

The value of confidence



Foreword of the Board of Supervisors

On behalf of the Board of Supervisors I would recommend that you read this public report on the activities in 2018 of the RvA.

This report also includes four interviews with stakeholders in the work of accredited conformity assessment. It is a view of the outside world on the importance of organised confidence in products, services and conduct of organisations. How does this add value?



e live in a society with a political system that increasingly aims at a 'risk-free' society.

That is why it is of major importance that organisations such as the RvA continue to emphasise that society should be able to trust conformity assessment to reduce risks but that this is not a zero fault or zero incident guarantee.

Human work is fallible. It is important to learn from this so that the chance of faults and their consequences are further reduced.

Therefore it is all the more important that the work of the RvA is carried out reliably and transparently as a sort of hygiene factor for Dutch society and as an assurer of confidence in the system of conformity assessment.

In the short period that I have been involved in this as a Chair, I have been able to see that the RvA applies core values which are embodied in the word *commit*: competence, impartiality and independence, market-orientation and people-orientation, integrity and transparency. This shows very clearly that the organisation is highly aware of – and is committed to – its important role.

It is a role which for many remains in the background.

By word and deed the Board of Supervisors supports and encourages the RvA's ability to continue to fulfil this role transparently, with integrity and efficiently.

On behalf of the Board of Supervisors,

Yvonne van Rooy, Chair

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Introduction

The World Accreditation Day to be held on 9 June 2019 has as its theme adding value to the supply chain. This was the reason we made the concept of value central to this public report, in particular in the interviews with stakeholders in accreditation. Whoever does not manage to add value with his main activity to clients and/or improvement chains, will sooner or later find that their right to exist is jeopardised. The following persons will have their say: Hans de Jong (Philips), Sijmon Hage (Danone Nutricia), Paul Hesselink (Kiwa) and Tjibbe Joustra (Dutch Safety Board).



heir visions confirm my impression that both conformity assessment and the RvA have a beckening future perspective. But judge this for yourself on the basis of what you read in this report.

CONFIDENCE IN OUR WORK

Adding value: It is said so easily. But how do you do it when it is all about confidence? It is difficult to measure value, as opposed to temperature or even client satisfaction for instance. And the level of trust is easily affected by incidents and messages in the media. The old saying *trust is hard to gain and easy to lose* seems to have lost none of its value. This also applies to the RvA. In order to keep that valuable confidence in our work as intact as possible, we operate on the basis of our core values: competence, impartiality and independence, market- and people-orientation, integrity and transparency. These are the core values which are a compass for the employees of the RvA and who each in their turn contribute to maintaining the confidence in our work.

Transparency is for instance reflected by our accountability to the public at large, to the User Council and to the Board of Supervisors. But it is also expressed by the periodic evaluations by our professional colleagues from other European countries which we undergo, the so-called peer evaluations of the EA (European Cooperation for Accreditation). In January 2018 we underwent another such evaluation, which we passed successfully. A short report on this was placed in a news item on our website. On that occasion we were also 'approved' for participation in the multilateral agreement (MLA) starting in 2019 for laboratories for the production of reference materials on the basis of ISO/IEC 17034. Because of this the RvA remains an EA-MLA signatory for all possible standards. This means that there is global confidence that bodies accredited by the RvA provide reliable work. This represents value.

In 2018 the International Accreditation Forum (IAF) expanded the MLA with ISO 14065 and the European Emissions Trading System (EU ETS). This means the verification of emissions, which is so important to the

climate discussions, has become more valuable by accreditation because it means global acceptance.

Transparency is also up for discussion if accidents or other incidents occur. In the aftermath of the mast breakage on board the historic sailing ship Amicitia, the Dutch Safety Board recommended the Ministers for Infrastructure and Water Management and of Economic Affairs and Climate for instance to improve the coordination between inspectorates/enforcement on the one hand and certification/ inspection on the other hand. To this end in 2018 the Human Environment and Transport Inspectorate and the RvA held a work conference with a clarification of the content of everyone's work and what is expected of it. In this connection the RvA explained how the system of conformity assessment works, but particularly also what the role is of legal requirements, private standards and schemes. With regard to schemes it is particularly often wrongly assumed that the RvA makes sure that they are in line with the law or legal requirements.

In the investigation into the Fipronil case the Sorgdrager Committee interviewed the RvA among others. On that occasion the RvA had the opportunity to explain where it does and does not play a role. In this case the *scheme* concept was less well understood with regard to the role of the RvA. For that matter, in its final report the Committee did not make any recommendations to the RvA.

Both cases were discussed with the Board of Supervisors. Partly in this connection we include in this report a brief, simplified explanation of schemes: how are they created and what role does the RvA have in relation to these schemes? We are convinced that the Association of Scheme Owners established in 2018 will contribute to a better understanding in this area.

We encouraged interaction with business relations and other interested parties through our conference on 7 June 2018, with the theme *Trust in a safe, digital society*. This was a subject that is everywhere high on the agenda but that has not yet been translated into criteria which are widely applicable for conformity assessment. Various topics were discussed, including the impact of the ongoing digitization and robotization, the shared concern about the

lack of attention to safety risks when new products are introduced and the increasing complexity of products and techniques affecting their supervision.

The conference was well attended and our clients appreciated the view of the possible future of conformity assessment. In addition, the majority of our participants agreed with the statement that conformity assessment/accreditation and innovation go well together.

WHAT WILL 2019 BRING US?

The coming year will be interesting in various areas. For instance, we will be completing two large transition processes:

- Until 30 June 2019 medical laboratories will have time to transfer from the non-harmonised standard CCKL Code of Practice to the internationally harmonised standard ISO 15189.
- For designating inspection bodies the Ministry of Social Affairs and Employment applied its own criteria on the basis of which the RvA assessed their competence, impartiality and independence. The transition to accreditation as a basis for the designation will be completed by the close of 2019. That means that as of 1 January 2020 the RvA will only carry out its work on the basis of harmonised standards. This is beneficial to the harmonisation and international comparability of our work.

Digitization of client processes is another main topic as part of the transformation we deployed to serve our clients better and to remain an attractive employer. We will also pay a lot of attention to this in 2019. And last but not least the Executive Board of the RvA will be transferred to a new two-headed Executive Board at the end of June.

In this way I want to thank all employees and assessors for their unwavering commitment to the realisation of confidence in accredited conformity assessment. Thanks also to you as a business relation or other person interested in the RvA for the trust placed in us. I hope you enjoy reading it.

Jan van der Poel, *Director/Chief Executive*

1

Developments in our work: new value?

This chapter gives a picture of several developments which lead to innovation in our work, broadening our activities and assuring good conformity assessments. We made a selection of developments which demanded a lot of attention in 2018. These are developments in the area of assessment criteria, international activities, new spheres of work and providing information about accreditation.

ASSESSMENT CRITERIA

In our work we must have criteria or requirements to use in our assessments. These criteria are usually incorporated in standards and sometimes in European or national legislation. In this connection we roughly distinguish between two groups:

- Standards and criteria which apply to organisations conducting conformity assessments (by this we mean 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 criteria; these standards are developed by ISO (International Organization for Standardization).
- Standards and criteria which are applied in a specific sphere of work on the basis of which clients of our accredited bodies receive a report or statement with regard to the assessed conformity. Such reports and statements enable businesses to create confidence amongst their customers, but also demonstrate to the authorities or society that they comply with certain rules. These standards can be developed and published at national (NEN), European (CEN) or global (ISO and/ or IEC) level, but also by a sector, an individual company or an authority.

The conformity assessment standards used for accreditation are all ISO standards. This enables the work of accreditation bodies to be recognized globally by the accreditation bodies which are members of the ILAC (International Laboratory Accreditation Cooperation) and the IAF (International Accreditation Forum). The IIAC and IAF are umbrella organisations promoting harmonisation between countries and regions at international level.

New technologies such as the internet of things also have consequences for our work.

In 2018 we have been active in the transition of ISO/IEC 17011, the standard which accreditation bodies must comply with., the standard used for accreditation of testing and calibration laboratories, the ISO/IEC 17025 was also revised. In both standards appeared at the end of 2017, the transition period ends by the end of 2020.

In addition, through the representation of an expert in the respective ISO/CASCO work group we put a lot of energy into the development of a new standard to be used for accreditation. This relates to the concept for ISO/IEC 17029 for organisations providing validation and verification activities. We expect this standard to be highly suitable for fast developing technology areas, sectors in which a lot of work is carried out with calculation models, where performance claims must be validated, etc.

At the level of the conformity assessment itself in 2018 the transition to the new versions of ISO 9001 and ISO 14001 were completed on time. In addition, in 2018 the implementation began of the new ISO 45001 (occupational health and safety) standard and the revised versions of ISO 22000 and ISO 20000-1.

INTERNATIONAL ACTIVITIES

In 2018 the RvA was actively represented in the bodies of the ILAC and IAF, and particularly in the EA (European Cooperation of Accreditation). Employees of the RvA regularly serve on the permanent EA Committees, where they sometimes also fulfil a management role. In addition, we put our view forward to the Board of the EA, via our manager of strategic and technical management.

Every year the RvA delegates lead assessors and team members for peer evaluations at other accreditation bodies within EA. In 2018 this related to the bodies in Germany, Belgium and Spain. In 2018 we received a study visit from the Ukraine among others and we provided peer advice and training in Moldavia.

NEW SPHERES OF WORK

In 2018 we granted an accreditation for business continuity management systems on the basis of ISO 22301 for the first time. We also granted the first ISO/IEC 17025 accreditation to a medical reference laboratory according to ISO 15195.

Furthermore, we collaborated with a forensic institute on an accreditation on the basis of ISO/IEC 17020 for crime scene investigation. We also wanted to witness an actual activity, which was not easy. Crimes cannot be planned and experts do not want to bind themselves unnecessarily over time. This was solved by witnessing a simulation.

Under the General Data Protection Regulation (GDPR) there are certification bodies which want to provide services that give confidence that organisations have their matters properly in order in connection with the GDPR. In this connection the RvA evaluates the applicability of the criteria in relation to the standard used for accreditation. Afterwards, the Dutch Data Protection Authority will check whether the scheme creates sufficient confidence that the legal requirements will be fulfilled. The first accreditation for this sphere of work is expected in the course of 2019.

New technologies such as the *internet of things* also have consequences for our work. In 2018 a large delegation of RvA assessors visited a workshop in Amsterdam where a steel bridge was printed with a metal printer.

