do this just for your clients, but in the end it is most important for them.

AB: I indeed experience in practice that the annual accreditation assessments just give that extra incentive to comply with the internally agreed rules.

External eyes just force something more. It also contributes to the extent of structure of all the measurements, whether or not they are carried out under accreditation. So in that sense accreditation always has a beneficial side-effect. But I do wonder: it often takes years before consensus on the standards has been reached. How do you ensure that those standards nevertheless remain functional for the developments you are undertaking?

BL: We established in Europe a special committee: ECSS (European Cooperation for Space Standardization). This committee developed a standard for aerospace; it is a standard which not only applies to ESA but also to the industry. There are permanent committees which keep an eye on whether the standard is still satisfactory.

#### Supervision of quality

BL: The quality supervision is also very important. You can see that already in the number of employees working in our Product Assurance & Safety department:

more than a hundred work there. One or two people from this department will be allocated to each project who have an independent role in managing all aspects of the quality and product assurance during the development of this project. They report to the head of the project as well as to the head of the department. And on top of this, this department applies standards for developing and testing software for the applications on a satellite. Not only hardware but software can also be sensitive to faults. I think ESA is quite capable of introducing and guaranteeing quality. In connection with which the policy is increasingly more to allow the industry to carry out the work itself so that ESA only has to deal with the quality. The industry also works with quality managers. Every deviation from specifications is recorded as non-conformity. If you look at the smallest institute or company that takes part, up to the prime contractor, then I think there are over a thousand non-conformities. Otherwise that quality will not be under control. So the documentation is enormous; everything is kept up to date for each item delivered in a so-called 'flight acceptance data pack'. We are obviously not talking here about a small laboratory which has perhaps eight non-conformities per annum.

AB: If I listen to you, in your case accreditation has proved its worth. Because being critical about your own work, recording what you do and especially also implementing concrete improvements where you notice non-conformities: that is what we are trying to achieve with accreditation. This is called the crux of quality care.

Ir. B. (Bernd) Lehmann was originally a physicist. Since 1991 he has been working as an engineer for the European Space Research and Technology Centre (ESTEC) in Noordwijk, the test and knowledge centre of the European Space Agency (ESA). Since 2010 he has been responsible for the coordination of the ISO 17025 activities in his department. At the moment ESA/ESTEC has five accredited laboratories at its disposal.

Ing. A.P. (André) Barel has an electro-technical background. As a lead assessor at RvA he directs assessment teams with (external) technical experts. He is qualified for various major standards, including the ISO 17025 (laboratories) and the ISO 17020 (inspections). In addition he assesses other accreditation bodies and he is regularly involved in the international coordination of accreditation criteria.

# Part 2

# Annexes

#### Annex 1

## Administrative bodies and advisory committees

This overview contains the composition of the administrative bodies and advisory committees as of 15 March 2017.

#### **Board of Supervisors**

- Drs. E.H.T.M. Nijpels (Chairman) 3rd term until 22 June 2016
- Dr. A.G.M. Buiting 3rd term until 1 January 2017
- Dr. ir. I. Mastenbroek

  1st term until 14 March 2019
- Ing. J. Visser
   3rd term until 27 March 2017
- Ir. L. Visser
   2nd term until 26 October 2017

For the report of the Board of Supervisors for 2016 we refer to the annual accounts for 2016, which you can download via our website. You can find more information there about the members of the Board of Supervisors and their additional functions.

#### **Board of Directors and Executive Board**

- Ir. J.C. van der Poel (Director/Chief Executive)
- Mr. J.A.W.M. de Haas (Operational Director)

#### **Accreditation Committee**

- Dr. W. Huisman (Chairman)
- K.J. van Schalm
- Prof. dr. ir. O.A.M. Fisscher
- Ir. C.K. Pasmooij

# Chairmen Committee for Objection

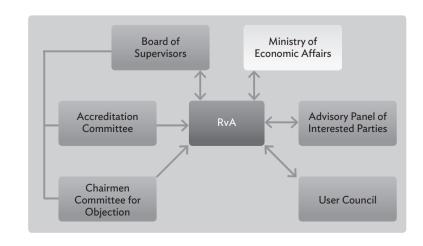
- Mr. L.A.F.M. Kerklaan
- Mr. M.N. van Zijl
- Mr. A. Pahladsingh

#### **Advisory Panel of Interested Parties**

- Prof. dr. Ph. Eijlander (scientific institutes, Chairman)
- Dr. P.H.W.M. Daverveldt (NEN)
- *Mr*. A.P. de Groene (*ministries*)
- Mr. J.A. van den Bos (inspections)
- *Ir.* N.F.J. Hendriks (certification and inspection bodies)
- Vacancy (laboratories and inspection bodies)
- Dr. R. Baumgarten (medical laboratories)
- *Ir.* M.P. Cuijpers (primary sector)
- *Ir.* F.W. Stuyt (scheme owners)
- *Ir.* J.J.N.M. Hogeling (industry)
- Vacancy (healthcare)
- Dr. P. van der Knaap (government Inspectorates)
- Ir. H.C.L. Vos (metrology)

