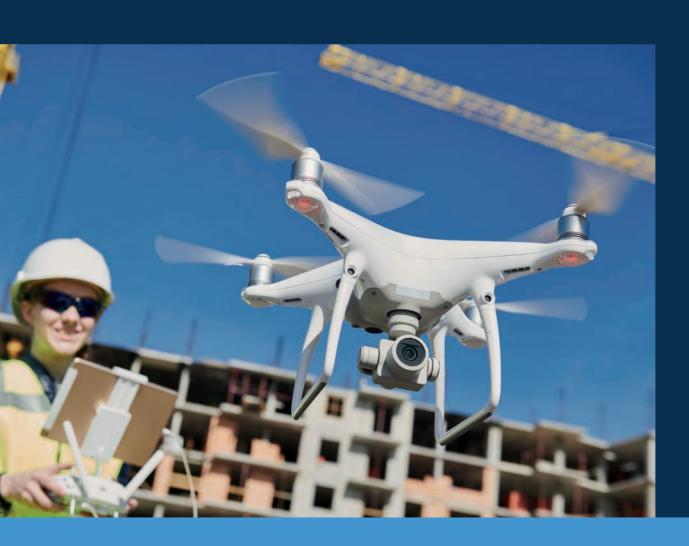


# INNOVATION SAFETY



# IMNOVATION SAFETY



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# Foreword of the Board of Supervisors

It gives us great pleasure to bring this report of the RvA and its activities in 2017 to your attention. We ourselves read this report with pleasure, more so because the theme chosen for the interviews, innovation and safety, is close to our heart. These are subjects which the RvA ought to look at and pay attention to for its future work.

he increasing digitalisation and the emergence of tech giants such as Google and Amazon, which means we rely on systems which we ourselves no longer can fathom, make us vulnerable as a society. On the other hand we do embrace the innovation which this enables. Where is the balance, or in other words: where should the balance be? How can we (continue to) trust that our information and data are not misused? That these questions are topical is also evidenced by the attention to cyber security and by the General Data Protection Regulation.

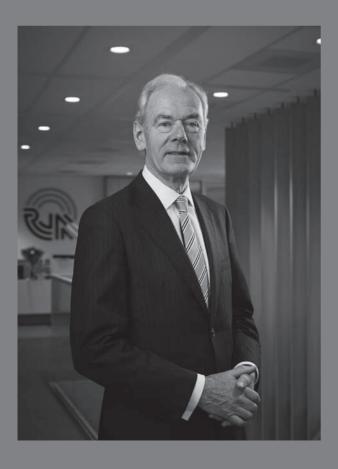
We think that in this connection the world of conformity assessment and accreditation, assisted by standardisation, can play a prominent role: guaranteeing trust in systems, products, processes and services on the basis of fast developing standards. It is a challenge for which we as the Board of Supervisors of the RvA would like to assist you in word and deed. Such forms of self-regulation on the basis of private standards can form an excellent stepping stone for flexible forms of legislation: legislation which can move in tandem with innovations from practice. This practice starts in the first place with enterprises; whether they are start-ups or multinationals or something in-between.

Stef Blok's round of introductions to various stakeholders of the work of the RvA (starting as chair at the beginning of 2018) confirmed our trust that the RvA is considered as an authoritative accreditation body, which does its good work in an impartial and independent way. As the Board of Supervisors, highly renovated in the past year, we would like to help in building this reputation of the RvA. At the same time we also keep an eye on matters such as efficient management, further digitalisation and communicating the merits of the system of accredited conformity assessments on the basis of private (international) standards. We are convinced that thereby the RvA contributes positively to the positioning of the Dutch business sector and to the trust that society can have in its products and services.

# Introduction

This year we chose the theme of *innovation* and safety. You are perhaps thinking, why this theme? The reason for this is the internationally set theme of the World Accreditation

Day (9 June 2018): delivering a safer world by using accredited services. By discussing this theme with our Advisory Panel of stakeholders, we ended up making the connection with innovation.



# HOW DO YOU DEMONSTRATE THAT INNOVATIONS ARE SAFE?

We are bombarded with information nearly every day via all kinds of media often about chip-/computer-based innovations, such as blockchain, internet of things, artificial intelligence, big data, fintech, gaming etc. etc. On the other hand we also increasingly see in the same media more articles about the reliability of those innovations: to what extent can society assume that they are safe? Concepts such as *cyber security*, *data protection*, *digital identity checks*, *system risks and privacy* come up.

It is often not easy for the business sector to demonstrate that innovations are safe and rightly claim the trust of society. That is not only caused by the business sector but certainly also by society, which after all has not yet developed any criteria (read: standards) against which to verify their safety. How could the trusted system of accredited conformity assessment, which has already been helping businesses for several decades to demonstrate that their services are safe and reliable, respond to this? This system is built on metrology, standardisation and conformity, but it is characteristic of innovation that usually there are not vet any standards for it. Society must first work with it and find out while working with it what reasonable standards could be. So standards for specific products, processes or services will always lag behind what is already available on the market.

But this is not to say that nothing is possible. On the contrary. After all, businesses themselves can take their own responsibility, explain what their products and services stand for and how they determine whether those claims are lived up to. An independent third party can then still assess whether they determine this in the right way. This might provide society or the industrial buyers of such a business with trust. However, sometimes you cannot do much more than critically examine the method, the way of determining, in order to see whether it is reproducible and could lead to substantiation (validation) of the claimed product or process characteristics. In my opinion, with the increasing chip content of sensors and processing equipment this approach will gain popularity.

Once every two years our Advisory Panel organises a conference for its supporters: the business sector, science, certification and inspection bodies, laboratories and calibration organisations and the public sector. In 2018 the Panel is doing it for the second time, on the basis of the theme of this report: *Innovation and safety.* 

In this report we will discuss in four interviews the theme of *innovation and safety* from completely different angles. This is particularly to give you and ourselves an idea of whether and, if so, how accredited conformity assessment can innovate to be able to continue in future to render a relevant contribution to the trust of society in the products and services of the business sector.

# DEVELOPMENTS IN THE PROCEDURES OF THE RVA

Apart from the theme of *innovation and safety*, which in actual fact is about the way in which we can also keep our good name in the future by creating trust, we realise that trust never gives 100% certainty and that nothing ever goes wrong. The fact that the Dutch Safety Board (Onderzoeksraad voor Veiligheid: 'OVV') issues several reports every year about incidents where things went wrong, is testament to this. There still appear to be blind spots in our system of regulators, certification and inspection agencies or the sensitivity for subjective interpretation is still too large. Words such as risk-oriented inspection and assessment are soon mentioned as panacea for all ills. After all, a 100% random check is not realistic. A random check of 0% in less large risk areas is not that either in my opinion. A risk assessment can be used to flesh out the random check: on which parts of an assessment are you spending most of the time?

This has induced the RvA in recent years to expand its methods of assessment. This means not only straightforward assessments on site at a prearranged moment, but also assessments via a conference call, an expost evaluation or an unexpected witness session on site. In other words: the approach is more focussed on obtaining impressions in various ways which together should give a consistent picture of the establishment. In our opinion, without a

physical presence at the assessed establishment, in the office as well as in the field, too much insight is lost in a dimension which we could indicate as *feeling* or *organisation culture*. Matters that can almost not be grasped in a standard but which often help the assessor to put his finger on the sore spot. This is necessary to generate sufficient trust in our work.

The OVV described our work as follows in a report:

'A business that wants to act as an inspection agency must be able to demonstrate that it meets all kinds of requirements with regard to independence and impartiality, expertise, methods, processes and quality assurance. Those requirements are collected in a standard and the Dutch Accreditation Council verifies whether the inspection agencies and their inspectors actually meet these requirements. An inspection agency and the inspectors working there are periodically re-assessed by the Dutch Accreditation Council.'

Where this quote speaks of *inspection agency*, you can also read: *certifying body, laboratory, inspection body or verification body.* 

Our image is also assisted by statements and signs from the outside world. The State inspectorates and the environmental or regional implementation departments increasingly contribute to this through their direct observations in the field. This possibility of information exchange is increasingly being recorded in information protocols with the State inspectorates. In order to be able to do our work as well as possible, and where possible ever better, and at acceptable cost, we are developing improved procedures and new methods and we are learning from the work of our international sister accreditation bodies. You can also read about this in this report.

On behalf of all our employees and assessors I hope you enjoy reading it.

Jan van der Poel Director/Chief Executive

# 1

# Innovation and safety in our organisation

When many things are changing in the outside world and different expectations arise regarding accreditation of conformity assessment, as the RvA we must be able to respond to this.

The expectations of the client and society have aspects relating to content and to the services. In this chapter we deal with these service aspects and the internal organisation of the RvA. We also briefly look at our commitment in 2018.

he public report for 2016 comprehensively described our progress in the strategic themes which we determined for the coming years:

- human resources;
- operational excellence;
- internal and external harmonisation;
- information and education about the application of accreditation and certification as a tool.

You can find the last two points particularly in chapter 2; the first two are mainly dealt with in this chapter.

# **HUMAN RESOURCES**

Assessment is and remains the core of our work: we establish whether conformity assessment bodies have the required expertise, impartiality and independence. These assessments are carried out by people who are qualified on the basis of competencies. And these competencies go further than rounded-off training courses and/or professional qualifications. Assessment is not only about knowing the standards used for accreditation but also about the capability to apply them in an assessment setting. This capability is also called *soft skills*. For people who are managing assessment teams as a *lead* assessor or team manager, these general skills are very important.

Because the RvA covers a wide range of conformity assessment activities, it is obviously desirable that teams have knowledge of all those areas. The technical assessors and/or specialists in the teams, experts in their field, provide this knowledge. The difference is that the last category can only do his work in the presence of a qualified assessor. We have a pool of approx. six hundred people who are qualified in the areas in which we are active.