The way in which the quality assurance was organised there requires a completely different view from what we are used to.

INFORMATION ABOUT ACCREDITATION

In 2018 we had several informative meetings related to Brexit with Dutch subsidiaries of British parent companies. They looked at what would be required to become accredited by the RvA for the spheres of work covered by the European directives and the accreditation of which must be suitable for notification in Brussels. In the event of a hard Brexit British parent companies will lose their notified body registration in Brussels. This means that they automatically lose access to the market for CE marks in Europe.

The RvA considered this as a new accreditation to which the ordinary policy rules apply. At the end of 2018 an explanatory document was published on this subject (T050) which can be viewed via our website: www.rva.nl/document/download/T050.

The way in which the RvA handles schemes of external scheme owners changed in 2017. In practice this regularly resulted in ambiguity amongst users, namely the accredited bodies and scheme owners . This has led us to organise several workshops on this theme.

In these the principles were once again explained and exercises carried out on the basis of the explanatory document T033 (www.rva.nl/en/document/download/T033) and the policy rule BR012 (www.rva.nl/en/document/download/BR012). These workshops were very well attended and were generally well appreciated by the participants.





Contributions to better diagnostics and treatments

Following his mechanical engineering study at Delft Technical University Ir. J.J. (Hans) de Jong started working for Philips, and held many positions at home and abroad. Since 2012 he has been the President of Philips Nederland. He serves on the Board of VNO-NCW, Stichting Brainport and FME, the employer's organisation for the technological industry.

Showing more to medical specialists in less time by using advanced technologies and data. This better enables them to make 'first time right' diagnoses and to treat patients more effectively and more efficiently. This is the aim of the high-tech products being developed by Philips. How do you assure the quality of such complex medical equipment, consisting of so many different components? We asked Hans de Jong, President of Philips Nederland.

INNOVATION BY COOPERATION

Trust in the quality of healthcare always starts with people. If something happens to you, you want to be able to assume that you can find a competent physician: someone who has not only had the proper training, but who is also sincerely interested in the wellbeing of his patients. In addition, you want to be sure that the underlying system is of a high level. But that is almost secondary. It is first and foremost about people. In general there is a lot of confidence in Dutch healthcare. Obviously perception plays a major role here: how do you experience the healthcare as a patient?

Our healthcare only remains among the world's best by being critical and by improving continuously. Innovation by cooperation in the chain: in this I think we distinguish ourselves from other countries. In order to maintain that lead, we need to improve the accessibility of patient information – because that is where the biggest obstacle is at the moment. To give a personal example: my daughter unfortunately has diabetes type 1. She got her bachelor's degree in Groningen and is now studying for her master's in Utrecht, whereas she lives in Amsterdam. The transfer of her medical information took months and in the end had to take place via fax because the IT systems of hospitals appeared to be incompatible. It is almost symptomatic of what is happening nowadays in the healthcare sector.

PLATFORM-DRIVEN SOLUTIONS

We must move towards a much more efficient exchange of medical images and data: platform-driven care. Philips wants to contribute to this by its technological innovations. Just take Azurion, our new platform for image-guided treatments consisting of equipment, software and services. This product enables medical specialists for instance to have all the necessary information immediately at their disposal during minimally invasive treatments. For instance, a touchscreen linked to a large screen hanging above the operating table, enables them to display in detail the surrounding blood vessels, tissues and organs. They get as it were "eyes in the body". In addition, they can view on site any images made previously such as X-rays and MRIscans, make 3D-visualisations and retrieve information from the electronic patient file. This helps to substantially improve the outcomes of such treatments.

Philips is at the end of a long chain. High-tech products such as Azurion are being realised in close collaboration with technical universities and academic hospitals throughout the world, so that they respond seamlessly to the needs of the market as well as having an optimum user experience. But we are also looking for the best partners for our development processes in other areas. For example, we are closely collaborating with Amazon Web Services, which specialises in data protection.

We must aim for a much more

efficient exchange of medical images
and data: platform-driven healthcare

It is knowledge we simply wouldn't be able to obtain ourselves. This requires good arrangements and protocols; you can't afford mistakes.

MANAGING USER RISKS

Our products must meet the highest quality standards. Before anything is placed on the market it has been verified and validated endlessly. The key question is always: would we entrust our loved ones to this device? There is no better yardstick. We develop the software largely ourselves and we also use suppliers for the hardware. We obviously impose the same high requirements on them; after all, the final responsibility lies with us. We try to assure the safety aspects – ranging from operating panels to data protection – as much as possible in the design. As a matter of fact it appears from research by the FDA – the American agency monitoring the quality and safety of medical products – that 30% of the problems relate to operator errors. And of those 30% you can avoid 50% by organising the design properly. We want our devices to be fail-safe.

Even after the installation of a device we continue to manage the user risks. For instance, we give comprehensive training, we monitor the use remotely and we take care of the required updates. It is impossible for hospitals themselves to do this. So they must rely on the technical expertise of their suppliers. Physicians and procurers know that our products are created in consultation with experts in the market and that the FDA and DEKRA are looking over our shoulder. It's true that these bodies are unable to assess our devices substantively, but they are able to assess whether we comply with the requirements in other areas – and they intervene if that does not appear to be so. We have a good reputation and have been cooperating with many hospitals for many years. All this gives sufficient confidence that the quality of our products is assured.

DIGITAL HIGHWAY

If we look at the coming years, a major change in the healthcare system is unavoidable. The rising costs – roughly 8 billion euros already in this cabinet period alone – put the system under enormous pressure. In addition, patients want to have more control over their health process. These developments will have a big impact on

The key question is always: would we **entrust our loved ones** to

this device?

how we organise the healthcare system in the future. We will have to focus more on prevention and remote monitoring. Technological solutions will help to improve the healthcare and to reduce the costs. For instance, the standard protocol of heart patients is that in the after-care process they regularly come for a check-up. But we also know that the chance of a relapse decreases considerably if instead of this they are remotely monitored. They will then receive a digital blood pressure monitor, a weighing scale and heart rate monitor to take home, which automatically send all the relevant monitoring data to the respective hospital several times a day. This means it is much easier to keep an eye on any changes and often can intervene before a problem arises.

The point is that such new healthcare pathways often do not fit into the current system. Because who is going to pay for it? Who has the responsibility? And who will be liable if something unexpectedly goes wrong? It is very complicated. The transformation to a new system is only possible if we manage to break through the compartmentalism in the healthcare system and care providers can exchange medical data digitally more easily and more safely. Technologically almost everything is possible. We also have relevant medical information at our disposal. But what is missing is a 'digital highway' where parties in the healthcare sector can exchange data. Other European countries are already active with this. Obviously this involves all kinds of difficult issues in the area of technology, privacy and information protection. That is why we advocate for open, 'generic' standards in an open (IT-) system and infrastructure. But it starts with the decision: this is the direction we want to go with each other. How are we going to organise this in a proper way? Because ultimately we all have the same goal in mind: better and future-proof healthcare.

2

Internal organisation and customer appreciation

When the outside world changes and different expectations about accreditation of conformity assessment bodies arise because of this, involving both substantive aspects as well as service provision, the RvA must be able to respond to them. It requires a flexible and responsive internal organisation.

n our service provision we aim for operational excellence. This should be expressed in good customer appreciation. Elements of particular importance are being proactive, providing factual and fast communication, shortening the turnaround time from the application to the decision, having unequivocal, client-friendly processes and transparent, flexible planning. In 2018 a lot of effort was put into implementing improvements on these points.

AVAILABILITY OF TECHNICAL EXPERTS

One of the bottlenecks in the planning of our activities is the number of available assessors with specific expertise. It is a permanent challenge to have sufficient technical experts in portfolio in all the spheres of work for which the RvA accredits or has been asked to accredit, in order to be able to plan flexibly. The more flexible, the simpler it becomes to shorten periods. It is more difficult for us to influence this on the part of the client. Sometimes spheres of work are linked to seasonal work or because of a lack of buyers there are really not many times when the client is active in his sphere of work – which also limits the assessment possibilities for the RvA.

The measures taken in 2017 to work with a special recruitment team, linked to digital tools such as LinkedIn and a separate recruitment site for freelance assignments (www.werkenvoorderva.nl), already bore their fruits in 2018. At year-end 2018 we have had fewer open positions for technical experts than we had at year-end 2017. In the meantime our LinkedIn page has over 2,150 followers and this number is growing steadily.

In addition, our monthly newsletter always draws attention to new freelance assignments. This increases the chance that we can actually achieve the required expertise.

HARMONISATION OF ASSESSMENTS

Assessment always remains human work, although this might be a dangerous statement with the emergence of robots and artificial intelligence. But we do know from experience that people do like to learn from each other, in order to be able to assess more uniformly. That is why we regularly organise harmonisation days for technical experts.

Since the end of the transition of medical laboratories to ISO 15189 accreditation is approaching and most of the assessors have gained experience with application of this standard, it appeared to us a good moment to organise two harmonisation days specifically for them. The first meeting was held in 2018 and the second one at the beginning of 2019. In total almost two hundred assessors attended these days. A need was met by offering an opportunity to exchange experiences and by explaining the interpretation of complex standard elements. In other areas too, including asbestos, meetings were organised for technical experts in 2018.

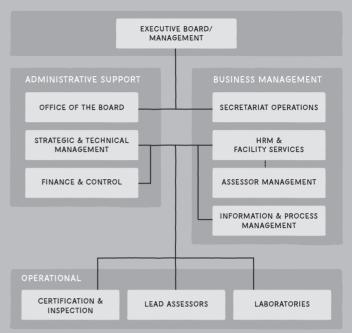
DIGITAL REPORTING TOOL

In 2017 we took the first steps to make possible a digital report on assessments by using an existing software package, and to make the results of those assessments available to the clients via a portal.

Unfortunately this development was stopped in the middle of 2018. The offered IT functionalities provided insufficient possibilities to use mutilple standards for accreditation at once. It also had difficulties to work for a large assessment team using the same client portal. This was a big disappointment for everybody who had been working hard on it.

That is why in September 2018 we started a digitalisation process for reports that can be set up flexibly for our own processes. In an *agile* setting the internal processes are

ORGANIZATIONAL STRUCTURE OF THE RVA



THE ORGANIZATIONAL STRUCTURE OF THE RVA IN 2018 IS SET OUT ABOVE. IN 2019 THE EXECUTIVE BOARD WILL BE TRANSFERRED TO A NEW TWO-HEADED EXECUTIVE BOARD.