#### **User Council**

- Ir. J.C. van der Poel (RvA, Chairman)
- S. ter Horst (NVCi)
- Ing. B. Meekma (NVCi)
- R. Karel (Fenelab)
- Vacancy (Fenelab)
- B. van Doorsselaere (VEROCOG)
- Dr. S.M. Bruisten (medical laboratories)
- Dr. B.G. Hepkema (medical laboratories)
- Mr. J.A.W.M. de Haas (RvA)



#### Annex 2

### **Brief financial overview**

The RvA is a non-profit organisation on the basis of its Articles as well as pursuant to the European Regulation 765/2008. Our independence is guaranteed via the Dutch National Accreditation Body Appointment Act (*Wet aanwijzing nationale accreditatie-instantie'*) and by a modern governance structure with the Board of Supervisors, the Accreditation Committee and the Advisory Panel of Interested Parties. We also guarantee our independence by a healthy but limited amount of equity capital. This makes us resilient against financial risks which might occur when conformity assessment bodies decide to discontinue accreditation because the RvA has taken a decision with which they disagree.

The amount of equity capital was evaluated in 2014. Partly considering the changed status of the RvA into an autonomous administrative authority, it has been decided to maximise the equity capital to be pursued at 4 million euros.

The figures in this Annex have been taken as a summary of the adopted annual accounts for 2016. No rights can be derived from them. You can download from our website the full annual accounts as prepared and adopted after approval by the Board of Supervisors and the Minister of Economic Affairs and provided with an unqualified report. You can obviously also approach us to request that a copy be sent. We can be contacted on telephone number 0031 (0) 30 239 45 00.

#### Balance sheet as at 31 December (x €1,000)

Assets	2016	2015
Fixed assets	607	689
Receivables and transitory assets	3,595	3,630
Liquid resources	3,110	3,283
Total	7,312	7,602

Liabilities	2016	2015
Equity capital	3,875	3,719
Short-term debts and transitory liabilities	3,437	3,883
Total	7,312	7,602

The income of the RvA is generated particularly from activities carried out on the basis of rates. We determine these rates on the basis of a discussion of the budget with the User Council and after approval by the Board of Supervisors and the Minister of Economic Affairs.

The turnover level in 2016 was 5% less than budgeted. This was particularly the result of a reduced turnover from public sector projects and a lower than budgeted turnover from re-assessments, witness audits and scope extensions. This was on the one hand the result of planning frictions, and on the other hand of more effective assessments.

The costs ended up 6% less than budgeted, for instance due to strict cost control, the postponement of an IT

project in connection with a shortage of capacity and later employment of internally qualified assessors than foreseen. Therefore the financial year of 2016 closed with a positive result. Two special purpose reserves were formed in order to guarantee that the qualification process of assessors and the IT project are completed in 2017 (without this being at the expense of the 2017 budget). On balance € 26,000 was added to the non-allocated reserves.

#### Profit and loss account (x €1,000)

Results	Budgeted 2016	2016	2015
Net turnover	14,726	13,993	13,586
Costs of turnover	5,084	4,787	4,626
Gross margin	9,642	9,206	8,960
Direct personnel costs	7,164	6,908	6,426
Other costs	2,467	2,161	2,479
Sum total of costs	9,631	9,069	8,905
Operational result	11	137	55
Interest income	40	19	42
Result	51	156	97

#### **Rates**

The starting point – subject to special circumstances – is that the rates increase by not more than the index of Statistics Netherlands (CBS) for business services. In 2016 we further reduced the annual contribution for the initial registration. In this way the difference from

a subsequent registration will be reduced. Eventually these rates should be level, regardless of the number of registrations. We managed to keep the daily rate for assessors, which determines the lion's share of our income, level with that of 2015. In 2016 the rates were adjusted as follows:

Rates	2016	2015
Index	1.4%	1.2%
Rate (lead) assessor	0%	+1.2%
Rate specialists	0%	+1.2%
Annual contribution to initial registration	-3.6%	-3.5%
Other rates	+1.4%	+1.2%

In 2014 the RvA appointed KPMG as the auditor for the financial years of 2014 up to and including 2016. This was based on a comprehensive selection process involving four accountancy firms. In 2017 a new selection process will be started for the audit of the following years.