In order to have sufficient subject-matter capacity available in all the main areas served by the RvA, it is essential to

localise people with specific technical knowledge quickly and effectively and then contract them in order to conduct assessments for the RvA. In the past we could often find such knowledge amongst people who took early retirement. Due to the disappearance of early retirement schemes and the increasing retirement age, this source has practically dried up. However, in its place self-employed professionals have become increasingly available. But this requires a new way of searching. That is why in 2017 we set up a compact recruitment team in the Human Resource Management department. These recruiters are fully focused on looking for possible candidates via our website, LinkedIn and other networks. We then identify and contract the right people. This approach is starting to bear fruit.

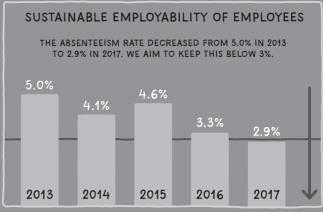
In order to support this new approach we developed a separate website in 2017: www.werkenvoorderva.nl, which is also linked to a LinkedIn business page with vacancies for which we are looking for assessors. In the meantime this has been well used. This means that we can respond more quickly to new market demands.

# DIGITISATION AND INFORMATION TECHNOLOGY

In 2017 the RvA determined the starting points for its further digital development. Apart from keeping the current IT house in order, this means choosing to apply standard software as much as possible, working in the cloud and the setup of a data warehouse whereby data are only recorded once.

We have established that we have to strengthen the IT function in our organisation with someone who keeps our IT architecture up to date and who can help us realise our 'digi-vision'. The vacancy for this position was filled at the beginning of 2018.

This does not mean that we were not active in 2017. After a private tender we selected the supplier of a software package enabling us to report digitally on assessments. This package also provides a so-called *portal*. In the future via this portal clients can simply communicate with the assessment team and the office of the RvA, also about the way in which they intend to solve any established findings.



TARGET PERCENTAGE < 3%



Every EU country has 1 national accreditation body. In the Netherlands this is the RvA.





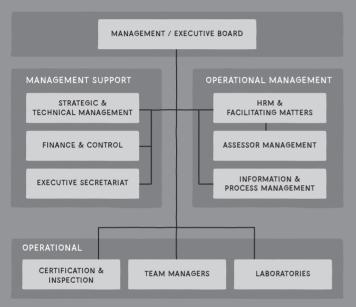
On an annual basis we conduct over 700 assessments at 720 different clients.



Our network currently consists of more than 600 freelance experts.

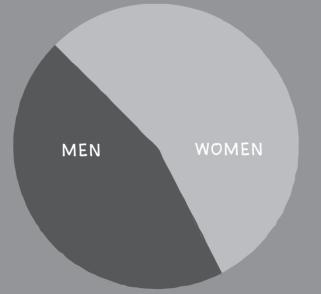


By using their expertise we can conduct assessments in over 100 spheres of work.



ORGANISATION CHART OF RVA

## NUMBER OF EMPLOYEES ON A PERMANENT BASIS



ON 31 DECEMBER 2017 105 EMPLOYEES WERE EMPLOYED BY THE RVA OF WHICH 58 WERE WOMEN AND 47 MEN

This will work faster for the client as well as for our office organisation, with a lower likelihood of errors. In the second quarter of 2018 we are going to test this package by working with several clients. During the course of 2018 this digital reporting tool will replace the traditional method of reporting.

In 2018 we will also make a business case for further digitisation projects. In implementing this we will particularly look at how these projects offer an improvement for our clients with regard to subject-matter and services. In this connection we obviously compare every possible improvement with the associated costs and the required manpower.

## **DATA PROTECTION**

In 2017 for the first time in our history we had to deal with a data leak. This leak was immediately reported to the Dutch Authority for Personal Data. This related to the still active CCKL website. Several personal e-mail addresses had become accessible to unauthorised people. In so far as can be ascertained, this had not been misused. The procedures at our provider for the website have been tightened up, as well as the internal procedure for handling data leaks. Part of this was having penetration tests carried out. They brought to light some other weak areas which have been remedied in the meantime.

Just like all other Dutch organisations the RvA must have implemented the General Data Protection Regulation into its organisation by the end of May 2018. In 2017 we made an initial inventory and at the beginning of 2018 we gave an assignment for a baseline measurement by a specialist agency.

### WHISTLEBLOWERS SCHEME

In 2017, after discussions with the Works Council and the Board of Supervisors, we implemented a reporting scheme for suspected misconduct or irregularity. Such a scheme is normally called a *whistleblowers scheme*. This scheme contributes to the feeling of safety of our employees.

# 'This work makes me feel that I contribute to quality improvement in the chain'

Taco Buissant des Amorie, an independent entrepreneur and freelance expert for the RvA

### **OPERATIONAL PERFORMANCE**

After the arrears in processing times were substantially made up in 2016, we have noticed that this has broadly continued in 2017. A substantiation in figures shows this in detail; see Annex 3 of this public report. We invested a lot of time in 2017 in gaining better access to subject-matter expertise for our assessment teams, the selection and a beginning of the implementation of the new digital reporting tool and the recruitment and training of employees who can act as *lead* assessors. The latter is particularly important for further harmonisation of assessments, which is much valued by our clients.

Throughout the year we monitor our performances via so-called *key performance indicators* (KPIs). These KPIs are determined at the beginning of the year for several areas in which we want to achieve improvement. In 2017 this was successful for most of the issues. We will address several issues in 2018 with extra energy. This particularly applies to the commitment of the permanent RvA employees in assessment teams and to the processing times of complaints, notifications and disputes. These two issues should contribute to our ambition of increasing the score of the client satisfaction survey from 7.3 in 2017 to 8.0 in 2018.

# LARGE TRANSITION PROJECTS

The largest transition project with which we are dealing is transferring about 250 CCKL accredited medical laboratories to accreditation according to ISO 15189. At the end of 2017 we still had to do seventy, the majority of which will transition in 2018. This means the project is well in line with the schedule. But this is not always easy because the increasing number of mergers of hospitals and laboratorics.

ries means the assessments are becoming more complex. On the one hand the concentration of laboratory tests is advantageous to a constantly high quality, on the other hand the more complex organisation of the logistics for instance of samples to be tested and of locations where these samples are taken (for instance where blood is taken), forms a risk to quality and in connection with the treatment of the individual patient.

The other large transition project relates to the conversion of the specific expertise assessments which we carried out for the Ministry of Social Affairs and Employment to accreditation assessments on the basis of harmonised standards. That project is also well on its way, certainly where it is easy to connect with the accreditation on the basis of European guidelines. For the areas in which national (commodities or working conditions) legislation is applicable, more effort is required to find a proper formulation of criteria. This project will also be rounded off in 2019.

# **CHANGING ORGANICALLY**

In order to serve the client increasingly better 'via digitalisation' and also to remain an attractive employer, we decided to re-organise the office set up. We put the emphasis on pooling the account management in the office according to the standard in which our accredited clients are active. At the same time we create a split between the more subject-matter oriented functions and the more process oriented functions. By doing this we want to achieve an unequivocal communication to and treatment of our accreditation subjects. It also becomes easier to arrange adequate replacement in the absence of the personal account manager.



Management consultations of the RvA (from I. to r.): Tischa Deinum, Astrid Derksen, Jan van der Poel, Mylène Pijnenburg, Joep de Haas, Willem de Lange, Ed Wieles, Ine Greven, Leon Schurgers, Evert van Beekhuizen.

A new staff team under a new manager has been formed, namely the Information & Process Management department. The quality function has been placed with the Strategic and Technical Management team. Thereby all internal audit functions have been placed outside the direct responsibility of the operations.

## **OUTLOOK FOR 2018**

In 2018 we will pay a lot of attention to the following matters:

- the extension of our Multilateral Agreement (MLA) recognition with ISO/IEC 17034;
- successfully undergoing the peer evaluation by the European co-operation for Accreditation (EA) in January 2018;
- the implementation of the General Data Protection Regulation;
- the implementation of the software for the new digital reporting system and the client portal for exchanging corrective measures;

- the composition and the functions of the RvA assessment team of the future:
- the implementation of adjustments in connection with the new ISO/IEC 17011;
- the implementation of the new version of the ISO/IEC 17025;
- the implementation of new functions in the office organisation;
- the organisation of the conference on behalf of the Advisory Panel of Stakeholders at the occasion of the World Accreditation Day; see www.iaf.nu/articles/ World\_Accreditation\_Day\_2018/547.

Keep up to date! Receive our digital newsletter with information about new accreditations, changed standards, international agreements, vacancies and other news items. This will mean you remain continuously aware of the latest developments. Sign up via www.rva.nl.



Over 90% of Dutch people live in an urban area and that percentage will increase further in the coming years. This has big consequences for the way in which we organise our living environment. How can we guarantee the safety and the quality of life in cities both now and in the future and how do technological developments contribute to this? A talk with Kees Jansen, town philosopher and expert in the area of smart cities.

## GOVERNING ON THE BASIS OF DATA

We are living in dynamic times. Cities are rapidly changing. People are residing, working and living differently from the past so that existing systems no longer suffice. This requires a review based on new technologies and contemporary views about sustainability and economic principles. For about a decade the concept of *smart city* – a city governed on the basis of data – has been placed high on the municipal agenda. As a matter of fact the people hardly notice this, but that is not necessary anyway. They should particularly be able to trust that everything is well organised behind the scenes: that traffic lights are set correctly, waste containers are emptied on time, etc. That sensors, data and algorithms are used smartly in this connection, should not make any difference.

Sensors are increasingly becoming smaller and cheaper, and can therefore be applied on an increasingly bigger scale. They are able to perform all kinds of measurements and to communicate with each other about them; this is also referred to as the *internet of things*. For instance we can adjust the strength or colour of the lighting in an entertainment area to the number of people walking about there in order to affect the atmosphere – and thereby their safety. Moreover, software is increasingly becoming more intelligent. For instance pilots are running using cameras which can recognise the behavioural patterns of pedestrians. This enormous increase in data offers great advantages but there is also a drawback. In the event of misuse the group suffering damage from this is much larger than in the past

because everything is connected with something else. Critics think that this will develop in the wrong way, that we are creating Big Brother-like circumstances, and this fear is often fed by the media. But I think that our society has an excellent self-correcting capacity and things would not get out of hand so fast.

