

### 10 years of ENAC clinical laboratory accreditation with the ISO 15189 standard

All throughout these years ENAC has deployed a wide range of activities for developing this accreditation scheme, as well as participating in international work groups and collaborating with scientific societies of all disciplines.

It has already been more than 10 years since the first version of the UNE-EN ISO 15189 standard in 2003. This standard came about in order to cover the existing demand among professionals in clinical laboratories around the world to have a specific rule that looked at requirements for demonstrating competence. Clinical laboratory professionals of all disciplines participated in preparing it, taking the ISO 17025 and ISO 9001 standards as reference. The UNE-EN ISO 15189 standard includes all the pre-analytic, analytic and post-analytic processes of a clinical laboratory, and is especially focused on the patient as a central pin of clinical laboratory activity.

The first major revision of the standard was published in 2012 (there had been one minor revision in 2007). The Spanish version was published in 2013 (UNE - EN ISO 15189:2013). This new version, without including major changes to requirements, makes its contents clearer as well as being better structured, so making it easier to interpret and implement them in clinical laboratories. It is worth noting that a new requirement, risk management has been included focusing specifically on patient safety.

All throughout these years, ENAC has deployed a wide range of activities for developing this accreditation scheme. So, in addition to participating in international activities (participating in EA and ILAC working groups to ensure homogeneity among accreditation bodies), ENAC has promoted collaboration with scientific societies of all disciplines as a way of incorporating the highest level of technical and professional knowledge into the accreditation processes.

Collaborating with companies has been very fruitful and enriching. Notably, from among many other activities, participating in preparing some of the documents developed for this scheme (CGA-ENAC-LCL, general criteria of clinical laboratory accreditation, NT-48, clinical laboratories accreditation scope), support in circulating these documents, the standard and the accreditation process in general (with ENAC participating in more than 70 conferences and external courses) and information on technical experts; candidates acting in ENAC's evaluation process (until December 2014, 190 professionals had been trained as technical experts in the UNE-EN ISO 15189 standard in ENAC).

Currently, the introduction of accreditation is uneven within our European environment. The number of countries is increasing where the health authorities require clinical laboratory accreditation either for all of their activities or for some disciplines or specific tests.

In Spain, the Ministry of Health has recently made accreditation a requirement for new-born screening laboratories wishing to be designated as Reference Centres (CSUR).

In this context, the number of accredited laboratories varies between countries, the obligatory nature logically being a determining factor but so is the history of accreditation in that country. Also the situation of countries where accreditation is not required, but have a very high

number of accredited laboratories, and a large percentage of their activity is carried out under accreditation. As is the case in Sweden and Finland which initiated clinical laboratory accreditation at the beginning of the 90s.

In Spain, according to the UNE-EN 45001 standard, the first laboratory accreditation was awarded to Bilbao Public Health Laboratory Standard in 2000 for new-born screening tests, the first accreditation according to the UNE-EN ISO 15189 standard occurred with accreditation (in 2005) to this same laboratory and the first hospital laboratory, to the A&E Laboratory of the La Paz University Hospital.

At the moment, 46 clinical laboratories are accredited by ENAC with accreditation scopes already covering all areas and 23% of these laboratories are for flexible scope. Currently a number of laboratories are in the accreditation process and it is foreseeable that in the coming years most clinical laboratories will opt for accreditation, a situation similar in neighbouring countries.

## The sector's opinion

*Answers agreed by the Spanish Association of Medical Bio-pathology (AEBM), the Spanish Association of Pharmaceutical Analysts (AEFA), the Spanish Society of Clinical Chemistry and Molecular Pathology (SEQC) and the Spanish Hematology and Hemotherapy Association (AEHH)*

*How has the introduction of the ISO 15189 standard affected accreditation in clinical laboratories?*

The complete character has been positive. The ISO 15189 standard, although in need of perfecting, represents a conceptual change that really makes the concept of the quality of laboratory professionals traceable using the criteria that accreditation bodies consider necessary. Undoubtedly, in complying with the specific clinical laboratory requirements of the ISO 15189 standard, the laboratory professional is able to objectively self-assess that the overall process functions correctly and can move towards providing excellent service (report of the results of analytical applications for patients).