## Annex 3

# Our work in figures

Trust also requires that audits are possible. In this Annex you will find an overview in figures of our activities in 2016. As a comparison we often added previous figures.

#### Accreditations granted as at 31 December 2016

Standard	Explanation	The Netherlands 2016	Abroad 2016	Total 2016	The Netherlands 2015	Abroad 2015	Total 2015
Certification							
ISO/IEC 17065	Products and services	43	3	46	41	3	44
EN 45011	Products and services	0	0	0	0	0	0
ISO/IEC 17021	Management systems	44	21	65	47	26	73
ISO/IEC 17024	Persons	6	0	6	6	0	6
Subtotal certification		93	24	117	94	29	123
Inspection							
ISO/IEC 17020	Inspection	127	2	129	125	2	127
Subtotal inspection		127	2	129	125	2	127
Laboratories RvA mark							
ISO/IEC 17025	Calibration	55	0	55	55	1	56
ISO/IEC 17025	Tests	243	9	252	242	10	252
ISO/IEC 17043	Proficiency trials	14	2	16	14	2	16
ISO 15189	Medical laboratories in Multilateral Agreement	105	3	109	44	3	47
ISO Guide 34	Reference materials	2	4	2	2	0	2
Subtotal laboratories		419	15	434	357	16	373
ISO 14065	Emission	5	0	5	5	0	5
Regulation (EC) no. 1221/2009 (EMAS)	EMAS verification	1	0	1	1	0	1
Total RvA mark		645	41	686	582	47	629
Laboratories CCKL mark							
CCKL Code of Practice*	Medical laboratories	141	0	141	215	o	215
Total number of accredi	tations granted	786	41	827	797	47	844

<sup>\*</sup> These accreditations fall beyond the scope of the autonomous administrative authority (ZBO).

# Geographical spread of the accreditations granted as at 31 December 2016 (RvA mark) $\,$

Country	2016	2015	2014
The Netherlands (autonomous administrative authority (ZBO)	645	582	532
Rest of Europe	3	5	4
Rest of the world	38	42	46
Total	686*	629*	582

<sup>\*</sup>Major causes of this increase are the transitions from the CCKL Code of Practice to ISO 15189.

# Total number of complete applications received for new accreditations per annum

	2016	2015	2014
Initial RvA mark	94*	90*	54 <sup>*</sup>
Extended RvA mark	272	256	221
Total	366	346	275

<sup>\*</sup>Including the ISO 15189 transition applications

#### New accreditations by type (number and processing time)

	New accreditations	Average processing time in calendar days	New accreditations	Average processing time in calendar days
Decision in	2016	2016	2015	2015
Certification	4	217	7	332
Inspection	8	232	7	257
Calibration laboratory	2	274	2	409
Test laboratory	8	342	15	312
Medical laboratory	62	334	28	325
EMAS/Emission	0	o	0	o
Other	0	o	2	343
Total	84		61	

Of the 84 new accreditations (including transitions from CCKL to ISO 15189) 6 had a processing time of over 12 months. This was caused by the fact that:

- The client needed more time to remedy nonconformities (2 times).
- The RvA had insufficient assessors or experts available or had them too late (4 times).

#### Extensions of scope of accreditation per type (number and processing time)

	Extensions	Average processing time in calendar days	Extensions	Average processing time in calendar days
Decision in	2016	2016	2015	2015
Certification	85	156	65	211
Inspection	38	119	34	199
Calibration laboratory	5	123	13	185
Test laboratory	141	141	125	146
Medical laboratory	5	241	4	214
EMAS/Emission	0	o	2	o
Other	2	132	4	380
Total	276		247	

Of the completed extensions 6 had a processing time of over 12 months. This was caused by the fact that:

- There was planning friction between the possibilities at the client and the possibilities at the RvA, in particular with regard to witness audits (5 times).
- The RvA-team had insufficient knowledge of the RvA and EA policy for flexible scopes (once).

#### Distribution of the billed time over the type of investigation (RvA mark)

Assessment type	2016 (total number of days 8,075 = 100%)	2015 (total number of days 7,218 = 100%)	2014 (total number of days 6,747 = 100%)
Initial assessment	5%	6%	4%
Extension	7%	10%	15%
Re-assessment	19%	14%	21%
Surveillance	52%	58%	57%
Transition to ISO 15189	17%	12%	3%
Total	100%	100%	100%

# Distribution of the billed time, broken down into the role in the assessment team (RvA mark)

Role	2016 (total number of days 8,075 = 100%)	2015 (total number of days 7,218 = 100%)	2014 (total number of days 6,747 = 100%)
Lead-assessor	45%	47%	48%
Assessor	8%	7%	8%
Technical expert	47%	46%	44%
Total	100%	100%	100%