## WINDOW-DRESSING OR COOPERATION?

This does not mean that we should close our eyes to privacy issues; we only have to approach them differently. How far do we go in these measurements? Who has access to what information? Etc. It is important that we hold a debate about how we can guarantee as best as possible the reliability of technological developments in cities. In this connection the authorities and the market should act much more as real partners. That is not simple because the initiative for innovation almost always originates from the private sector and they have their own interests. They see the increasing value of data, and thereby the chance of a growing market share. The result is that urban issues are still being considered too much as a type of money-making machine. In the end everybody still wants to be the new Uber in his sector. Municipalities also partly went that way. What happened previously for instance with land speculation is now happening with data. As long as the growth perspective remains the main concern, in my view it is all about window dressing and proper cooperation remains something for the future.

Urban issues are now still too much considered as a type of money-making machine

But slowly but surely a shift can be seen. Increasingly more businesses are operating with corporate social responsibility. Authorities are waking up and realising that they must impose conditions on suppliers of smart products and services; and to start with providing more transparency. The talks are ongoing but the process passes slowly. For instance I have not yet seen any tender letter in which clear rules on this subject are described. In order to progress, a fundamentally different view is necessary. Why are we here on earth? Do we only want to earn money or do we primarily consider our social value? It might sound very ideological, but I do think it touches the core. That shift will come, but it needs time.

### INDIVIDUAL SWARMING

In the meantime the tempo at which technological developments are taking place is so high that we can no longer keep up with it. We have to consider this as a fact. We originally used to think in terms of universal solutions; big solutions effective for years to come. But problems are become increasingly more temporary. Just take the emergence of electric cars. Municipalities are now installing charging points everywhere. At the same time the batteries in these cars are becoming better and better. So it can be quite possible that the charging points become superfluous in two or three years and that all the investment has been for nothing. Temporariness requires flexible, modular solutions: standard devices provided with smart software which can be replaced quickly and simply when there are new developments. I think that in public spaces we should also take that direction much more.

Furthermore it is interesting that new technologies make it possible to provide tailored solutions. A good example is the experiment with traffic lights in Tilburg, whereby the elderly and people with mobility problems can install a pedestrians' app on their smartphone. Via this app the traffic light signifies that someone is approaching who needs more time to cross the road safely. In that case the light will remain green a little longer. So the device remained the same but the software has become much more intelligent. In this way you not only organise it well for the masses but

# No **permanent** solutions for **temporary** problems

also for those who deviate from that. I call this *individual* swarming: the continuous switch between an individual and the larger whole.

### ROAD MAP FOR THE CITY OF TOMORROW

Such forms of tailored solutions have consequences for the agreements we make with each other. It means that we must organise quality systems more flexibly so that they not only indicate clear boundaries but also leave sufficient room for innovation and experiments. The golden rule is: 80% standard and 20% tailored work. This requires a different angle: what we want to achieve, instead of: what is all not allowed? Authorities should take charge in this respect; they are and remain primarily responsible for public safety. They must show clearly where standardisation is a requirement and where market parties can go their own way – and which rules apply to that. The business sector supports this by bringing innovative solutions into the public domain.

A good example of this joint action is the Lombok neighbourhood in Utrecht. There they are using a revolutionary energy storage system. Via smart charging points batteries of electrical cars can be charged as well as discharged. These loading points are linked to the solar panels of local residents, schools and businesses. In this way they can provide buildings in the immediate surroundings with an enormous quantity of energy. Such innovations require optimum cooperation. My advice to municipalities and businesses: jointly develop a road map for the coming five years with an outlook on the coming ten years. Also involve other stakeholders for example in training institutes and residents. Evaluate this road map every year and where necessary make adjustments. In this way it is possible to respond to fast changing circumstances.

# 2

# Developments in our work

In this chapter we give a picture of several developments which lead to renovation in our work, broadening our activities and guaranteeing good conformity assessments. We made a selection of developments which demanded a lot of our attention in 2017.

his is about developments in the area of assessment criteria, evaluation of schemes, private schemes and standards versus supervision and enforcement and information about accreditation.

# DEVELOPMENTS IN THE AREA OF TEST CRITERIA

As you already read in the introduction, we cannot do our work without criteria for testing. These criteria are usually incorporated in standards and sometimes in European or national legislation. We can roughly distinguish two groups of criteria:

- standards and criteria which apply to organisations conducting conformity assessments (we mean by this the accredited business relations of the RvA) and to organisations granting accreditation (such as the RvA). The international term for these standards and criteria is Conformity Assessment Standards;
- 2 standards and criteria which are applied in a specific work area on the basis of which clients of our accredited subjects want to obtain a report or statement with regard to the establishment of conformity. With such reports and statements businesses can create trust amongst their customers, or demonstrate to the authorities or society that they comply with certain rules.

## **Conformity Assessment Standards**

Pursuant to European Regulation 765/2008 it is the public task of national accreditation bodies to accredit on the basis of European harmonised standards. In practice these are the harmonised, that is to say European acknowledged, ISO/CASCO standards. These standards are formulated by the ISO Committee on conformity assessment. National standardisation bodies are represented on its sub-committees, aided by experts. The standards determined in it are not only used in Europe but all over the world.

# Changes require much development work and training, at testing and calibration laboratories as well as at the RvA itself.

This enables accreditation organisations to acknowledge each other's work. After all, they use the same criteria, the standards for conformity assessments. Because the competency of assessors and how much time they are given for their work is also important in assessments, in the international context they are working hard on harmonising these starting points. This takes place in the context of the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC). The outcomes of the harmonisation consultations are recorded in mandatory documents for all accreditation bodies. A mandatory document is a document which all affiliated accreditation bodies must observe globally.

The international consultations are prepared in multiple regions. Europe is one of these regions. In this region we cooperate in the European Cooperation for Accreditation (EA). The EA itself can issue supplementary mandatory documents if there is reason to do so due to the regional demand. The innovation is in this case not so much about a ground-breaking, technological breakthrough or a totally new way of working, but particularly in reaching a collectively supported package of criteria that enables businesses to work reliably with new technical-specific standards in a way which enjoys global recognition. To be assured of this as a business, gives a feeling of security.

The conformity assessment standards themselves are also renewed. For instance at the end of 2017 two harmonised standards were renewed which are important to us and to our accredited subjects. During both adjustments the RvA was represented as an expert. This relates to ISO/IEC 17011 and ISO/IEC 17025:

- ISO/IEC 17011 contains the criteria with which
  accreditation bodies must comply. Major changes are a
  tightening of the competency criteria of the assessment
  system and the risk-oriented assessment of the accredited subjects during the accreditation cycle.
- ISO/IEC 17025 contains the criteria for the organisation and operation of test and calibration laboratories.
   Major changes in this are a greater focus on the laboratory making process risk analyses and more attention paid to the organisation of the independence of the laboratory.

Both standards have a transition period of three years and therefore must be implemented by the end of 2020. The changes require a lot of development work and training, at the test and calibration laboratories as well as at the RvA itself.

In 2017 the RvA was acknowledged as a signatory of the multilateral agreement for the accreditation of organisers of proficiency tests comparisons, often better known under the English name of *proficiency testing*, according to the harmonised standard ISO/IEC 17043. This means that the work by accredited organisers of proficiency test comparisons is internationally accepted.

In 2018 the RvA will use the possibility to be acknowledged for accreditation of reference material producers on the basis of ISO 17034.

# Technical-specific criteria

Technical-specific criteria are used in everyday life by organisations in order to establish whether they satisfy



their own requirements, the requirements of clients and/ or the requirements of the society and the authorities. An external, independent conformity assessment of these criteria is possible.

As is common in a market economy, new products and services are launched and are embraced by the market or not. Only when something has become generally accepted and more providers appear is this often followed by standardisation. Already the number of ISO and NEN standards alone has apparently skyrocketed. Only a small part of these are intended and suitable for ascertaining conformity with the agreed criteria. In 2017 several new accreditation processes for existing standards have been put in motion or completed and the consequences of new standards or new versions of standards have been mapped for the RvA:

- ISO 45001: requirements of management systems for working conditions;
- NEN 7510-1: requirements for management systems for information security in the care sector;
- ISO 22870: requirements for Point-of-Care tests;
- ISO 22301: requirements for business continuity management systems;
- ISO 55001: requirements for asset management systems;
- ISO 20000-6: requirements for certification of management systems for IT service management;
- ISO 13485: requirements for management systems for medical aids;
- ISO 15195: requirements for medical reference laboratories in combination with an accreditation for ISO 15189.

Apart from this we closely followed the transition to the 2015 versions of the ISO standards 9001 and 14001 at the respective certification bodies. The transition period for these standards ends in September 2018. It is striking that many organisations certified for these are apparently hesitating to switch to the new standard version. This requires attentiveness by accreditation bodies in order to avoid a new certificate being granted too easily just before the transition period expires.

## **EVALUATION OF SCHEMES**

In 2017 we implemented the new policy for the evaluation of schemes. This is now analogous to the European procedure for schemes. The word *scheme* means 'conformity assessment scheme', a document formulated by an individual body or by a sector or another group of stakeholders who with the involvement of all relevant interested parties jointly stipulate further requirements for the way in which conformity is assessed. The scheme particularly provides for the 'what, how and who'.

By assessing and accepting schemes and the owners of schemes in advance, in the past the RvA came too close to an advisory role. This is inappropriate for the independent and impartial position of the RvA. This approach was also clearly different from that of our colleagues elsewhere in the world. That is why we shifted the responsibility for the proper setup and operation of schemes clearly back to where according to the standard this ought to be: with the conformity assessment bodies. The RvA placed an explanatory document (T-33) on the website to support the accredited and external scheme administrators. Never-

It is commonly assumed that certification, inspection or testing is obviously meant to guarantee 100% compliance

theless, in the first year it appeared that the respective parties are finding the transition difficult. That is why in 2018 the RvA will organise several training sessions in the area of scheme evaluation.