On 31 December 2018 the RvA employed 105 salaried employees, of which 59 were women and 46 men.

SUSTAINABLE EMPLOYABILITY OF EMPLOYEES



THE ABSENTEEISM RATE ROSE FROM 4.1% IN 2014 TO 4.2% IN 2018.

600

Our network currently consists of approximately 600 freelance experts. In 2018 we contracted just under 100 new technical experts. We regularly place new freelance assignments on www.werkenvoorderva.nl.



VIA OUR MONTHLY NEWSLETTERS WE KEEP OUR BUSINESS RELATIONS INFORMED OF NEW ACCREDITATIONS, INTERNATIONAL DEVELOPMENTS, FREELANCE ASSIGNMENTS AND OTHER MATTERS. IN 2018 OUR NEWSLETTER WAS GIVEN A NEW LOOK AND FEEL.



On 31 December 2018 our business page on LinkedIn had over 2,150 followers.

first analysed and streamlined and subsequently built into modular software. For the application of determining findings in connection with assessments and the communication which is required to close non conformities, a working demo was recently submitted to a client panel as a final optimisation measure. This digital reporting tool will become operational in the course of 2019.

DIGISHIFT RV@

The Digishift Rv@ program is a first step in our transformation towards more IT-driven services. We defined the following projects: the planning of assessments and witness audits, the administrative treatment of recruitment and selection and processing digital procurement invoices. Funds have been reserved for these projects in 2018. They are expected to result in a clearer picture for our clients and job applicants and accelerate our processes. In addition, over time efficiency benefits will become visible, because fewer internal acts will be required.

DIGITAL SECURITY

Digital security is an important topic everywhere in the Netherlands, including at the RvA. We implemented the General Data Protection Regulation on time and registered a data protection officer with the Dutch Data Protection Authority. There is a periodic audit of whether our systems are secure. Several times in 2018 we had a potential data leak, because information had been sent to a wrong recipient. In this connection no vital information had been compromised. As a result extra instructions to the employees were given to be alert with regard to the automatic completion of email addresses.

In order to make our own infrastructure more secure, in 2018 we defined how a secure IT infrastructure can be achieved according to the current standards.

The conclusion is that we will switch from our own server farm with internal management to a cloud solution with external management. Tendering for this will take place in the first half of 2019.

AN ORGANISATION IN MOTION

Our office organisation changes in line with these developments. On the one hand this is to obtain a clearer focus and to create more harmonisation in the service provision to our clients, and on the other hand to strengthen the basis of digitalisation. In 2019 in the two operational units active in the planning of and communication about assessments and their contents, there will be a clearer separation of functions focused on processes and functions aimed at the harmonisation of size and contents of assessments.

After a comprehensive advisory process our Works Council gave a positive advice on this in the beginning of 2019. The implementation will follow in May 2019.

In our technical policies we are also continuing the harmonisation of the application of the standards for accreditation. It is a harmonisation that must take place internationally as well as internally at the RvA. At the close of 2018 the ultimate responsibility for all issues in this area was placed in the hands of the manager of strategic and technical management.

The quality assurance function has also been placed there.



STAY INFORMED!

We like to keep our business relations informed of new accreditations, (international) developments and freelance assignments.

Do you too want to keep informed? This is possible via:

- our monthly newsletter. You can register on our website: www.rva.nl. On the home page at the bottom left you will find a blue button.
- (news)updates on our LinkedIn page. Follow us on www.linkedin.com/company/raad-vooraccreditatie/.
- the news page on our website. We regularly publish news items and publications of explanatory documents on www.rva.nl/en/news.
- our recruitment site www.werkenvoorderva.nl.
 Here we regularly place new assignments for freelance experts.

On **www.rva.nl** you can find more information about the RvA.





For over a hundred years the factory of Nutricia Cuijk, part of Danone since 2007, has been producing food for the youngest in our society: babies and toddlers. This includes both standard and specialised products, for instance for children with a food allergy. How should the quality of such products be assured? And how can the work of the RvA support this? Sijmon Hage, Factory Director of Nutricia Cuijk, gives his vision.

WHAT DOES CONFIDENCE MEAN?

The first thousand days of a human life, from conception to about two years of age, are crucial. It is the period in which children go through the most important growth of their existence. Their brains, metabolic organs and immune system are developing at lighting speed, their length doubles and their weight quadruples. Healthy food supports the development and helps to avoid diseases such as obesity and diabetes. We obviously know that breast feeding provides the best food for babies, because it contains all the necessary components. Breast is best.

But if you cannot breastfeed for any reason whatsoever, or decide to stop breastfeeding, you would like to have a high-quality alternative at your disposal: a product you can rely on a full 100% every day, because it meets the highest quality and safety requirements.

This confidence of parents is for us by far the most important factor. Every day all over the world millions of children are consuming our products, from premature babies to toddlers. This often includes those with special dietary needs because they have for instance a cow's milk allergy or a lactose intolerance. This is an extremely vulnerable group; you do not want to imagine anything going wrong. This means that we don't take any risks and adhere to the highest standards.

FOCUS ON QUALITY AND INNOVATION

By combining science, innovation and production of high-quality food, we are trying to make the difference in those first thousand days. That is why we have at our disposal an excellent microbiological laboratory, researching products for the presence of micro-organisms. But the chemical-analytical lab is just as important. It tests for instance whether a product contains all the necessary raw materials. A baby is, certainly in the first months of life, fully dependent on this food. That is why there should be certainty that it contains exactly enough vitamins, minerals, omega-3 fatty acids and the like. In addition we have a sensory lab, aimed particularly at the use of products: does something taste good, has the powder the proper dissolving properties, is the intensity of the powder homogenous, etc. Those first two laboratories are particularly important for the quality and the safety of our food products.

Moreover, there must obviously be continuous innovation. We see for instance worldwide a clear increase in the number of children with a food allergy. Research has shown that 20% of all children develop an allergy. With good food it is possible to prevent an allergy or its symptoms. We are doing a lot of research into this at Danone Nutricia Research, our R&D centre in Utrecht, and we closely cooperate with universities and other parties. That is also a condition of being able to continue to produce high-quality products.

THE VALUE OF CULTURE

We recently opened our new state of the art factory in Haps, where the production of specialised baby food is a core business. In the construction we invested heavily in sustainability, because we think that our responsibility does not cease at the factory gate. We work according to a zero

Healthy food supports development and helps
to avoid diseases such as obesity and diabetes.

You can never cover *quality* completely by *systems*; it should also be embedded in the *culture*.

waste principle: everything is recycled. Our CO₂ emissions decreased by 50%, we are running on 100% renewable electricity and in our production processes we consume 60% less water and 25% less energy compared with our old factory. So one planet and one health go hand in hand. We deliberately chose to build this factory in the Netherlands. First because the made in Holland label is trusted worldwide. We have a high-quality industrial sector, competent government, competent inspection bodies and professional parties who supervise. This helps the entire chain towards a higher quality level. This is important for us because if an incident occurs somewhere in that chain, for instance in the dairy or agricultural industry, it also affects us and we experience the consequences of it immediately.

Our corporate culture formed the second reason for establishing the factory here. You can never completely cover quality by systems; it should also be embedded in the culture. In our work quality is clearly central. One of our golden quality rules is for instance that employees must report any quality deviation, no matter how small. If there is a drop of oil or a bolt on the floor? We will investigate this further. We have various quality ambassadors walking around. Our employees follow continuous training and every meeting starts with the safety and quality themes. Quality runs as a natural red thread through our work, so that our staff are thoroughly aware of its importance and are intrinsically motivated to look at things with eagle eyes. This is priceless. The new location is a stone's throw from the old factory, so that we could "move the culture along with us'.

If this would not have happened, it would have put us at a huge disadvantage.

OUR OWN QUALITY STANDARDS

Quality assurance starts with a carefully constructed culture. Apart from this you need a sound quality system. We regularly receive inspection bodies and accredition bodies such as the RvA, who assess whether we meet the set requirements. It's very important because you learn from this. In addition, it opens doors: other countries accept our products, so that we are able to export relatively quickly. We expect our suppliers to also have the necessary certificates. But we even go one step further: we apply our own quality standards which are much stricter than the national and international requirements. For instance, in the area of clothing: for each zone and product line in our new factory we have a separate dressing room, where you dress in specific clothing for that zone or product line. In some areas of the factory you even have to undress down to your underwear and you are given a shirt and overall. If you subsequently go to another zone or product line, you have to change clothes again. Legally this is not mandatory but we consider it important that those 24 zones and the product lines remain strictly separated. That's why we go the extra mile.

We conduct our own audits on the basis of these standards, internally as well as at our suppliers, where we zoom in on aspects we ourselves consider important for our products. A special audit team flies all over the world to visit our suppliers. In doing so, of course, a consideration is made as to which ingredients or materials entail the most risks. An ingredient such as sugar is for instance very pure and therefore less exciting but with diary you have to delve much deeper into the chain. Every year we tighten up our standards and we have a strong need to go further than anyone else. Baby food is a whole different ballgame because it is meant for a vulnerable target group. This requires peak performance every day.

Quality management: continuous improvement

The RvA has its own management system in order to assure the fulfilment of its mission and the realisation of its objectives. In order to monitor and optimise the proper operation of this system we include the use of observations during internal audits, complaints we receive and feedback which users of accredited services give in conversations, by complaints and in client-satisfaction surveys.

very year a management eview establishes whether the management system assures that we realise our objectives and that we continue to meet our own requirements, the requirements of ISO/IEC 17011, European Regulation 765/2008, the Designation of National Accreditation Body Act (Wet aanwijzing nationale accreditatie-instantie) and the Dutch Independent Executive Agencies Framework Act (Kaderwet zelfstandige bestuursorganen). In addition, in 2018 a peer evaluation was held by the EA and the RvA started to implement the amended version of ISO/IEC 17011.

The management review is discussed with the Board of Supervisors. Dealing with complaints, objections and appeals forms a permanent item on the agenda of the meetings of the Board of Supervisors and of the Board Meetings.

INTERNAL AUDITS AND IMPROVEMENT MANAGEMENT

Apart from the standard practice referred to above in order to achieve improvement actions, the employees of the RvA regularly conduct internal theme audits. During a theme audit a specific closer look will be taken at a part of our process, for instance compliance with work instructions, procedures and the like. These audits not only yield a lot of information for process owners but also contribute to knowledge sharing and a better understanding of each other's work and views. On this basis methods are revised, training or instructions initiated and process improvements implemented which reduce the likelihood of errors and/or which lead to a better service to accredited organisations and accreditation applicants.