# Distribution of the billed assessment time, including the assessment of corrective measures and witness audits

Deployment	2016 (total number of days 8,075 = 100%)	2015 (total number of days 7,218 = 100%)	2014 (total number of days 6,747 = 100%)
At client location	50%	49%	49%
Preparation/report	48%	48%	48%
Travelling outside the Netherlands	2%	3%	3%
Total	100%	100%	100%

#### Number of assessments according to the CCKL Code of Practice

Assessment type	2016	2015	2014
Initial assessment	0	0	13
Audit assessment	55	69	89
Document audit	0	7	4
Re-assessment	4	5	44
Total	59	81	150

#### Disputes, suspensions and withdrawals

A *dispute* is a difference of opinion between the assessed body and the RvA assessor about the interpretation of the standard requirements.

Organisations can temporarily lose their accreditation if it turns out that they no longer meet the set standards. This entails a suspension.

In that case they are given six months to implement the required improvements and to have them assessed. It can also be the case that organisations lose their accreditation permanently. This entails a *withdrawal*: the accreditation agreement will be dissolved. Suspensions and withdrawals are voluntary or imposed. In both cases an organisation can no longer use the accreditation mark for the respective activities.

#### Disputes

At year-end	2016	2015	2014
Total number of disputes	89	52	26
Non-conformity is maintained unchanged	28%	37%	35%
Non-conformity is maintained but reformulated	20%	23%	11%
Non-conformity withdrawn	30%	24%	23%
Other outcome of dispute	1%	2%	19%
Pending	7%	12%	0%
Inadmissible	14%	2%	12%
Total	100%	100%	100%

#### Suspended accreditations

Accreditation category	Voluntary 2016	Imposed 2016	Total 2016	Voluntary 2015	Imposed 2015	Total 2015
Certification	3	4*	7	1	4**	5
Inspection	2	0	2	1*	0	1
Calibration laboratories	1*	1*	2	0	1	1
Test laboratories	1	1	2	1	0	1
Medical laboratories	0	0	0			
Other	0	0	0	o	0	0
Total RvA mark	7	6	13	3	5	8

<sup>\*</sup> Of which one partial suspension

#### Withdrawn accreditations

Accreditation category	Voluntary 2016	Imposed 2016	Total 2016	Voluntary 2015	Imposed 2015	Total 2015
Certification	10**	1	11	10***	0	10
Inspection	5	0	5	9*	0	9
Calibration laboratories	5**	0	5	2*	0	2
Test laboratories	9**	1	10	9**	1	10
Medical laboratories	2*	0	2	0	0	0
Other	0	0	0	2	0	2
Total RvA mark	31	2	33	32	1	33

 $<sup>^* \</sup>hspace{0.5cm} \hbox{Of which one partial with drawal} \\$ 

\*\*\* Of which three partial withdrawals

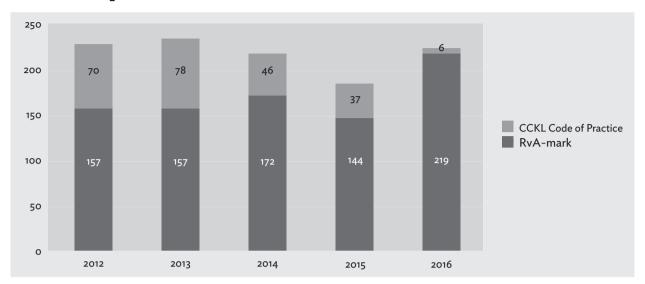
The following are the reasons for withdrawal most given:

- The activites no longer had to be carried out under accreditation or the body no longer carried out the activities (four times).
- As of 2012 onwards there is a more restrictive foreign policy (six times).
- There was a take-over by another accredited body or by another legal entity of the client itself (seven times).
- The client could not or did not want to comply with the RvA policy rules (insufficient staff, no lift of the suspension or non-payment of invoice; four times).
- Activities could already be carried out under an existing accreditation (three times).

<sup>\*\*</sup> Of which two partial suspensions

<sup>\*\*</sup> Of which two partial withdrawals

#### Number of reports submitted to the Accreditations Committee



#### Recommendations given by Accreditations Committee per report

	RvA mark 2016	Care 2016	Total 2016	RvA mark 2015	Care 2015	Total 2015
Initial assessment positive recommendation	39%*	0%	38%	42%*	22%	38%
Re-assessment of positive recommendation	60%	100%	61%	58%	78%	62%
Postponed reports	0%	0%	0%	0%	0%	0%
Negative recommendation	1%	0%	1%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%

<sup>\*</sup>Including the transitions from the CCKL Code of Practice to ISO 15189  $\,$ 

In 2016 all recommendations given by the Accreditations Committee were adopted by the Director.

#### **Publication info**

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