# PRIVATE SCHEMES AND STANDARDS VERSUS SUPERVISION AND ENFORCEMENT

Private standards and schemes were originally particularly meant for smooth running trade. They form a means for organisations to communicate that they meet certain criteria which their customers and interested parties consider important. Public supervisory authorities and enforcers can also derive trust from this. However, this is only possible insofar as those criteria overlap or flesh out legal requirements. But that has to be established. The Netherlands Food and Consumer Product Safety Authority (Nederlandse Voedsel- en Warenautoriteit: 'NVWA') determines whether food safety certification schemes are acceptable for its supervisory support, with the result that the supervision pressure of the NVWA itself may be reduced.

However, such an explicit establishment of suitability for the purpose is often lacking. It is regularly assumed that certification, inspection or tests are obviously meant to guarantee 100% compliance. That they should provide trust is clear but if trust for the one means that nothing should be wrong, but for the other that things are going well in 99.5% of cases, there is not only a gap in expectations but also a communication problem. This type of problem emerged in the past with the Odfjell case and with the mast break of the Amicitia. The OVV formulated a comprehensive report in 2017 about both incidents. In connection with the mast break the OVV explicitly recommended that the Cabinet realise proper communication between the Dutch Human Environment and Transport Inspectorate and the RvA. At senior management level this was initiated in 2017 and in 2018 this should result in an information protocol and in information about what can

and ought to be expected from the work of the RvA in relation to the agreed schemes and the type of conformity assessment that has been laid down in it.

Previously such an information protocol was agreed with the Dutch Social Affairs and Employment Inspectorate and the Netherlands Emission Authority. In asbestos release inspections as well as air emission measurements this contributed to mutual understanding and avoiding duplication. This makes the supervision more effective.

# INFORMATION ABOUT ACCREDITATION

We cooperated with various ministries in order to ensure that no wrong expectations are created when they wish to incorporate accredited conformity assessment into legislation and regulations. We worked for instance on:

- an accreditation programme for sampling fertiliser analyses;
- accreditation under the Dutch Betting and Gaming Act (Wet op de kansspelen):
- accreditation for tests under the regulation for alcohol, drugs and medicines in traffic;
- accreditation for the electronic Identification Authorisation and Trust Services (eIDAS) Regulation;
- accreditation of the verification of maritime emissions (MRV Regulation);
- accreditation of the certification of archaeological research;
- accreditation and certification in connection with the General Data Protection Regulation and the Cybersecurity Act;
- regulations with regard to biomass.

A special category was formed by companies in 2017 with their head office in the United Kingdom, who wanted information about the possibilities of moving their *notified body* activities to the European continent – a Brexit effect. In short, *never a dull moment* for the RvA in 2017.





Prof. dr. A.B. (Bob) Hoogenboom is a professor in fraud and regulations at Nyenrode Business University and lecturer at the Police Academy. He publishes and advises about current police and safety issues. For his dissertation 'Het Politiecomplex' [the Police Complex] he received the Publication price of Stichting Maatschappij en Veiligheid.

Recent research of Statistics Netherlands shows that criminality in our country is decreasing. Is the Netherlands indeed becoming increasingly safer? What role has technological development in this? And what does the future of criminology looks like? We asked Bob Hoogenboom about this. He is a professor in fraud and regulations at Nyenrode Business University and lecturer at the Police Academy.

### WORKING ON TRUST

If we are talking about insecurity, we often mean the most visible forms of criminality: the increasing aggression in nightlife, the cannabis growers in residential areas, the many confused persons walking around in the streets, etc. These are all issues requiring the continuous attention of the police and the judicial authorities. But what I find striking and also quite worrying is that in our society we have the blinkers on for 'other' safety issues. I mean for instance the gas problems in Groningen, the fertiliser complots in Brabant and Limburg or the profiteering policies of insurance companies. These are situations in which the safety interests of the people are consciously overridden due to economic interests.

That this happens is one thing. But it is another thing altogether that we do not really enter the debate about the harmful consequences of this. This makes me as a citizen lose my faith in public administration somewhat. From various angles – politically, socially, scientifically, journalistically – a lot more attention should be paid to this economic insecurity causing great social damage. We are now particularly looking at individual incidents. They are fully in the news for a short while, are investigated and then disappear again from the radar. That is insufficient. We should also have a close look at the underlying social processes. What non-compliance do we find in the senior management of companies? Where does the regulation of market

The police have become

one of the many

organisations in the

'police complex'

processes fall short? And how do we deal with this as a public authority?

### THE RISE OF SAFETY PARTNERS

Criminology hardly deals with this. Public law enforcement, the traditional domain of police and justice is, and remains, obviously important but forms an increasingly smaller part of social control. Over 80% of critical infrastructure is monitored by the market. New safety issues are coming up. The number of cyber, fraud, food, climate and energy incidents are increasing at a rapid rate. This has caused all kinds of new forms of supervision, detection and enforcement to arise – in addition to the traditional services of police and justice. There is a sharp increase in public, semi-public and particularly private services, which will become increasingly more important in the coming decades. Where we once started with police and justice as 'the centre of the world' in the meantime this has evolved into a police extended family.

With these external safety partners - municipal supervisors, special investigating officers, inspectorates, authorities and a professional corporate security world - the playing field has completely changed. The police have become one of the many organisations in the 'police complex'. In particular private security services are sharply on the rise. ABN AMRO, KPN, DSM, Google: they all have their own corporate security department for economic interests. There they know exactly what is taking place in this dynamic world because they are faced with it every day. Here fast technological and digital developments are closely followed, for instance in the area of sensing, dataveillance and robotics. The actual renovations take place here, outside the domain of police and justice. Nobody knows exactly how many organisations are involved, but it is estimated there are many hundreds. Thereby safety is increasingly becoming a greater responsibility of the

# In five to ten years *a large part*of the police work will have been *taken over*by the *market* and by *technology*

business sector. And that is why the mutual dependence of the State and market increases in direct proportion.

### A CHANGING POLICE FUNCTION

These market developments have big consequences. Joint ventures are springing up more and more; at local level but also around specific themes such as fraud, cyber criminality and terrorism. It's not an easy process because of office politics. Self-interest sometimes clashes with the general interest. In addition, Dutch legislation does not always allow information to be shared. But I expect that many of these barriers will have been sorted within five to ten years and that the policing of the future will consist of continuously changing coalitions, which with the aid of new technologies will be working on current safety issues. A nice example is Schiphol; a microcosm of how that social control is developing within our society. At Schiphol parties such as the Royal Netherlands Marechaussee, the National Coordinator for Counterterrorism and Security, the Customs and corporate security departments of airlines are working with each other in multi-disciplinary teams to be able to identify and check the enormous flow of people and goods as quickly and properly as possible. They do this by linking data flows, knowledge and competencies to each other.

It is important that police and justice respond at a strategic level to these changes. Currently that still happens too little. The view must shift from inwards to outwards. What is going on in our society? What police and safety issues will we have to face? How do we relate to this new world? What does technological progress of policing means for our work? And how can we cooperate in this connection with other, particularly private, services? In five to ten years a large part of the police work will have been taken over by the market and by technology. The surveillance on the street will then for instance take place through sensors. That requires a fundamental change of policy.

### THREE LINES OF DEFENCE

That the safety domain is structurally changing is not the problem. That is the way our society is developing. The point is that the private system of supervision and enforcement is much less sophisticated than the public system with its checks and balances – and too little attention is given to that. The shift from public to private is also associated with a shift in conflict settlement: criminal law is much less applied because companies hardly use it. They prefer to arrange their affairs themselves. Economic interests are paramount in this respect. Because those economic interests offer much less stringent guarantees, non-compliance may take place more easily. The supervision of this now has no practical relevance. The judicial authorities do not or hardly interfere with the management and the control function of the police is not given priority.

It is of major importance that we are going to organise the supervision of private security services properly, but particularly the integrated public-private security provision. This is certainly also the case because this intertwining of organisations implies that the use of private data and the connection between them - and we have no idea how this would develop further, what the consequences will be and how we can control this. I am a great believer in multi-stage supervision, three lines of defence. The primary responsibility rests on the companies themselves. In addition, the market needs a system to guarantee the safety interests of the people through quality instruments such as certification and accreditation. Are the employees of a company experts? Are the financial accounting and reporting requirements met? Etc. And last but not least an independent institute must be established that supervises and enforces. An institute with teeth, with sufficient employees, powers and means. How we are going to organise this is quite a challenge.

# Quality management: continuous improvement

The RvA has its own management system in order to guarantee the carrying out of its mission and the realisation of its objectives. To monitor and optimise the proper operation of this system we for instance use observations during internal audits, complaints received and feedback provided by users of accredited services in talks, via complaints and in customer satisfaction surveys.

whether the management assessment will determine whether the management system ensures that we realise our objectives and whether we continuously meet our own rules, 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 Independent Executive Agencies Framework Act (Kaderwet zelfstandige bestuursorganen).

The management assessment 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 Board meetings.

# INTERNAL AUDITS AND IMPROVEMENT MANAGEMENT

Apart from the standard practice set out above to achieve improvement actions, after a short audit training the employees conduct theme audits amongst each other. They then scrutinise a specific part of our process in order to see whether work rules, procedures and the like are being observed. These audits not only yield a lot of information about process owners but they also contribute to knowledge sharing and a better understanding of each other's work and views. On this basis procedures are adjusted, training and instructions initiated and process improvements implemented reducing the likelihood of errors and/or leading to a better service to accredited organisations and applicants.

In 2017 concrete examples of this included:

- the simplification of the decision-making process; this will further help shorten the processing time of applications in 2018;
- digitisation of the invoicing; the invoices are sent sooner after completion of an assessment, leading to fewer discussions about the items on the invoice;
- making the planning of assessment activities visible to the accredited subject during the accreditation cycle of four years; this contributes to transparency and increases predictability.

## PROCESSING COMPLAINTS

In accordance with the Dutch General Administrative Law Act (*Algemene wet bestuursrecht*) the RvA has a complaints procedure in place for any complaints about the RvA as an administrative body. This procedure, QA-008 is directly accessible via our website (www.rva.nl).