In 2018 some concrete examples of these include:

- The process of continuous improvement is formulated such that the PDCA principle (*plan*, *do*, *check*, *act*) is better applied in this process.
- The ways in which the RvA acts in a relocation of laboratories and the transfer of accreditations are
 described in the work instructions. This means that the
 rules from policy rule BR011, available on our website
 (www.rva.nl/en/document/download/BR011), are
 better applied and more harmonised.
- The function flow diagrams describing the processes for internal use have been improved on several points, in order to further harmonise the methods internally.
- Several standard texts for decisions have been changed, partly on the basis of feedback from our clients. These new texts should improve the uniformity and legal accuracy of the decisions taken by the RvA and the conditions under which accreditation is granted.

PROCESSING COMPLAINTS

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

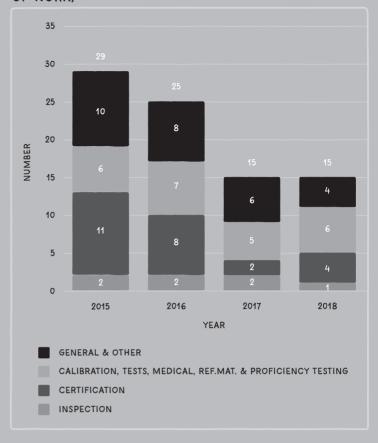
The adjacent figure represents the number of complaints during the past years and the client group from which they arose.

In 2018 fourteen complaints were dealt with. Three of these dated from 2017. At year-end 2018 four complaints were still being processed. Although complaints are usually dealt with faster than in previous years, the percentage dealt with within the period (38%) is too low. That is why at the end of 2018 the internal work method has been simplified by limiting the number of handling steps in the process.

The complaints related in particular to:

- conducting assessments and/or the conduct of (lead) assessors;
- the administrative processing of projects or the project management;

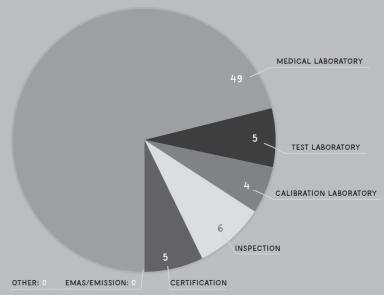
NUMBER OF COMPLAINTS ABOUT THE RVA PROCESSED (WITH A BREAKDOWN BY THE COMPLAINANT'S SPHERE OF WORK)





In 2018 the RvA granted a total of 810 accreditations.

NEW ACCREDITATIONS BY TYPE

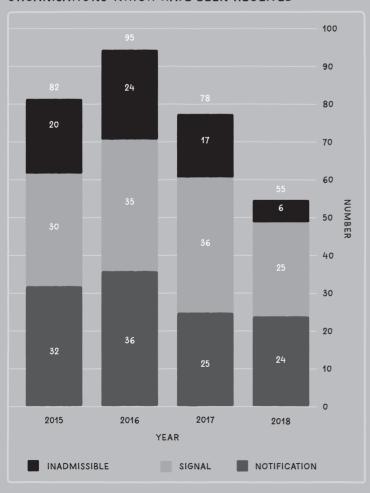






It's our ambition to increase the average score of the client satisfaction survey from 7.3 in 2018 to 8.0 in 2019.

NUMBER OF SIGNALS AND REPORTS ABOUT ACCREDITED ORGANISATIONS WHICH HAVE BEEN RECEIVED



- the representation of accredited activities in the scope of accreditation;
- the communication by the organisation with the client.

Since the end of 2016 the clients of the RvA have had the opportunity to give their opinion in a low-threshold way in the client satisfaction survey regarding the way in which the RvA operates in the three phases of the accreditation process: the application, the assessment on site and the decision.

Particularly at certification bodies the interpretation of standard texts sometimes leads to an almost legal discussion. In several cases this is attributed to the assessor and results in a complaint. In order not to cloud the complaints procedure unnecessarily, a dispute procedure has been established. If a major substantive difference of opinion about the interpretation of the standard occurs those assessed can submit this to the RvA by notification of an interpretation dispute. The number of disputes developed favourably from 88 in 2017 to 65 in 2018. In particular the assessment of medical laboratories yields fewer disputes as the transition from assessment against the CCKL Code of Practice to assessment against ISO 15189 progresses.

REPORTS AND SIGNALS

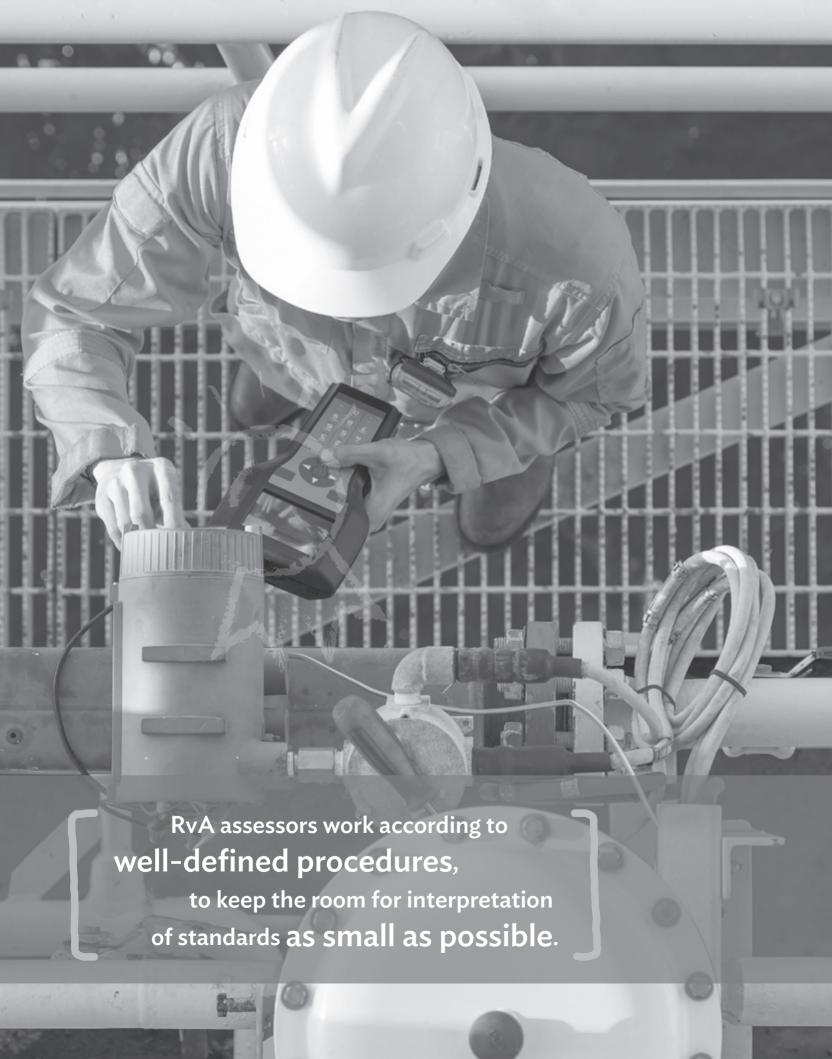
In case of dissatisfaction or doubts about the work of an accredited organisation it is possible to submit a report or signal to the RvA. The RvA investigates the report or the signal at the accredited party. A report is followed by feedback to the submitter. No feedback takes place on a submitted signal.

The numbers have developed in recent years as represented in the adjacent figure.

The admissible reports and signals related in particular to the following aspects:

- the work method of accredited bodies;
- the handling of complaints by accredited bodies;
- the impartiality of accredited bodies.

The admissible report and signals related in particular to bodies which are accredited for certification or inspection.



We regularly conduct **internal theme audits**, in order to further **improve** our services.

In connection with a report or signal the Executive Board of the RvA may decide to conduct an extra assessment if the content of the fact detected is such that the reliability of the work of the accredited bodies must be doubted. In 2018 it was decided to conduct an extra assessment three times. In one case the doubt appeared to be justified and the conformity assessment body concerned had to take measures to prevent future recurrence. In the other two cases we did not establish any non-conformities.

HANDLING OBJECTIONS, APPEALS AND WOB APPLICATIONS

In 2018 no WOB applications (applications under the Dutch Government Information (Public Access) Act) were submitted.¹

In 2018 objections were raised six times to a decision of the RvA.² The decisions against which objections were lodged related to:

- the conditions in an individual accreditation decision;
- withdrawal of a part of the accreditation of a conformity assessment body;
- the limited duration of the granted accreditation;
- the scope of the accreditation;
- non-acceptance of an accreditation application.

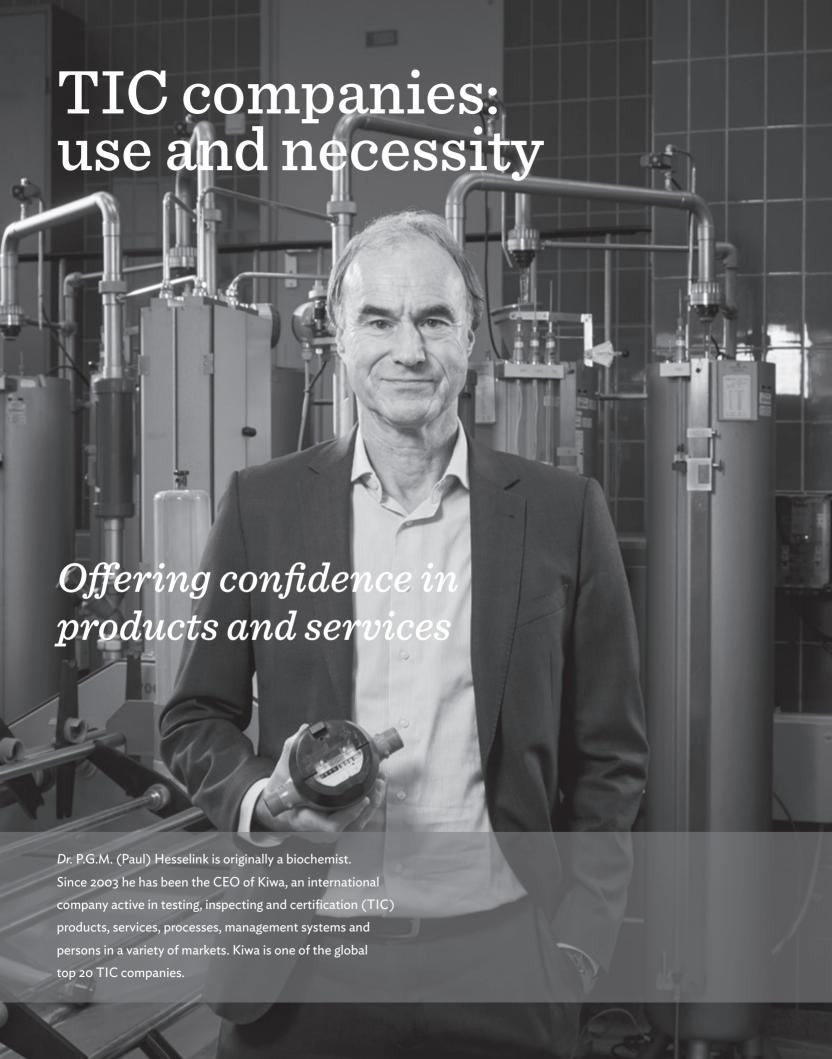
Two objections were declared (partly) well-founded. Three objections were withdrawn after consultation between the RvA and the objectors. One objection was declared unfounded.