**There are no known exhaustive studies about the effect of this rule in Spain. However in the 2012 survey by the Quality Specification Experts' Committee of AEFA, AEBM and SEQC, the laboratories accredited by the ISO 15189 standard showed a more pronounced profile for good practice standards than others.**

Although the number of accredited laboratories in Spain to date is much lower than that of other European countries, the entire process of training, learning and gaining the standard per se, represents a substantial improvement in the quality of laboratories.

*Do you think that laboratory accreditation is valued by the health authorities, the contractors and by the clients?*

Not as it should be. For Health authorities there is a general lack of knowledge about the details of the standard, as the confusion with the certification and accreditation terms proves. And except in some very specific cases, it is an initiative made from the laboratory to the management rather than the other way round. More often than not it is seen as an expense or

tolerated as a marketing, rather than quality, element. When a clinical laboratory decides to introduce ISO 15189 standard accreditation, and does not initially have the support or commitment of the hospital or facility's management and executives, it inevitably fails. Therefore, it is fundamental and vital that the management and executives are totally on board with the accreditation and assessment of technical competence in the laboratories and of laboratory personnel. The reality is that introducing a quality management system according to the ISO 15189 standard, carries important investments, both in material resources as well as human. These are not totally to the "liking" of management, because of the pressure they experience and pass on to us due to the current environment of cutbacks in which we find ourselves. In addition to the problem of economic cost, with few exceptions, health authorities do not consider ISO accreditation to be a strategic objective of clinical laboratories. This view is most evident in the Autonomous Communities (CCAA) which have their own clinical laboratory quality certification procedures. In these Autonomous Communities, when it is time to provide resources to laboratories to set up a quality management program, their own certification takes precedence over the ISO accreditation. And, in keeping with this policy, there are sometimes marked differences in the scales used to assess laboratories and their professionals, prioritizing their own certification over the ISO accreditation.

**An institutional work is necessary to inform society of how important knowing and using the ISO 15189 standard accreditation criteria is for choice and confidence in health centres and laboratories. Assessing laboratories' technical competence, as a body and their personnel, to carry out activity will be strictly needed to move towards excellence and achieve customer satisfaction (clinical physicians and patients).**

Another different perspective is how accreditation is valued by customers and contractors of services offered by clinical laboratories. These are positive at all times. Customers favourably valued accreditation as it directly affects the quality of the services offered by the laboratory and patient satisfaction. The service contractors, currently include this concept in their surveys of assessment criteria and positively value the fact that the laboratory is accredited by the ISO 15189 standard.

**In future, it is a criterion that will be required by all laboratories to contract their services. If you compare the situation in other countries, such as France or Germany, where authorities already require clinical laboratory accreditation, in Spain the authorities should be able to demand accreditation requirements in the not-too-distant future.**

*Has accreditation had some effect on the scientific community?*

Undoubtedly there has been a significant effect. The scientific community has created specific groups/committees/commissions to address the requirements of the ISO 15189 standard. Documents with recommendations have been developed to help professionals set up the ISO 15189 standard, as well as different formative and informative actions to publicize the standard, both at the level of each particular society and at the level of setting consensus between different societies through congresses, symposiums, conferences, and so on.

It is common to receive inquiries by professionals in order to resolve doubts about the standard and the accreditation process. Also scientific societies have taken this fact into account when defining their policies of continuous education, conferences and External Quality Supervision Programs.

### *What role does the scientific community play, and must play, in laboratory accreditation?*

It plays an essential role at the standard's integration level concept and at the training level in specific aspects or areas. It has created Guides with recommendations, provided training, offered information and resolved technical issues regarding accreditation. And as the practice has demonstrated, collaboration between societies on these issues should be a clear goal. The scientific societies: SEHH, SEQC, AEBM and AEFA are part of the AENORCTN 129 Committee - IN VITRO DIAGNOSTIC AND CLINICAL LABORATORY SYSTEMS, and is co-partner for developing the standard and giving explicit support.

ENAC exerts the role of orthodoxy in relation to the standard, by ensuring it is rigorously upheld, even if the reality is sometimes complex and difficult to adjust to the standard. Then, the societies, made up of specialists, are capable of detecting application problems and so propose alternatives to their own professionals and propose interpreting or applying different criteria to the standard. It is good that we are separate bodies; because of the independence of criteria with a common goal, great benefits can be obtained for clinical laboratories in this country. Well-applied technical discrepancies and differences are a source of improvement.