The figure on the right represents the number of complaints in recent years and the client group from which they originate.

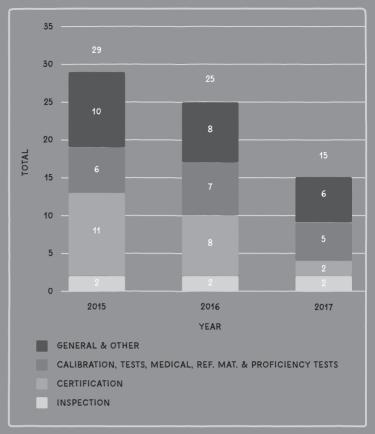
In 2017 twenty complaints were dealt with<sup>1</sup>; eight of these dated from 2016. At year-end 2017 there were still three complaints being handled. Although the complaints processing generally goes faster than in previous years, the share of complaints (42%) being settled within the period is too small. That is why in 2018 the internal procedure will be simplified. The number of transfer moments in the process will be reduced.

The settled complaints particularly concerned:

- the performance of the assessment(s) and/or the conduct of (lead) assessors;
- the administrative settlement of projects, or the project management.

In 2017 the number of complaints about the communication with the RvA dropped significantly. Since the end of 2016 our clients have had the opportunity to give their opinion in this respect in a low-threshold way in the client satisfaction survey.

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 scheme unnecessarily, a dispute settlement scheme has been set up. Should there be an important specific difference of opinion about the interpretation of the standard, the assessed establishments can submit this to the RvA by reporting an interpretation dispute.

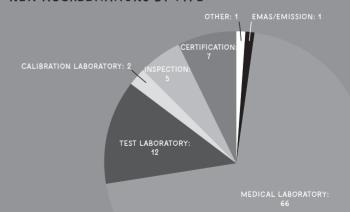


NUMBER OF COMPLAINTS ABOUT THE RVA RECEIVED (WITH A BREAKDOWN INTO THE SPHERE OF WORK OF THE COMPLAINANT)



In 2017 the RvA granted a total of 825 accreditations.

### NEW ACCREDITATIONS BY TYPE



<sup>1</sup> There were 25 in 2016.

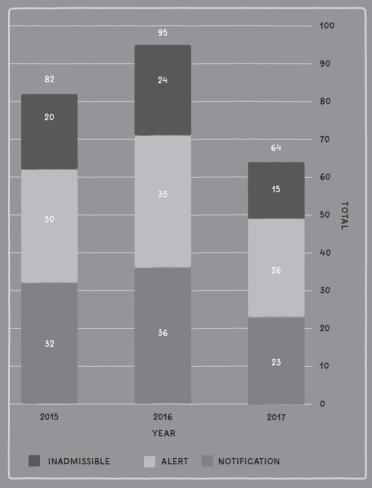


SINCE THE BEGINNING OF 2018 WE HAVE SOFTWARE AT OUR DISPOSAL BY WHICH WE ARE ABLE TO REPORT DIGITALLY ON ASSESSMENTS. THIS PACKAGE ALSO PROVIDES A SO-CALLED PORTAL. IN FUTURE VIA THIS PORTAL CLIENTS CAN COMMUNICATE SIMPLY WITH THE ASSESSMENT TEAM AND THE OFFICE OF THE RVA, INCLUDING ABOUT HOW THEY ARE GOING TO SOLVE THE FINDINGS THAT HAVE BEEN MADE.

**7,3** 

Our ambition is to increase the score of the client satisfaction survey from 7.3 in 2017 to 8.0 in 2018.

# NUMBER OF ALERTS AND NOTIFICATIONS RECEIVED REGARDING CONFORMITY ASSESSMENT BODIES



# **NOTIFICATIONS AND ALERTS**

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

The numbers developed over the past years are represented in tje figure on the left.

The valid notifications and alerts related in particular to the following aspects:

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

The valid notifications and alerts particularly related 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 organisation. An extra assessment was decided on ten times in 2017. In six cases the doubts appeared justified and the respective organisation had to take measures to avoid a future recurrence. In three cases we did not ascertain any non-compliances and in one case the extra audit at the end of 2017 had not yet been fully completed.

# PROCESSING OBJECTIONS, APPEALS AND WOB APPLICATIONS

No WOB applications (applications under the Dutch Government Information (Public Access) Act (*Wet open-baarheid van bestuur*) were submitted in 2017.<sup>2</sup>

<sup>2</sup> There were five in 2016.



In 2017 five objections were lodged against a decision of the RvA.<sup>3</sup> The decisions objected to involved:

- a suspension of the accreditation of a body.
- the conditions in an order.

All the objections were declared unfounded. All notices of objection originated from asbestos inspection bodies of which four were from the same asbestos inspection body.

's-Hertogenbosch regarding a decision by the RvA given on an objection with regard to a suspension of an inspection body in relation to a release of an asbestos removal inspection. On 7 December 2017 the court declared that the appeal was upheld. The RvA decided to appeal from this decision to the Council of State.

An appeal was brought in 2017 before the District Court of

<sup>3</sup> In 2016 objections were lodged three times.



There are few sectors facing so many rapid changes as the care sector. Disruptive developments are taking place in all kinds of areas: the computerisation, technology, diagnostics, pharmacy ... How do hospitals respond to this in their endeavour to provide excellent patient care and to maintain their strong position in Europe? A talk with Yvonne van Rooy, Chairman of the Netherlands Association of Hospitals (Nederlandse Vereniging van Ziekenhuizen: 'NVZ').

### TOP OF THE BILL

Just like airline or oil companies hospitals are proper safety businesses. The number of risks is huge, which is something that the outside world luckily does not much realise. This requires a strictly protocolled environment. Everything has to be all the time 'top of the bill'. Attention to behavioural components is crucial in this: risks can only be minimised if everyone in an organisation deals with those protocols in exactly the same way. Several years ago at the NVZ we developed the VMS Safety Programme, with the aim of increasing and guaranteeing patient safety in hospitals through a certified safety management system (veiligheidsmanagementsysteem: 'VMS'). This enabled us to achieve a lot in a short time. For instance avoidable mortality and damage has been reduced by 50%.

Safety is something on which you have to keep working continuously with each other. In the Netherlands we will be leading at world level in this and continue to do so. It is not for nothing that we regularly emerge as the best in the annual research of the Health Consumer Powerhouse into the quality of healthcare in Europe. One of the reasons why we are successful in this is that Dutch hospitals, just like for instance KLM and Shell, are strictly trained in a learning culture. Errors are made everywhere, even in the care sector. It is important to investigate with each other where it unfortunately went wrong and what adjustments are necessary to avoid a repetition. The Dutch Health Inspectorate wants every incident to be reported but also indi-

Safety is something on which you have to keep working continuously with each other

cates that the number of incidents does not have anything to say about the quality of the care provided. This encourages a learning culture.

## THE PATIENT AS PARTNER

Technological developments offer fantastic opportunities for further improving the quality and safety of care. One major shift is that due to new opportunities in the area of ICT patients increasingly obtain more control over their own health process. That changes their position: patients are becoming partners which is something that has a big impact on the way in which we organise healthcare. Hospitals are increasingly fine-tuning their infrastructure and portfolio choice to the wishes and needs of their patients. There are many good examples, but I will highlight one of them. The Isala hospital organisation recently developed a toolkit for women with a complex pregnancy. These patients must often remain in the hospital for a varying number of weeks at the end of the pregnancy in order to prevent their child being born too early. With the toolkit they can now make heart recordings themselves at home and send the data via an iPad to the hospital. A nurse specialist there will see whether everything is fine. This is a major turnaround; for the patients because they receive the same care in their own environment but also for hospitals because they must prepare themselves properly and ensure standardised safety procedures.

In other words, digitisation forms a crucial part of the primary process and it is also becoming an increasingly important component in training courses. ICT innovations offer unprecedented opportunities and digital aids are springing up everywhere. They help healthcare providers to record medical data and to communicate with colleague professionals and patients. Big data are increasingly playing a more crucial role. This also raises new issues. How do we ensure that those many systems are properly standardised?

How do we avoid over-treatment by an excess of diagnostics? How do we take all patients, from highly educated to low-literate people, along in these developments? How do we align ourselves with the new European privacy legislation? Etc. These are pressing issues which we must discuss with all stakeholders.

infrastructure, but also a culture shift. Healthcare providers will have to deal with their patients in a completely different way and would have to change their procedures fundamentally. Boards of governors will have to be prepared to facilitate this and to invest in this. The impact of such an organisational change is often still underestimated.

### DIGITAL INFORMATION EXCHANGE

We obviously also look at what is happening beyond our borders in this area. The HIMSS, the world's biggest conference in the area of ICT and health, which is organised every year by the American Healthcare Information and Management Systems Society, always provides a nice look into the future. A couple of years ago it appeared for instance that real-time access to your own medical details would become a major development. When the Máxima Medical Centre and the University Medical Centre Utrecht started this three years ago, there were many sceptics. In the meantime we developed a program that makes it possible for every hospital to implement this change: it is called the Acceleration Program for Information Exchange between Patient and Professional (Versnellingsprogramma Informatie-uitwisseling Patiënt en Professional: 'VIPP'). That is how fast it goes!

The VIPP Program is the first step into a large-scale digitisation process. It is subsidised by the Ministry of Health, Welfare and Sports and its higher aim is that hospitals ensure that patients can view their medical details in a safe way on-line and where possible contribute to it for instance with self-measurements from medical wearables or E-health applications. In this way patients will get more of a grip on their own health process. The implementation of standards supports this aim; because without standardisation there simply cannot be any information exchange. Such a program not only requires an adjustment to the ICT

### CONFIDENCE IN THE FUTURE

If you want to stay ahead, you must always continue to invest in innovation. Therefore more programmes in the area of digitisation in hospitals will follow. Public sector support is vital in this connection. The real art is to implement subsidy schemes for the public sector in such a way that the ministry considers the proposed approach justified and at the same time hospitals do not experience too much red tape because this stifles any form of development. Here is a nice job for us as a sector association. We provide hospitals with the necessary tools to implement innovation 'in-house' and encourage them to set high standards in this connection.