In January 2018 the RvA appealed to the Council of State with regard to a judgement of the District Court of Oost-Brabant concerning a suspension of an inspection body in relation to final inspections after asbestos removal. On 20 February 2019 the Council of State ruled in favour of the RvA.

In 2018 an appeal was brought to the District Court of Zeeland-West-Brabant concerning a decision on an objection with regard to a change in the conditions attached to the accreditation of an inspection body. There has not yet been a hearing in this case.

¹ In 2017 there were no WOB applications either.

² In 2017 objections were lodged five times.



Quality institute Kiwa has grown in recent years into a global player in the area of testing, inspecting and certification (TIC) in a variety of sectors. In 2018 this home-grown TIC company has been in existence for seventy years. How do independent quality assessments and statements of conformity add value in international trade? And how can accreditation play a supporting role in this? An interview with Paul Hesselink, CEO of Kiwa.

TRUSTED THIRD PARTY

Why is there a demand for our services? Companies are first faced with legal requirements. Do products or services form a risk in the area of health, safety or the environment? If so they are obliged to engage an independent party who checks whether they meet the set requirements. In addition there are countless standards formulated by the business sector to serve international trade interests. An independent statement of conformity will then give assurance that products or services of suppliers meet the respective standards. Finally, there are purely voluntary agreements created on personal initiatives. This is a new group which is very much on the rise. For instance, IKEA - after McDonald's the biggest restaurant chain in the world - has its own rules which must be complied with by all restaurants in the group. We inspect branches throughout Northern Europe on the basis of these agreements.

The role of a trusted third party such as Kiwa can be compared with that of a referee: we are on the field with the rule book in our hand and blow our whistle. In doing this we are independent, impartial and competent. At the same time we see that the playing field in which we operate is changing. The people are becoming more critical and articulate, in particular via social media, and want more transparency about the quality of products and services. Increasing globalisation leads to much more complex and more extensive trade chains. There are more and more legal rules and voluntary agreements. This means that the number of TIC activities is increasing. Our raison d'être is that we can also offer confidence for this changing playing

field, that we blow the whistle in a fair match. We do this by working with good standards and by performing our activities at home and abroad under accreditation.

THE GOLDEN TRIANGLE

However as far as I am concerned we could go one step further: in the ideal situation a party such as the RvA doesn't only supervise our work but also the quality of the standards against which we assess - because you see considerable differences in that. This will then not be about 'umbrella standards' such as ISO/IEC 17065, the standard for product certification which describes how we should act as a body, but about the particular standards which fall under them. This is because those particular standards say something about the quality of the product or the service in question. For instance, a coffee cup has a completely different rule book than a light bulb, a car wheel or an organic carrot. The RvA now assesses whether we are sufficiently capable of doing our work and whether we are able to assess against certain particular standards. But that third component is still missing: assessing whether particular standards are correct. And that is just as essential, because even the best referees are nowhere without clear rules. A good standard, a competent conformity assessment body and a 'stamp of approval' of the RvA: this is what we call the golden triangle. In this way you create confidence in the entire chain.

In addition, I think that we should put the value of accreditation more into the spotlight. As conformity assessment body we are proud that we may carry the accreditation

A good standard, a competent conformity assessment body and a 'stamp of approval' of the RvA:

we call this *the golden triangle*.

The most important question

we should ask ourselves is:

how can we **remain relevant**?

mark, because thereby we distinguish ourselves in a positive way. Even more so: without that accreditation mark we could not even carry out many activities.

It is for instance cabinet policy that we are allowed to take over certain government duties and that the government can have confidence in us to do this in a proper way if we work under accreditation. But for the public at large it is still a well preserved secret that the government created an independent administrative body to assure the quality of products and services in the Netherlands, by monitoring the parties such as Kiwa. This may be brought to attention a little more -not just by the RvA.

THE IMPACT OF DIGITISATION

Just like other sectors the TIC industry has to deal with digital developments. They affect our work in two ways. Firstly in the way in which we collect data. In the past this was done almost exclusively by inspectors; nowadays we increasingly deploy new techniques such as drones and sensors. If for instance we want to know how much a machine is vibrating and if this meets the standard, we stick a sensor on it that continuously performs measurements. We obviously have to continue to check regularly whether that sensor is operating properly. It's a new way of working, but you still talk about collecting data. In addition, digitisation led to a completely different area: facilitating data platforms. Chains are becoming more and more complicated. Information exchange creates more transparency and better chain control. If for instance something appears not to meet the quality requirements, it will be possible via tracking and tracing to work out where exactly it went wrong. Kiwa collects, verifies and manages this information.

Moreover, as a result of digitisation we also see the emergence of new production methods of clients. Provided these are products of which multiple copies can be made, we can follow the usual route of product certification. In this way we can assess whether a batch of 3D printed bricks meet the requirements and whether we should trust that the subsequent batches are created in the same way.

It is different when a one-off bridge or staircase is printed. Then you can really only make statements about the calculations made, the raw materials used and the like.

CONFIDENCE IN THE FUTURE

Our sphere of work is constantly changing. The most important question we have to ask ourselves is: how can we remain relevant? In other words: how can we keep the trust in our statements of conformity? This not only relates to the confidence of the clients we serve but particularly also the confidence of the customers of our clients. This is because they must blindly trust our assessment. The art is to offer added value on two fronts: you must be able to operate local for local and also be able to follow global trade chains. Most TIC activities require a local for local approach: you communicate locally with customers to provide security locally. The healthcare, education or building sector comes to mind. But there are also activities which require a global network, such as transport, oil or vegetables and fruit. Medium-sized parties such as Kiwa traditionally focus particularly on the first, and increasingly also on specific cross-border trade chains, whereas big companies such as TÜV and SGS focus particularly on broad international activities.

In addition, there is a permanent increase in small specialists who respond smartly to new assessment areas such as IT security.

Conformity assessment is increasingly becoming more important from an international perspective. The TIC-sector can help promote its trade flows and contribute to the confidence in products and services. The value of our work is not always recognized particularly at European level. It is our task to convince governments and other stakeholders of this, to change the image completely. To this end we have to join forces. With the TIC Council recently established in which ninety frontrunners from the international TIC sector have seats, we obtained a collective vote. This is the first step.

4 Schemes for conformity assessment

In our work we regularly notice that there are ambiguities concerning schemes and the role which the RvA plays in this. This is understandable, because it is not always quite clear. One often thinks, wrongly, that we make sure that these schemes are in line with the law or legal requirements. In 2018 this gap in expectations played a role for instance in incidents such as the mast breakage in Harlingen and the Fipronil case. That is why this chapter gives a simplified idea of the essence of schemes in the system of (accredited) conformity assessment.

WHAT ARE SCHEMES?

The starting point is that the principles of conformity assessment come from the private domain. It is based on providing products or services in accordance with the requirements agreed with the customer. The customer can simply trust in the blue eyes of the supplier, but could also look for more security to reduce as much as possible the risk of disappointment in the supplier and/or his products or services. This is possible by consulting another party who provides similar products or services, but it is also possible to allow an independent third party to assess on the basis of agreed methods whether the supplier supplies according to the requirements. Such independent third parties are called conformity assessment bodies (CABs).

In order to give the customer even more confidence that the CAB is competent in the field of application and operates independently and impartially, international standards have been determined against which the CAB can assess its activities. If required, the CAB can have itself accredited by an accreditation body such as the RvA. These ISO standards are applicable throughout the whole world. That is why they have in general not been written very prescriptively.

In other words: there is still room for interpretation. So it is important what type of methods a CAB chooses in order to determine conformity. In many cases this is not desirable and a better comparability between the results of different CABs is required. Often in such cases a scheme is used. A scheme governs the *what*, *how* and *who* of a conformity assessment activity.

What: a description of the object of the assessment and the requirements imposed on the object.

How: a description of the processes, procedures and also for instance the work method which a CAB must follow in an assessment, such as a test method, frequency of surveillance and the like.

Who: a description of the requirements which apply to the CAB. This for instance may relate to an organisation, a work method, the competence of the staff, the equipment used, the report, etc.

In a scheme customers can see what the CAB does in order to determine that the supplier of products or services assures that the agreed requirements are met. Equally for instance government inspectorates can see what they can expect from the CAB as well as the supplier with regard to check points.

HOW ARE SCHEMES FORMED?

Schemes can be made in three ways:

- A CAB can formulate a scheme itself. In doing so a
 panel of experts, consisting of representatives of
 market parties, is often consulted to ensure that the
 desired level of confidence is supported by the scheme.
 This is also called the own scheme.
- Several CABs can jointly formulate a scheme and in doing so make use of a joint panel of experts. Such a scheme is 'the own scheme' for the participating CABs.
- A party other than a CAB may formulate and manage a scheme. This variant has already been in existence in the Netherlands for a long time. Such a scheme is particularly used to harmonise as much as possible the outcomes of the work of CABs at a level of confidence that is agreed by a wide group of interested parties. The scheme owner promotes the market support for the scheme by taking balanced account of the interests of all parties involved.

This latter variant is also used by the legislator in cases where conformity assessment is deployed for instruction or for direct incorporation in the legislation and regulations.

In the private sector schemes occur most often in applying accredited certification. Sometimes requirements are also imposed in the scheme on accreditation. This latter is only possible with the prior consent of the accreditation body, because it has to establish that there is a justified market demand as well as that by doing so it will not contradict the requirements of ISO/IEC 17011 or European Regulation 765/2008. In particular the government also uses schemes in areas such as inspection and tests. Those schemes are often indicated by concepts such as *accreditation scheme* or *protocol*.

Therefore the RvA has no influence on the agreed level of confidence, on the agreed requirements. They are definitely determined by the private sector or by the public sector.

WHAT IS THE ROLE OF THE RVA IN SCHEMES?

The RvA assesses CABs by applying the standards harmonised by the EU. This is the task we have pursuant to European Regulation 765/2008 and the Dutch National Accreditation Body Designation Act (*Wet aanwijzing nationale accreditatie-instantie*).

The various harmonised ISO standards used for accreditation have the common denominator that, apart from requirements for the CAB with regard to the improvement system and the internal organisation, there is particular attention paid to expertise, methods, means and impartiality. They also all require that a CAB must make clear what its 'promise to the market' is and how it is going to realise it: the what, how and who.

Therefore the RvA does not assess whether compliance with the law or legal requirements can be achieved by a scheme. Those formulating a scheme must take care of this themselves, they remain responsible, the determination of whether the law has been complied with is up to the court or to the law enforcers.

Neither does the RvA have an opinion about the agreed level of confidence forming the basis of the what, how and who. This is up to the parties who want to trust each other. Each party has in this respect their own responsibility.

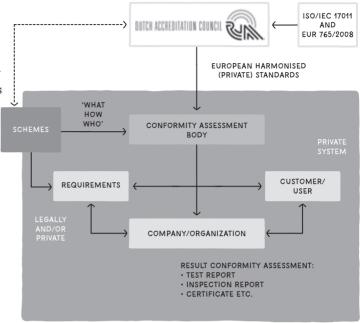
But what the RvA does instead is evaluate in its assessments of individual CABs whether the what, how and who have been sufficiently organised in an unequivocal and validated way. Even with regard to schemes of scheme owners it is still possible as a result of the way a CAB is organised, that there is a difference in the way in which such a scheme is applied in practice.

In order to avoid an unnecessary administrative burden, the RvA has the possibility that a scheme owner itself asks for an evaluation of a scheme by the RvA. This is only possible if at least one accreditation application by a CAB has been submitted. The RvA evaluates the question of whether the scheme is in principle suitable for use under accreditation, but always makes the reservation that the scheme will only be included in the list of schemes applied under accreditation after it has been assessed in practice at a CAB that the standard requirements for accreditation have been met.

In brief, the role of the RvA is aimed at assessing the how, what and who has been organised in a sufficiently unequivocal and validated way and in doing so verifying whether a scheme is in principle suitable for accreditation. The RvA does not assess whether with a scheme the law has been complied and does not give a value judgement about the level of confidence reached or the quality of a scheme (or standard).

We are often asked the question of whether the RvA wants to give a quality judgement about a scheme or standard. We don't do this because this could prejudice our impartiality and independence. What we do instead is publish a list of schemes applied under accreditation. That is a factual observation. This list can be found on our website: www.rva.nl/en/document/download/BR010-lijst.

The following figure gives an overview of the explanation set out above of the essence of schemes in the system of (accredited) conformity assessment:



It would be difficult to do justice here to all the possible nuances. For those who like to delve deeper into the matter of schemes which can be applied under accreditation, we refer you to:

- the website of the Association of scheme owners in the Netherlands: www.schemabeheerders.nl;
- the document of EA (European co-operation for Accreditation) about schemes, EA-1/22:
 european-accreditation.org/publications/ea-1-22-a;
- the policy of the RvA with regard to schemes set out in policy rule BRo12:
 www.rva.nl/en/document/download/BRo12;
- The explanatory RvA document about schemes, To33: www.rva.nl/en/document/download/To33.



In the event of accidents, people in society often say easily and quickly that self-regulation has failed and that the government should again take the issue in hand. But is that indeed the right approach? And how can private activities such as testing, inspecting and certification contribute to a safer society along with government monitoring and enforcement? An interview with Tjibbe Joustra, Chair of the Dutch Safety Board.

CULTURAL DIMENSION

Safety cannot be guaranteed, but you should be able to assure it with up-to-date knowledge. The moment things go wrong, for instance in the food industry or in aviation, it is often said that the safety level is higher than ever and that there are so many fewer victims than several decades ago. This comparison with the past is striking because people are living now. Whether we do it better nowadays than fifty or hundred years ago is less relevant. The question always first and foremost in connection with safety is: could this have been avoided with current knowledge and technology? And what lessons can we draw from this for the future? If faults are avoidable, they should in principle be prevented. That is the standard. People can expect organisations to go to great lengths to meet this.

In the event of serious accidents or disasters it is seldom that one single cause can be implicated; often it is due to a combination of factors. Often it is also based on a cultural dimension. Just take the mortar accident in Mali, where two Dutch soldiers died during a shooting exercise and a third one became seriously injured. It emerged from our investigation that various things went wrong, but more importantly: that there was a clear pattern visible and that the defence organisation had for many years been systematically tackling this type of matter wrongly. This touches on the culture of an organisation. Many incidents result from something that should really have been considered long ago but nothing was done – until the facts are suddenly pushed to the fore.

SELF-REGULATION IN PERSPECTIVE

Self-regulation alongside government supervision and enforcement can certainly contribute to a safer society, but we must continue to look critically at its application. Organisations are primarily responsible for the safety of their activities. It is of major importance that directors take their own responsibility seriously. This appears obvious but unfortunately it's not always the case. In investigations we regularly experience that organisations use certificates and supervision by inspectorates as an excuse to no longer have to address safety issues. This means that your approach is fundamentally wrong. Certificates are not meant to embellish the entrance to the board room; you should also do something about them. If this does not really happen at the top, certification is just a formality. Just take the Major Accident Hazards (MAH) companies: the approx. one hundred most hazardous companies in the Netherlands. Some Supervisory Boards always want to start with the theme of safety: what incidents took place, were near-accidents detected, etcetera. Others pay little attention to this. This is already a clear sign: is this embedded in the core or not?

A second point is that the system, in which private bodies monitor compliance with legislation and regulations by companies themselves, can work very well, but a form of government supervision will always be required and that this falls or stands with the question of whether private parties consider this compliance as something obvious and want to take care of 95% of this themselves. But what if the

Certificates are not meant to embellish

the entrance to the Board room;

you should do something about them.

latter is not the case? This is like mopping up with a running tap. Finally, we see that government services still deploy self-regulation sometimes without first thinking properly about the question whether a sector is really ready for this. They then use the tool to take the pressure off themselves. Almost all inspectorates are struggling with a lack of time and a big outflow of expertise, sometimes also with a rather exaggerated drive for change in organisations, but this should not be a reason to apply other means.

WHAT DO CERTIFICATES MEAN?

So self-regulation only works if private parties are handling it in the correct way. We still see that too often the credibility of the system is undermined.

For instance, a large tank storage company has all the required certificates on its wall whereas everybody knows that things are happening that are wrong. Or after we announced an investigation into a hospital it appears three days later that it has suddenly disappeared from the list of certified healthcare institutions, because they already had doubts. This is rather curious to put it mildly. I can imagine that an organisation such as the RvA certainly keeps an eye on this. But it is certainly not a simple thing, considering the large number of certification bodies in all kinds of sectors.

Something similar applies to inspectorates. It is impossible to supervise so many different parties and therefore choices have to be made. Where are the risks and how are we going to handle this? Where can we also be guided by certificates? This consideration is logical, but should not lead to blind spots in the system of supervision and certification. Take the incident on board the historic sailing ship the Amicitia, where the mast broke off and three tourists died. The general picture in this sector was striking: that the inspection does not count for much. In talks with the Living Environment and Transport Inspectorate it appeared that due to the large number of inspections other choices were made in the supervisory task. This is understandable but it is not how it was ever supposed to be. You must then indicate very explicitly that some areas are no longer being monitored. Now the wrong pattern of expectations was created: People think that something has been covered by a certificate, whereas this is not the case.

That *cultural dimension*, much could be *gained* here.

OPPORTUNITIES FOR CERTIFICATION BODIES

In the coming years there will be many opportunities for certification bodies to contribute to a safer society. This applies particularly to sectors where there is the will to deliver the responsibility for safety. This makes it difficult to make general statements. But what we do see is that digital safety is a big problem – partly also because the size of companies makes it very complicated. How can this be dealt with? This is a question with which many parties are struggling. I think it may be interesting to see how certification could play a larger role in this.

In addition, there are opportunities in the area of culture. It is striking that we consider culture as something very soft, whereas it can be as hard as rock. Culture is something in connection with which people are brought to account. Culture is the reason why certain things are happening. That is not soft, these are rock-hard preconditions! Those who are close to the fire, often no longer notice it. Once we drew up a report about earthquake risks in Groningen, in which we concluded that the sale of gas was more important, not the safety of the people. People were very angry that we just picked up that element in the report. But it was the culture of this sector. In certification systems more attention should be paid to this. How are things dealt with in this organisation? How often are there meetings with the Supervisory Board? How often has the Management Board put safety as an item on its agenda? Etc. Much could be gained by that cultural dimension.

5 Supervision and advice

The RvA can and must operate with a high degree of independence, but in this respect the forms of supervision of the work and advice in the decision-making process about accreditation are of major importance. They guarantee the competence, impartiality and independence of the RvA and provide a critical assessment of our activities and business operations.

n the performance of our activities this supervision and advice also contributes to the confidence of the public sector, the society and our clients. To this end various administrative bodies and advisory committees of the RvA are active:

- The Board of Supervisors;
- The Accreditations Committee;
- The Chairmen Committee of Objection;
- The Advisory Panel of Stakeholders;
- The User Council.

In this chapter we describe in outline the role and activities of various administrative bodies and advisory committees and any changes in 2018. Annex 1 of this report includes an updated composition of these bodies and committees. You will find a comprehensive explanation to their role and activities on our website (www.rva.nl).

The forms of supervision and advice outlined in this chapter contribute to a major extent to the confidence in our work that our clients, the society and the public sector can continue to have. We would like to thank everybody who is active in the administrative bodies and advisory committees for their input in 2018.