Optimum patient care in a high-tech environment: that's what it's all about. At the HIMSS considerable attention was paid this year to systems enabling the monitoring of patients at home. This shift in care from the hospital to their own environment will rise sharply in the coming years. In addition, we see that the combination of health and big data is becoming an increasingly more important field, under the denominator of *predictive medicine*. In other words: how can we diagnose much more precisely by using big medical databases and artificial intelligence? This is not to replace the medical specialist, but as a major support with a view to quality improvement. With VIPP we are creating a basis for applying both developments in the Netherlands in the future.

# Optimum patient care in a high-tech environment:

that's what it's all about

# 4 Supervision and advice

The RvA may and should 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 our management.

upervision and advice also contribute to the trust of the public sector, society and our clients in performing our activities. Various governing bodies and advisory committees are active to this end in the RvA. We give here in outline the role of various governing bodies and any changes in 2017. Annex 1 to this report includes the current composition of our governing bodies and advisory committees.

On our website (www.rva.nl) you will find a comprehensive explanation of the role and activities of each governing body.

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. We would like to thank everyone active in the governing bodies and advisory committees for their input in 2017.

# **BOARD OF SUPERVISORS**

The Board of Supervisors ensures that the Executive Board 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
- healthcare/medical
- food and goods
- quality

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.

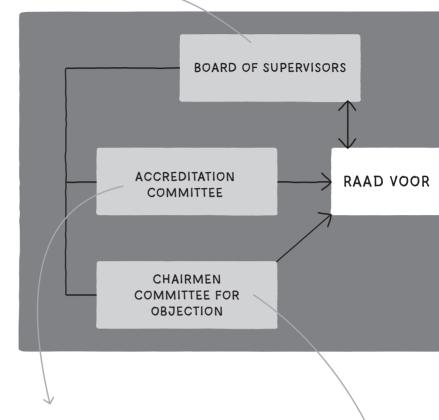
Members of the
Board of Supervisors
who resigned
Drs. A.G.M. Buiting
Ing. J. Visser

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

Members of the
Board of Supervisors
who joined
Prof. dr. J. van den Heuvel
Ir. P.F. van Rhede van der Kloot
Drs. S.A. Blok, Chairman
(from 1 January up to
5 March 2018);
Drs. E.H.T.M. Nijpels,
Deputy-Chairman

(since 7 March 2018)

We are extremely grateful to all the resigning members of our Board of Supervisors for their contributions to the activities of the RvA and at the same time we sincerely welcome their successors. On 5 March 2018 Mr. Blok resigned from the Chairmanship in order to be appointed Minister of Foreign Affairs. On 7 March 2018 the Board of Supervisors filled the vacancy of (independent) Chairman by temporarily appointing Mr. Nijpels. This allowed time to follow the search procedure for a new Chairman with due care.



# ACCREDITATION COMMITTEE

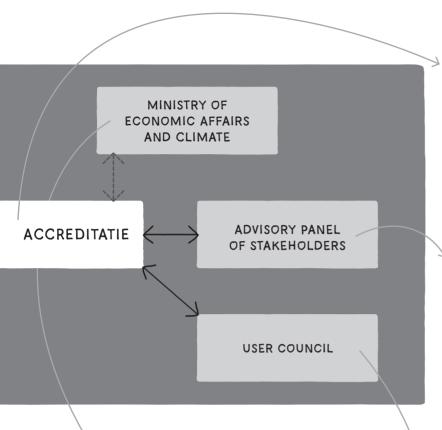
The Accreditation Committee consists of four members appointed on the basis of their expertise in accreditation, their integrity and independence. Its duty is to advise the Board of Directors on the granting of accreditations.

 $AC \, member \, who \, resigned \qquad AC \, member \, who \, joined \\ Dr. \, W. \, Huisman \, (Chairman) \qquad Prof. \, dr. \, E. \, Bakker$ 

We hereby express our appreciation for Mr. Huisman as one of the pioneers of accreditation of medical laboratories in the Netherlands. We thank him sincerely for his unabated commitment to the transition of accreditations on the basis of the CCKL practice standard to the international ISO 15189 standard. Since 2008 he did that within the context of the RvA.

# CHAIRMEN COMMITTEE FOR OBJECTION

In the event of objections to a decision by the RvA a member of this Committee will be engaged. The Members of this Committee are strictly independent.



# MINISTRY OF ECONOMIC AFFAIRS AND CLIMATE

The RvA must comply with the relevant provisions of the Dutch Independent Executive Agencies Framework Act (*Kaderwet zelfstandige bestuursorganen*) and European Regulation 765/2008. The Ministry of Economic Affairs and Climate supervises this. Insofar as this relates to the subject-matter side of the work of the RvA, it can rely on the EA *peer* evaluations which the RvA undergoes every four years.

# 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 ten 'peers' in the form of a peer evaluation.

# MANAGEMENT AND EXECUTIVE BOARD

The Director/Chief Executive is for instance responsible for the realisation of the objectives of the RvA and is assisted for its management by the Operational Director. Jointly they form the Executive Board of the RvA. They are also assisted by two advisory panels: the Advisory Panel of Stakeholders and the User Council.

## ADVISORY PANEL OF STAKEHOLDERS

Represented on this panel are the public sector, direct clients of the RvA, direct customers of the conformity assessment organisations, scheme administrators and scientific institutes. The aim of the Panel is twofold:

- giving advice on general policy matters whether or not requested;
- guaranteeing the impartiality of the RvA in the further development of the subject-matter policy.
- Items discussed in the Advisory Panel in 2017 were for instance:
- the evaluation of the Analysis of interested parties, whereby particularly the aspect of impartiality of the RvA in its actions was discussed;
- the areas of activity for which the RvA can and wants to grant accreditation (RvA Areas of Activity policy rule);
- the state of affairs in the development of new standards for conformity assessment bodies and standardisation developments:
- the internet of things and other digitisation developments;
- the policy for the evaluation of conformity assessment schemes;
- the recommendations in the report on the mast break of the OVV:
- determination of the theme for the conference for stakeholders of the RvA on 7 June 2018: trust in a secure, digital society.

## **USER COUNCIL**

The User Council consists of representatives of the direct RvA clients and advises the RvA on the budget and rates and about the level of service.



New technologies such as the internet of things, artificial intelligence and quantum computing have far-reaching consequences for the way in which we live and work. This so-called fourth industrial revolution, affecting every sector, is characterised by acceleration of digitisation. Blockchain is a good example of this. A talk with Egbert-Jan Sol, Chief Technology Officer at TNO Industry, about the impact of digital innovation.

### BLOCKCHAIN: A UNIVERSAL DATABASE

The internet as we know it now developed in a timespan of twenty years; ranging from scientific use to calling via a landline and mobile use by a broad public. Blockchain, in short a universal database with information about all the transactions performed within a network, is expected to develop even faster and to change the world completely within ten years. Where we learned with the internet to exchange digital *information*, via e-mail and webpages, blockchain will make it possible to exchange *values* digitally. This is a fundamental innovation.

The killer applications of the internet were at the time the browser and the worldwide web. Suddenly the people understood that they no longer had to go to a library, but that they could collect unlimited information at home via a computer. Such a paradigm shift is currently taking place again with the emergence of cryptocurrency, the killer application of blockchain. Suddenly we can transfer money to each other globally, or transfer value, while it practically costs us nothing. Most of the people currently hardly understand how it works yet, but mind: the same once applied to the internet. Now we find it quite normal that we can see in the street via an app whether it is going to rain. This was unthinkable ten years ago.

The next step is that all kinds of conditions are attached to this value transfer by means of autonomous programs. The payment for a container will then for instance only take place on delivery, via an autonomous sensor. But we should obviously be able to trust that sensor and container. Is it really the sensor that says that it observes the container? Or has someone meddled with that sensor?

## RELIABLE DIGITAL IDENTITIES

The use of blockchain will increase sharply in the coming years, in various sectors. But before this is the case we have to solve several fundamental problems; for example in the area of digital identities. If we are going to transfer values via blockchain, we must be able to be certain that the other party is really the person who he says he is. We don't want anybody to get in-between who copies the value to himself and then disappears. So a reliable digital identity is an essential condition for the further development of blockchain. It is not only about digital identities of persons, but also of legal entities, like a type of Chamber of Commerce number. Objects will also have to be given digital identities. Because if in future for instance we are going to use autonomous sensors to have payments performed without human intervention, those sensors must have an identity. And if they for instance measure a quantity, then this sensor with this digital identity will be validated. A digital identity must be able to be connected to virtual objects such as an order via the internet, because such an order itself will also do all kinds of things on the internet.

Blockchain is expected to develop

even faster than the internet and to change

the world completely within ten years

It is crucial that these digital identities are extremely reliable. But how are we going to organise that for 8 billion people? With all *legal identities* and (virtual) objects we don't even have enough with 8000 billion digital identities! So we must try to develop a standard for this. For bitcoin really just anything was chosen. It was a solution the thinking behind which was: this should do. But if we are going to accept things like this for everything, we will end up with many individual solutions. That is why *global identity identifiers* are increasingly emerging. In the end we will have to aim at a type of universal identity on the basis of a world standard and at organisations issuing digital identities as a government now issues passports. Such organisations must then obviously be reliable.

### CONTINUOUS RETRAINING

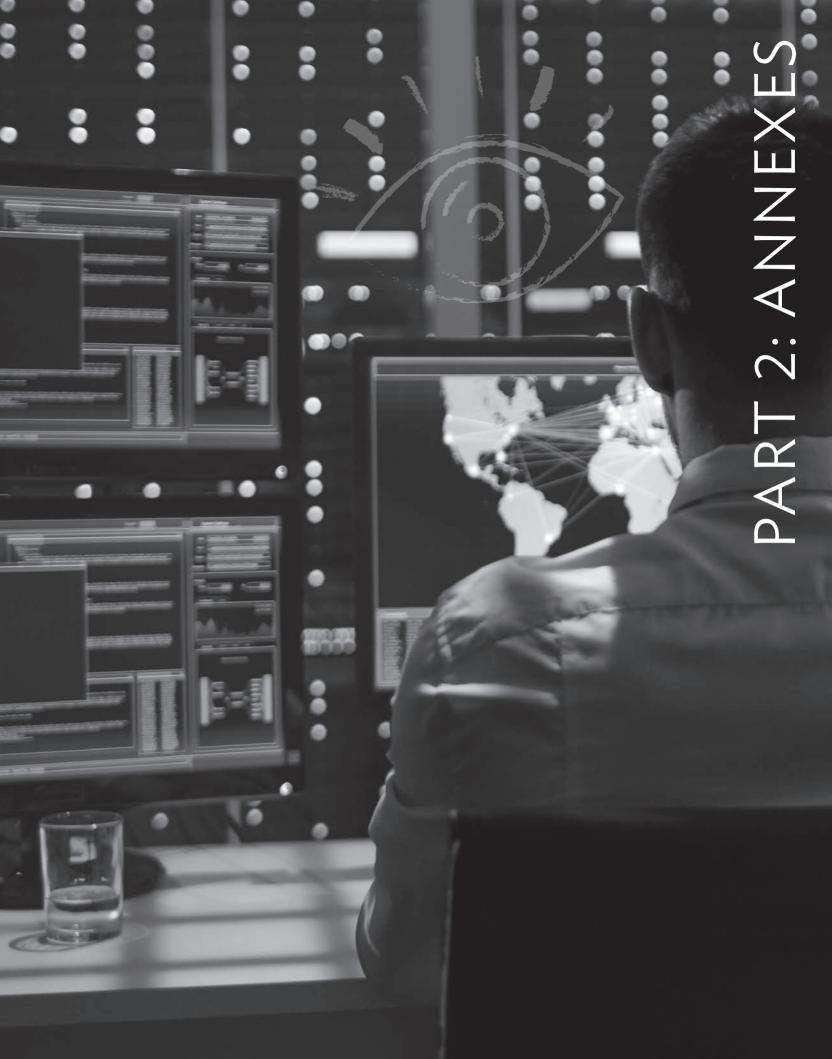
Another big challenge facing us - which starts in the industry sector but which will apply to the entire society - is that we must offer everybody continuous training opportunities. Because we will see rapid digital developments such as blockchain, but also with artificial intelligence and quantum computing, the jobs of today will essentially be different in ten years' time. Someone who is currently 35 years old will have once or twice in his career a completely different job content, with tasks he has not been trained for. That is why we should also reorganise the education system in the coming ten years so that everybody can be retrained at any moment. We are already doing this in the industry sector, for instance via skills labs, but this development will soon play in all sectors; smart industry, smart health, smart finance, smart mobility, smart energy ... Nurses will soon have to be able to work with robots, bank employees with blockchain, taxi drivers with autonomous driving cars, etc. So we are not moving towards fewer jobs but to a completely different way of working, with different tools. If we do not anticipate this now, there will soon be a threatening, enormous shortage of skilled personnel.

# Due to *digital* developments such as *blockchain*the jobs of today will be essentially *different* in *ten years*

### A ZERO DEFECT IN PRODUCTION

In the smart industry the internet of things has a particularly enormous impact. When everything communicates with everything, sensors report values and computers check whether everything is right, the production process can be stopped at any moment if an error occurs. Where in the past we now and then made a measurement to inspect the quality, randomly or at the end of the process, we can now monitor whether something goes wrong continuously at every step in the production. In this way we can achieve a 100% inspection check and a zero defect in the production. And when subsequently every object in the production has its own identity, we can record in a blockchain the entire history of the product: all the transactions of the components in it, how those components are made, how the product is used and how ultimately it can be disassembled to separate valuable parts and materials.

One of the things that still now and then goes wrong in product traceability, for instance in the food chain, is that someone at the beginning inputs data which are incorrect. The blockchain might be beautifully organised, but there is no guarantee that what has been recorded is correct. Who says that that farm belonged to that farmer where the food came from? And how do we know that the mechanic of the machine that is installed at the farmer's, is not a hacker? We will be continuously faced with this type of problem and this requires a lot of technique in the future. More so than is currently the case. Human nature will not change due to that technique; someone who wants to cheat will be looking how he can do it. But with blockchain on the basis of reliable standards this will soon become much more difficult.



# **ANNEX 1**

# Governing bodies and advisory committees

his overview contains the composition of the governing bodies and advisory committees as of 1 March 2018.

# **Board of Supervisors**

Drs. E.H.T.M. Nijpels (Deputy Chairman)<sup>4</sup>

Since 7 March 2018

Prof. dr. J. van den Heuvel

1st term until 1 August 2021

Dr. ir. I. Mastenbroek

1st term until 14 March 2019

Ir. P.F. van Rhede van der Kloot

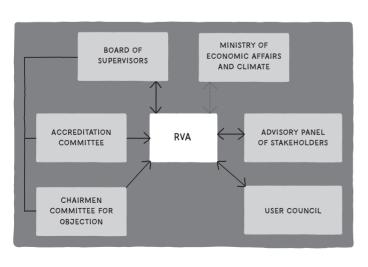
1st term until 1 September 2021

Ir. L. Visser

3rd term until 26 October 2020

For the report of the Board of Supervisors for 2017 we refer to the annual accounts for 2017, which you can download via our website (www.rva.nl). You can find more information there about the members of the Board of Supervisors and their additional functions

4 Drs. S.A. Blok was Chairman from 1 January until 5 March 2018.



# Management and Executive Board

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

### **Accreditation Committee**

Prof. dr. ir. O.A.M. Fisscher (Chairman)

Prof. dr. E. Bakker

Ir. C.K. Pasmooij

K.J. van Schalm

# Chairmen Committee for Objection

mr. L.A.F.M. Kerklaan

mr. M.N. van Zijl

mr. A. Pahladsingh

# Advisory Panel of Stakeholders

Prof. dr. Ph. Eijlander (scientific institutes, Chairman)

*Ir*. R.H. van Terwisga (NEN)

mr. A.P. de Groene (ministries)

mr. J.A. van den Bos (inspectorates)

Ir. N.F.J. Hendriks (certification and inspection bodies)

R. Karel (laboratories and inspection bodies)

Dr. R. Baumgarten (medical laboratories)

*Ir.* M.P. Cuijpers (primary sector)

Ir. F.W. Stuyt (scheme administrators)

*Ir.* J.J.N.M. Hogeling (industry)

Dr. H.C. Ossebaard (Dutch National Healthcare Institute)

Dr. P. van der Knaap (supervisors public sector)

Dr. V. Fokkema (metrology)

Ing. G.J.W. Kerkman (Dutch Association of Insurers)

### **User Council**

Ir. J.C. van der Poel (RvA, Chairman)

S. ter Horst (NVCi)

R. Karel (Fenelab)

Dr. B.M.A. Kroon (Fenelab)

B. van Doorsselaere (VEROCOG)

Dr. S.M. Bruisten (medical laboratories)

Dr. B.G. Hepkema (medical laboratories)

Ir. O.T.H. van Panhuys (NVCi)

mr. J.A.W.M. de Haas (RvA)

# **ANNEX 2**

# **Brief financial overview**

he 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 Super-

visors, the Accreditation Committee, the Advisory Panel of Interested Parties and the User Council. We also guarantee our independence by a healthy capital position. This is why we are resilient against financial risks which might arise, for instance if conformity assessment organisations would decide to terminate the accreditation.

### FINANCIAL ACCOUNTS

The figures below have been taken as a summary from the adopted annual accounts for 2017. No rights can be derived from them. You can download the full annual accounts via

our website (www.rva.nl) or request them from us via telephone number +31 (0)30 239 45 00.

# PROFIT AND LOSS ACCOUNT (X €1,000)

Results	Budgeted 2017	2017	2016
Net turnover	14,397	14,618	13,993
Costs of turnover	4,696	5,032	4,787
Gross margin	9,701	9,586	9,206
Direct personnel costs	7,532	7,214	6,908
Other costs	2,159	2,228	2,161
Sum total of costs	9,691	9,442	9,069
Operational result	10	144	137
Interest income	18	7	19
Result	28	151	156

The result will be fully added to the equity capital.

# BALANCE SHEET AS AT 31 DECEMBER (X €1,000) AFTER APPROPRIATION OF THE RESULT

Assets	2017	2016
Fixed assets	491	607
Receivables and transitory assets	3,365	3,595
Liquid resources	3,661	3,110
Total	7,517	7,312
Liabilities	2017	2016
Equity capital	4,026	3,875
Short-term debts and transitory liabilities	3,491	3,437
Total	7,517	7,312

The capital need was evaluated recently in 2014 and will be re-evaluated in 2019. Partly considering the changed status of the RvA in 2010 into an autonomous administrative authority, it has been decided to maximise the buffer capital (equity capital -/- special-purpose reserve) to be pursued in the coming years at 4 million euros. The amount of the buffer capital at year-end 2017 was 3,798,303 euros; at year-end 2016 this was 3,744,914 euros.

The selection procedure for the audit announced last year has been postponed by one year. In consultation with the Board of Supervisors it has been decided to extend the assignment to the accounting firm KPMG by one year. In the second quarter of 2018 the selection procedure will commence for the accounting services with regard to the audits for the coming years.

# **RATES**

The starting point - subject to special circumstances - is that the rates increase on average by no more than the index of Statistics Netherlands (CBS) for business services. In 2017 we increased the annual contribution for the initial registration by a mere 0.3%. The rate for subsequent registration has been increased by 1.4%. The difference

between both rates has thereby been further reduced. Eventually these rates should be level, regardless of the number of registrations. We also adjusted the day rate for assessors, who determine the majority of our income, by 1.4%. The next table represents the development of the rates:

Rate development	2017	2016
CBS-index	1.3%	1.4%
Rate (lead) assessor	1.4%	0.0%
Rate specialists	1.4%	0.0%
Annual contribution to initial registration	0.3%	-3.6%
Other rates	1.4%	1.4%

# **ANNEX 3**

# Our work in figures

rust also requires that audits are possible. In this Annex you will find an overview in figures of our

activities in 2017. As a comparison we also added previous figures in several cases.