BOARD OF SUPERVISORS

The Board of Supervisors ensures that the Executive Board realises the objectives of the RvA. Selection of the members takes place on the basis of expertise and competencies. By preference the following areas of competence are represented on the Board of Supervisors:

- trade and industry
- public sector
- research/technology
- healthcare/medical sector
- food and products
- quality

The Board of Supervisors appoints the members of the Accreditation Committee and the Chairmen Committee for Objection according to the Statutes. These two committees operate independently of the Executive Board.

Resigned members

drs. S.A. (Stef) Blok, Chair (from 1 January 2018 until 5 March 2018) drs. E.H.T.M. (Ed) Nijpels, Deputy Chair (from 7 March 2018 until 1 December 2018)

Member who joined

mr. Y.C.M.T. (Yvonne) van Rooy, Chair (as of 1 December 2018)

We appreciate the interest Mr. Blok showed in us in the short time that he was Chair. We obviously fully understand his considerations. We thank Mr. Nijpels for his deputizing role as Chair in the search for a new Chair.

ACCREDITATION COMMITTEE

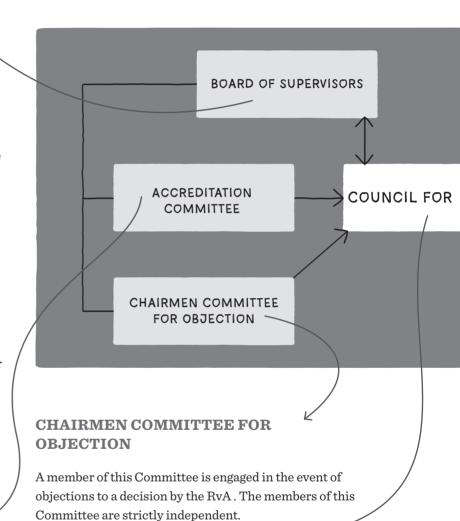
The Accreditation Committee consists of four members on the basis of their competence in accreditation fields, their integrity and independence. Its duties are to advice the Executive Board on granting accreditations.

Resigned member

K.J. (Klaas) van Schalm, as of 1 February 2019

Member who joined dr. G.H.M. (Guillaume) Counotte, as of 1 February 2019

Here we would like to thank Mr. Van Schalm for his constructive input to the Accreditation Committee.

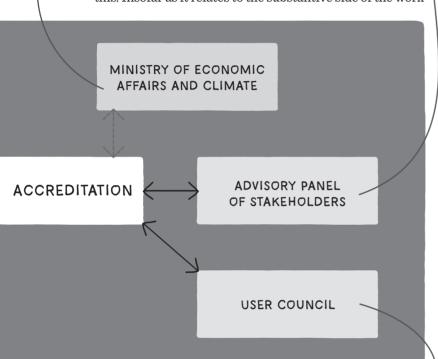


EXECUTIVE BOARD AND MANAGEMENT

The Director/Chief Executive is for instance responsible for the realisation of the objectives of the RvA, and he is assisted in the operational 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.

MINISTRY OF ECONOMIC AFFAIRS AND CLIMATE

The RvA must meet the relevant provisions of the Dutch Executive Agencies Framework Act (*Kaderwet zelfstan-dige bestuursorganen*) and European Regulation 765/2008. The Ministry of Economic Affairs and Climate monitors this. Insofar as it relates to the substantive side of the work



of the RvA, it can rely on the *peer evaluations by the* EA (European co-operation for Accreditation) which the RvA undergoes once every four years. In 2018 we successfully passed this peer evaluation. Representatives of the Ministry witnessed certain components of this evaluation.

EA MULTILATERAL AGREEMENT COMMITTEE

In order to remain a signatory of the Multilateral Agreement (MLA) of the EA, the RvA must meet the requirements of European Regulation 765/2008 and the international standard ISO/IEC 17011. Every four years the RvA is assessed by a team of about ten 'peers' in the form of a peer evaluation. Most recently in January 2018 a peer evaluation of the RvA took place, which was completed by a positive final report.

ADVISORY PANEL OF STAKEHOLDERS

This panel consists of representatives of the public sector, direct clients of the RvA, direct customers of the conformity assessment bodies, scheme owners and scientific institutes. The aim of the panel is twofold:

- giving advice on general policy matters whether or not requested;
- assuring the impartiality of the RvA in the further development of the subject-matter policy.

Items discussed in the Advisory Panel in 2018 included: the *peer* evaluation of the RvA;

- the areas of activity for which the RvA can and wants to grant accreditation (Policy Rule BR010 Areas of Activity RvA);
- the state of affairs in the development of new standards for conformity assessment bodies and standardisation development;
- the evaluation of the policy with regard to schemes for conformity assessment introduced in 2017;
- the assessment of confidentiality requirements by the RvA in relation to the GDPR;
- the cabinet's response to the recommendations in the report of the Dutch Safety Board concerning the mast breakage on board the historic sailing ship the Amicitia.
- the Fipronil case;
- the conference for stakeholders of the RvA, in connection with the World Accreditation Day on 7 June 2018, with the theme: confidence in a safe, 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 on the level of service. In addition, the User Council is informed of our plans concerning and the content of the digitisation projects which are in development. By a small number of client panels it is possible to pool thoughts about the setup of the user interface of those systems.



ANNEX 1

Administrative bodies and advisory committees

his overview shows the composition of the administrative bodies and the advisory committees as of 1 March 2019.

Board of Supervisors

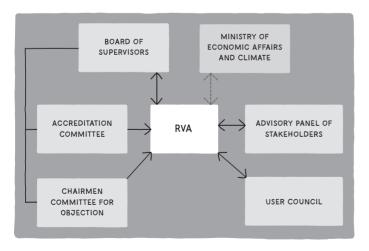
- mr. Y.C.M.T. van Rooy (Chair) 1st term until 1 December 2021
- *ir.* L. Visser (*Vice-Chair*)

 3rd term until 26 October 2020
- prof. dr. J. van den Heuvel 1st term until 1 August 2020
- dr. ir. I. Mastenbroek 2nd term until 13 March 2022
- *ir.* P.F. van Rhede van der Kloot 1st term until 31 August 2020

For the report of the Board of Supervisors we refer to the financial report for 2018, which you can download on our website (www.rva.nl/en/our-organisation). In this you can also find more information about the members of the Board of Supervisors and their additional functions.

Executive Board and Management

- *ir.* J.C. van der Poel (*Director/Chief Executive*)
- mr. J.A.W.M. de Haas (Operational Director)



Accreditation Committee

- prof. dr. ir. O.A.M. Fisscher (Chair)
- prof. dr. E. Bakker
- *ir*. C.K. Pasmooij
- K.J. van Schalm (until 1 February 2019)
- dr. G.H.M. Counotte (from 1 February 2019)

Chairmen Committee for Objection

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

Advisory Panel of Stakeholders

- prof. dr. Ph. Eijlander (scientific institutes, Chair)
- dr. R. Baumgarten (medical laboratories)
- mr. J.A. van den Bos (Inspection Board, State Inspectorates)
- *ir.* M.P. Cuijpers (*LTO*, *primary sector*)
- ir. N.F.J. Hendriks (NVCi, certification and inspection bodies)
- *ir.* J.J.N.M. Hogeling (VNO-NCW, industry)
- mr. A.M. Jonk (Ministry of Economic Affairs and Climate, ministries)
- R. Karel ('Fenelab', laboratories and inspection bodies)
- ing. G.J.W. Kerkman (Dutch Association of Insurers, non-life insurers)
- dr. P. van der Knaap (SWOV, public sector regulators)
- dr. H.C. Ossebaard (Dutch National Health Care Institute, standardisation)
- dr. M.W.H. Pieksma a.i. (VSL, metrology)
- *ir.* F.W. Stuyt (VvS, scheme owners)
- *ir*. R.H. van Terwisga (NEN, standardisation)

User Council

- ir. J.C. van der Poel (RvA, Chair)
- dr. S.M. Bruisten (medical laboratories)
- B. van Doorsselaere, (VEROCOG)
- dr. B.G. Hepkema (medical laboratories)
- S. ter Horst (NVCi)
- R. Karel (Fenelab)
- dr. B.M.A. Kroon (Fenelab)
- 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 Statutes as well as pursuant to European Regulation 765/2008. Our independence is assured in the Dutch National Accreditation Body Appointment Act (*Wet aanwijzing nationale accreditatie-instantie'*) and by a modern governance structure with the Board of Supervisors, the Accreditation Committee, the Chairmen Committee for

Objection, the Advisory Panel of Stakeholders, and the User Council. We also assure our independence by a healthy capital position. This is why we are resilient to financial risks which might arise, for instance if conformity assessment bodies would decide to terminate the accreditation.

ANNUAL ACCOUNTS

The figures below have been taken as a summary from the adopted annual accounts for 2018. No rights can be derived from them. You can download our full annual accounts via our website (www.rva.nl) or request them from us by telephone number +31 30 239 45 00.

Following a private tender we awarded the contract for the annual financial audit and the verifications of the subsidies as of the financial year of 2018 to the auditing firm Mazars. This means that Mazars succeeds KPMG as the external financial auditor of the BvA.

PROFIT AND LOSS ACCOUNT (X €1,000)

Result	Budgeted 2018	2018	2017
Net turnover	14.223	14.595	14.618
Expenditure			
Personnel	8.457	8.161	8.067
Costs of outsourced work (incl. travel and accommodation costs)	4.423	4.853	5.032
Depreciations	139	124	132
Other expenses	1.374	1.277	1.243
Total expenditure	14.393	14.415	14.474
Balance of income and expenditure	-170	180	144
Interest income	12	2	7
Result*	-158	182	151

^{*} For the budgeted result a withdrawal of 180,000 euros from the fund for special purposes has been taken into account in the budget.

From the result 170.000 euros will be added to the fund for special purposes. The remainder will go to the equalisation

accrual (10,214 euros) and to the other reserve (1,287 euros).

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

Assets	2018	2017
Fixed assets	373	491
Receivables and transitory assets	3.797	3.365
Liquid resources	3.532	3.661
Total	7.702	7.517
Liabilities	2018	2017
Equity capital	4.208	4.026
Provisions	36	115
Short-term debts and transitory liabilities	3.458	3.376
Total	7.702	7.517

The capital requirement was recently evaluated in 2014 and will be re-evaluated in 2019. Partly considering the status of the RvA which changed in 2010 into an autonomous administrative authority, it was decided to maximize

the target buffer capital (equity capital -/- reserve for special purposes) in the coming years to 4 million euros. The amount of the buffer capital at year-end 2018 amounts to 3,809,804 euros; at year-end 2017 this was 3,798,303 euros.