# **ACCREDITATIONS GRANTED AS AT 31 DECEMBER 2017**

Standard	Explanation	Netherlands 2017	Abroad 2017	Total 2017	Netherlands 2016	Abroad 2016	Total 2016
CERTIFICATION							
ISO/IEC 17065	Products and services	45	3	48	43	3	46
ISO/IEC 17021	Management systems	45	19	64	44	21	65
ISO/IEC 17024	People	5	0	5	6	0	6
Subtotal certification		95	22	117	93	24	117
INSPECTION							
ISO/IEC 17020	Inspection	129	2	131	127	2	129
Subtotal inspection		129	2	131	127	2	129
LABORATORIES RVA	MARK						
ISO/IEC 17025	Calibration	55	0	55	55	0	55
ISO/IEC 17025	Testing	245	8	253	243	9	252
ISO/IEC 17043	Ringtests	15	1	16	14	2	16
ISO 15189	Medical laboratories in Multilateral Agreement	170	5	175	105	4	109
ISO Guide 34	Reference materials	2	0	2	2	0	2
Subtotal laboratories		487	14	501	419	15	434
ISO 14065	EMAS/Emission	4	1	5	5	0	5
Regulation (EG) No. 1221/2009 (EMAS)	Verification EMAS	1	0	1	1	0	1
Total RvA mark		716	39	755	645	41	686
Laboratories CCKL mark							
${\tt CCKL\ Code\ of\ Practice}^*$	Medical laboratories	70	0	70	141	0	141
Total number of accredi	tations granted	786	39	825	786	41	827

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

# GEOGRAPHICAL SPREAD OF THE ACCREDITATIONS GRANTED AS AT 31 DECEMBER 2017

Country	2017	2016	2015
Netherlands (Autonomous administrative authority (ZBO))	716	645	582
Rest Europa*	4	3	5
Restwereld	35	38	42
Totaal	755	686	629

<sup>\*</sup> At the request of the local accreditation body.

# TOTAL NUMBER OF COMPLETE APPLICATIONS RECEIVED FOR NEW ACCREDITATIONS PER ANNUM

	2017	2016	2015
Initial*	83	94	90
Extension	249	272	256
Total	332	366	346

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

# NEW ACCREDITATIONS BY TYPE (NUMBER AND PROCESSING TIME FROM APPLICATION TO DECISION)

	New accreditations	Average processing time in calendar days	New accreditations	Average processing time in calendar days
Decision in	2017	2017	2016	2016
Certification	7	247	4	217
Inspection	5	149	8	232
Calibration laboratory	2	337	2	274
Test laboratory	12	305	8	342
Medical laboratory	66	339	62	334
EMAS/Emission	1	61	0	0
Other	1	309	0	0
Total	94	<b>314</b> *	84	318*

<sup>\*</sup> This is a weighted average.

Of the 94 new accreditations (including transitions from CCKL to ISO 15189) eight applications $^5$  had a processing time of over twelve months. This was caused by the following:

# EXTENSIONS OF THE SCOPE OF ACCREDITATION PER TYPE (NUMBER AND PROCESSING TIME FROM APPLICATION TO DECISION)

	Extensions	Average processing time in calendar days	Extensions	Average processing time in calendar days
Decision in	2017	2017	2016	2016
Certification	55	210	85	156
Inspection	32	87	38	119
Calibration laboratory	6	232	5	123
Test laboratory	123	128	141	141
Medical laboratory	17	245	5	241
EMAS/Emission	1	104	0	0
Other	4	78	2	132
Total	238	151*	276	144*

<sup>\*</sup> This is a weighted average.

Of the completed extensions eight<sup>8</sup> had a processing time of over twelve months. This was caused by the following:

- In six cases<sup>9</sup> the client needed more time to remove non-compliances.
- In two cases  $^{10}$  the cause was mainly on the part of the RvA.

<sup>•</sup> In four cases<sup>6</sup> the client needed more time to remove non-compliances.

<sup>•</sup> In four cases<sup>7</sup> the RvA had insufficient assessors or experts available or had them available too late.

<sup>6</sup> in 2016: two cases.

<sup>7</sup> in 2016: four cases.

<sup>5</sup> in 2016: six applications.

<sup>8</sup> in 2016: six cases.

<sup>9</sup> in 2016: five cases.

<sup>10</sup> in 2016: one case.

# DISTRIBUTION OF THE BILLED TIME OVER THE TYPE OF INVESTIGATION

Assessment type	2017 (total number of days 8,817 = 100%)	2016 (total number of days 8,075 = 100%)	2015 (totaal number of days 7,218 = 100%)
Initial assessment	5%	5%	6%
Extension	8%	7%	10%
Re-assessment	23%	18%	13%
Audit assessment	43%	45%	54%
Witness session	10%	8%	5%
Transition to ISO 15189	11%	17%	12%
Total	100%	100%	100%

# DISTRIBUTION OF THE BILLED TIME, BROKEN DOWN INTO THE ROLE IN THE ASSESSMENT TEAM

Role	2017 (total number of days 8,817 = 100%)	2016 (total number of days 8,075 = 100%)	2015 (totaal number of days 7,218 = 100%)
Lead-assessor	44%	45%	47%
Assessor	10%	8%	7%
Specialist	46%	47%	46%
Total	100%	100%	100%

# DISTRIBUTION OF THE BILLED ASSESSMENT TIME, INCLUDING THE ASSESSMENT OF CORRECTIVE MEASURES AND WITNESS SESSIONS

Deployment	2017 (total number of days 8,817 = 100%)	2016 (total number of days 8,075 = 100%)	2015 (totaal number of days 7,218 = 100%)
At client's site	47%	50%	49%
Preparation/report	50%	48%	48%
Travelling outside the Netherlands	3%	2%	3%
Total	100%	100%	100%

# NUMBER OF ASSESSMENTS ACCORDING TO THE CCKL CODE OF PRACTICE

Assessment type	2017	2016	2015
Initial assessment	0	0	0
Audit assessment	11	55	69
Document audit	0	0	7
Re-assessment	2	4	5
Total	13	59	81

# **DISPUTES, SUSPENSIONS AND WITHDRAWALS**

A *dispute* is a difference of opinion between the assessed party 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	2017	2016	2015
Total number of disputes	88	89	52
Non-compliance is maintained unchanged	17%	28%	42%
$Non-compliance is \ maintained, but \ re-formulated$	19%	20%	25%
Non-compliance withdrawn	18%	30%	31%
Other outcome of dispute	0%	1%	0%
Pending	18%	7%	0%
Inadmissible	28%	14%	2%
Total	100%	100%	100%

# SUSPENDED ACCREDITATIONS (FULLY)

Accreditation category	Voluntary 2017	Imposed 2017	Total 2017	Voluntary 2016	Imposed 2016	Total 2016
Certification	0	1	1	3	3	6
Inspection	0	6	6	2	O	2
Calibration laboratories	2	0	2	0	O	0
Test laboratories	1	2	3	1	1	2
Medical laboratories	0	1	1	0	O	0
Other	0	O	0	0	O	0
Total RvA mark	3	10	13	6	4	10

This only relates to suspensions for the entire scope. For part-suspensions – suspensions covering a part of the area of activity – we would like to refer to our website (www.rva.nl).

# WITHDRAWN ACCREDITATIONS (FULLY)

Accreditation category	Voluntary 2017	Imposed 2017	Total 2017	Voluntary 2016	Imposed 2016	Total 2016
Certification	7	0	7	8	1	9
Inspection	2	1	3	5	0	5
Calibration laboratories	2	0	2	3	0	3
Test laboratories	9	0	9	7	1	8
Medical laboratories	2	0	2	1	0	1
Other	1	0	1	0	0	0
Total RvA mark	23	1	24	24	2	26

# WITHDRAWN ACCREDITATIONS (FOR A PART OF THE AREAS OF ACTIVITY)

Accreditation category	Voluntary 2017	Imposed 2017	Total 2017	Voluntary 2016	Imposed 2016	Total 2016
Certification	1	0	1	2	0	2
Inspection	0	0	0	0	0	0
Calibration laboratories	1	0	1	2	0	2
Test laboratories	2	0	2	2	0	2
Medical laboratories	12	0	12	1	0	1
Other	0	0	0	0	0	0
Total RvA mark	16	0	16	7	0	7

The following are the reasons for withdrawal most occurring:

- The activities no longer had to be carried out under accreditation or the body no longer carried out the activities (thirteen times).
- Since 2012 there is a more restrictive foreign policy or there is a transfer to a local accreditation body (twice).
- There was a takeover of another scope (six 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; twice).

# Vision, mission and core values

# What is accreditation?

### **VISION**



The RvA provides its services:

- with integrity and in a professional, transparent and independent way;
- with dedication of competent, motivated employees and external networks of experts;
- in accordance with the national and international requirements determined.

In doing this it takes the interests of the Dutch market, the public sector and the people into account.

## MISSION



# **CORE VALUES**



The RvA adheres to the following core values:

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

If we put the first letters of these words next to each other, it results in the abbreviation 'commit'. It's an abbreviation that stands for commitments, or involvement. Particularly that involvement based on core values provides our clients with actual guaranteed trust.

### CREATING TRUST



Accrediting literally means: creating trust. Nationally and internationally buyers want to be able to blindly trust the quality and safety of products and services provided. If they are guaranteed, this not only benefits the buyer but also the supplier: it 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 applies to every imaginable sphere of work: healthcare, environment, construction, energy, food, transport, finances etc.

### CHAIN OF TRUST



Does a supplier meet the requirements? If so he will receive a certificate of conformity, in the form of a certificate or report. Assessing organisations are therefore called conformity assessment organisations. This statement has most value if the assessing organisation is expert, impartial and independent. The RvA has been appointed by the authorities as the national accreditation body with the aim of verifying the expertise, impartiality and independence of conformity assessment organisations. It the result is positive an accreditation mark will be issued. Thereby the RvA forms the last link in the chain of trust.

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