RATES

The starting point is that the rates are increasing on average – subject to special circumstances – by the CBS index for business services at most. In 2018 we increased the annual contribution for the initial registration by 1.1%. The rate for subsequent registrations has been increased by 4%. This means that the difference between both rates has

been further reduced. Eventually these rates would have to be equal, regardless of the number of registrations. We adjusted the daily rate for assessors, determining the lion's share of our income, by 1.5%. The next table represents the rate development.

Rate development	2018	2017
CBS index for business services	1,6%	1,3%
Rate of (lead) assessor	1,5%	1,4%
Rate of technical expert	1,5%	1,4%
Annual contribution of initial registration	1,1%	0,3%
Other rates on average	3,0%	1,4%



Dutch National Accreditation Body Appointment Act and a modern governance structure.

ANNEX 3

Our work in figures

onfidence also requires the possibility of controls. In this Annex you will find an overview in figures of our

activities in 2018. In several cases we also added previous figures for comparison.

ACCREDITATIONS GRANTED AT 31 DECEMBER 2018

Standard	Explanation	Netherlands 2018	Abroad 2018	Total 2018	Netherlands 2017	Abroad 2017	Total 2017
CERTIFICATION							
ISO/IEC 17065	Products and services	47	3	50	45	3	48
ISO/IEC 17021	Management systems	44	17	61	45	19	64
ISO/IEC 17024	Persons	5	0	5	5	0	5
Subtotal certification		96	20	116	95	22	117
INSPECTION							
ISO/IEC 17020	Inspection	128	1	129	129	2	131
Subtotal inspection		128	1	129	129	2	131
LABORATORIES RV	A-MARK						
ISO/IEC 17025	Calibration	57	0	57	55	0	55
ISO/IEC 17025	Testing	242	7	249	245	8	253
ISO/IEC 17043	Proficiency testing	14	1	15	15	1	16
ISO 15189	Medical laboratories in MLA	210	5	215	170	5	175
ISO Guide 34	Reference materials	2	0	2	2	0	2
Subtotal laboratories		525	13	538	487	14	501
ISO 14065	EMAS/Emission	4	1	5	4	1	5
(EC) Regulation Nr. 1221/2009 (EMAS)	EMAS Verification	0	0	0	1	0	1
Total RvA-Mark		753	35	788	716	39	755
Laboratories CCKL mark							
${\tt CCKLCodeofPractice}^*$	Medical laboratories	22	0	22	70	0	70
Total number of accred	itations granted	775	35	810	786	39	825

 $^{^{}st}$ These accreditations fall beyond the scope of the autonomous administrative authority.

GEOGRAPHICAL SPREAD OF THE ACCREDITATIONS GRANTED PER ANNUM

	2018	2017	2016
Netherlands (autonomous administrative authority 'ZBO')	753	716	645
Rest of Europe*	4	4	3
Rest of the world	31	35	38
Total	788	755	686

^{*} At the request of the local accreditation body.

COMPLETE APPLICATIONS FOR NEW ACCREDITATIONS RECEIVED PER ANNUM

	2018	2017	2016
Initial*	42	83	94
Scope extension	224	249	272
Total	266	332	366

^{*} Including the ISO 15189 transition applications.

NEW ACCREDITATIONS PER 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	2018	2018	2017	2017
Certification	5	332	7	247
Inspection	6	304	5	149
Calibration laboratory	4	291	2	337
Test laboratory	5	343	12	305
Medical laboratory	49	332	66	339
EMAS/Emission	0	0	1	61
Other	0	0	1	309
Total	69	328*	94	314*

^{*} This is a weighted average.

Of the 69 new accreditations (including transitions from CCKL to ISO 15189) sixteen applications 3 had a processing time of over twelve months. This was the result of the following:

- In seven cases⁴ the client needed more time to resolve *non-compliances* or to relocate the premises or to merge.
- In eight cases⁵ the RvA had insufficient assessors or technical experts or had them too late, three of these were the result of the death of one of our broadly deployable lead assessors.
- One case related to a development process for a new activity with which hardly any experience existed elsewhere in the world. This was done in proper consultation with the applicant.

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

	Extension	Average processing time in calendar days	Extension	Average processing time in calendar days
Decision in	2018	2018	2017	2017
Certification	60	232	55	210
Inspection	10	222	32	87
Calibration laboratory	6	279	6	232
Test laboratory	120	117	123	128
Medical laboratory	29	220	17	245
EMAS/Emission	1	169	1	104
Other	1	177	4	78
Total	227	170*	238	151*

^{*} This is a weighted average.

Of the scope extensions dealt with \sin^6 had a processing time of over twelve months. This was the result of the following:

³ In 2017: eight applications.

⁴ In 2017: four cases.

⁵ In 2017: four cases.

[•] In four cases⁷ the client needed more time to resolve *non-compliances*.

[•] In two cases⁸ the cause was particularly attributable to the RvA.

⁶ In 2017: eight applications.

⁷ In 2017: six cases.

⁸ In 2017: two cases.

DISTRIBUTION OF THE INVOICED TIME OVER THE TYPE OF ASSESSMENT

Type of assessment	2018 (total no. of days 8.680 = 100%)	2017 (total no. of days 8.817 = 100%)	2016 (total no. of days 8.075 = 100%)
Initial assessment	5%	5%	5%
Expansion	7%	8%	7%
Re-assessment	17%	23%	18%
Surveillance assessment	51%	43%	45%
Witness audit	10%	10%	8%
Transition to ISO 15189	10%	11%	17%
Total	100%	100%	100%

DISTRIBUTION OF THE INVOICED TIME, BROKEN DOWN BY ROLE IN THE ASSESSMENT TEAM

Role	2018 (total no. of days 8.680 = 100%)	2017 (total no. of days 8.817 = 100%)	2016 (total no. of days 8.075 = 100%)
Lead-assessor	45%	44%	45%
Assessor	11%	10%	8%
Technical expert	44%	46%	47%
Total	100%	100%	100%

DISTRIBUTION OF THE INVOICED TIME, INCLUDING THE ASSESSMENT OF CORRECTIVE MEASURES AND WITNESS AUDITS

Input	2018 (total no. of days 8.680 = 100%)	2017 (total no. of days 8.817 = 100%)	2016 (total no. of days 8.075 = 100%)
On site at the client	47%	47%	50%
Preparation/report	50%	50%	48%
Travel abroad	3%	3%	2%
Total	100%	100%	100%



DISPUTES, SUSPENSIONS AND WITHDRAWALS

A *dispute* is a difference of opinion between the assessed party and the RvA assessor concerning the interpretation of the standard requirements. Bodies may temporarily lose their accreditation if it becomes apparent that they no longer meet the set standards. This will be a *suspension*. In that case they are given six months to implement the necessary improvements and to have them assessed. It

may also be the case that bodies lose their accreditation permanently. This will be a *withdrawal*: the accreditation agreement will then be terminated. Suspensions and withdrawals are voluntary or imposed. In both cases the body is no longer allowed to use the accreditation mark for the respective activities.

DISPUTES

At year-end	2018	2017	2016
Total number of disputes	60	88	89
Non-conformities reformulated by lead assessor after consultation	7%	0%	0%
Non-conformities withdrawn by lead assessor after consultation	13%	0%	0%
Non-conformities maintained without any changes	27%	17%	28%
Non-conformities maintained, but reformulated	10%	19%	20%
Non-conformities (partly) withdrawn	25%	18%	30%
Other outcome of the dispute	3%	0%	1%
Being processed	12%	18%	7%
Inadmissible	3%	28%	14%
Total	100%	100%	100%

SUSPENDED ACCREDITATIONS (FOR THE ENTIRE SCOPE)

Accreditation category	Voluntary 2018	Imposed 2018	Total 2018	Voluntary 2017	Imposed 2017	Total 2017
Certification	1	0	1	0	1	1
Inspection	1	0	1	0	6	6
Calibration laboratories	1	0	1	2	0	2
Test laboratories	4	0	4	1	2	3
Medical laboratories	0	1	1	0	1	1
Other	0	0	0	0	0	0
Total RvA mark	7	1	8	3	10	13

SUSPENDED ACCREDITATIONS (FOR PART OF THE SPHERES OF WORK)

Accreditation category	Voluntary 2018	Imposed 2018	Total 2018	Voluntary 2017	Imposed 2017	Total 2017
Certification	0	1	1	0	1	1
Inspection	0	0	0	0	0	0
Calibration laboratories	1	0	1	0	0	0
Test laboratories	0	0	0	0	0	0
Medical laboratories	0	0	0	0	0	0
Other	О	0	0	О	0	0
Total RvA mark	1	1	2	0	1	1

WITHDRAWN ACCREDITATIONS (FOR THE ENTIRE SCOPE)

Accreditation category	Voluntary 2018	Imposed 2018	Total 2018	Voluntary 2017	Imposed 2017	Total 2017
Certification	3	0	3	7	0	7
Inspection	6	1	7	2	1	3
Calibration laboratories	1	0	1	2	0	2
Test laboratories	7	0	7	9	0	9
Medical laboratories	5	0	5	2	0	2
Other	2	0	2	1	0	1
Total RvA mark	24	1	25	23	1	24

WITHDRAWN ACCREDITATIONS (FOR A PART OF THE SPHERES OF WORK)

Accreditation category	Voluntary 2018	Imposed 2018	Total 2018	Voluntary 2017	Imposed 2017	Total 2017
Certification	1	0	1	1	0	1
Inspection	1	0	1	0	0	0
Calibration laboratories	0	0	0	1	0	1
Test laboratories	6	0	6	2	0	2
Medical laboratories	29	0	29	12	0	12
Other	О	0	0	0	0	0
Total RvA mark	37	0	37	16	0	16

These are the most common reasons for withdrawal:

- The activities no longer had to be carried out under accreditation or the body no longer carried out the activities (ten times).
- The client could not or did not want to comply with the policy rules of the RvA (for instance due to insufficient staff, not lifting a the suspension or non-payment of the invoice; seven times).
- There was a merger or take-over of activities by another organisation (six times).
- There was a transfer to another/local accreditation body (twice).

Our lead assessors and assessors follow specific courses and training, and regularly hold harmonisation consultations, enabling them to improve continuously.



We make sure that your confidence in products and services is justified.

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