In conclusion the role and prominence of the scientific community will be key. Members of the scientific societies are professionals who can help ENAC prepare guidelines and recommendations for later circulation.

### *What do you consider should be the collaboration between scientific societies and ENAC?*

At this point we must thank ENAC for its initial approach to conducting meetings and building bridges between the scientific societies. The three societies AEBM, AEFA and SEQC, along with the SEHH have maintained a good relationship. It may be time to review this relationship and enhance it. From the understanding that we are different, independent bodies, with our own not always compatible or adjustable criteria, but with a common mission: excellence in the performance of clinical laboratories in Spain. There is more that unites us, than can at any time keep us apart. It is the obligation of those in charge of the scientific societies and ENAC to prioritize the mission in specific situations and to define a level of collaboration for health-oriented results.

A two-way relationship of constant cooperation must be established between the scientific societies and ENAC regarding accreditation, to promote improved understanding and to ease the introduction of the EN ISO 15189 standard for clinical laboratories. Cooperation must be firmly established through regular meetings, consultations, preparing of joint papers, informative sessions, workshops, and so on.

## **Interview with Dr. Antonio Buño. Head of Analysis Service - La Paz Clinic University hospital (H. U. La Paz)**

### **How has the introduction of the 15189 standard affected laboratory activity?**

Remembering a bit of history, the La Paz University Hospital's A&E laboratory obtained certification by the ISO 9001:2000 standard in 2003, Dr. Teresa Contreras led the project and remained in charge of the laboratory which was then taken over by Dr. Felicitas Mateos. Already at that time, there was a culture of quality management beyond the traditional concept of quality in the laboratory. In 2005, when we opted to take the step to accredit the

technical competence of the laboratory's activities, we started from an advantageous position as the standard's management requirements were already practically in place after a few years of experience. Since the beginning, we knew that we had raised the bar and were convinced that we would be able to succeed, a fact that time has shown to be true. Every beginning is always difficult and more when we did not have anyone to 'copy' from or to ask, given that we were the first laboratory to achieve this in November 2005, 9 years ago. At the beginning, certain concepts were hard to fix in the daily routine, especially in the case of a 24-hour laboratory that always has to deal with added difficulties. But over time, I can say that we have won with our safe procedures, we are more organized and predictable, and uniform in our responses to any unexpected event or incident.

**All this obviously results in a better patient care service which is undoubtedly the true motivation for our work and that has been the main benefit provided by accreditation.**

At the end of 2009, after four years of experience, we decided to expand the range of high resolution laboratory activities for patients with kidney disease in the A&E laboratory, as well as the Service's extraction unit and part of the pre-analytic area. It was an extension of knowledge, methods and ways of acting that we recognized to be good and positive in other areas. Over time we were again the first to obtain accreditation through flexible scopes which, as its name suggests, refers to the flexibility of allowing newly-added activities into the portfolio of services in order that we can benefit from the good things that accreditation has done for technical competence.

I must admit that the rest of the Service's activities still not under the accreditation scope are an important part of the work under the influence, if I may use the expression, of the ISO 15189 standard. The Service's know-how should be used by other areas that can benefit, not only inside the Service, but for other Services and clinical laboratory Units in the hospital.

**I also think that it has assumed an outstanding reputation for the Hospital and, without a doubt, the Service has had positive consequences besides assistance, in areas of teaching and research, both important development facets in the Hospital.**

**What benefits brought by the ENAC accreditation would you highlight?**

I think you can group the benefits obtained by accreditation in 4 dimensions. Benefits for our customers understood as both clinics and patients, organizational benefits for the institution, benefits for workers and economic benefits.

In relation to the first dimension, and as previously stated, it has provided us with safety and uniformity in our actions. Helped no doubt by the fact that the results and reports issued from the laboratory are more reliable contributing to less errors and complaints due to better laboratory procedure management. I would stress a lot that we have worked throughout these years on everything related to the quality control of the analytical phase and on greatly improving the quality of the results. It has almost become a genuine profession and it is undeniable that it has clearly affected the better patient care. Likewise regulated assessments following protocols recognized internationally as CLSI (Clinical and Laboratory Standards Institute) for method and validation assessment before issuing any patient results, also brings clear benefits in this dimension.

Another indisputable benefit is the clinical services' increased confidence in the laboratory. It has contributed to the long-standing laboratory coming together with all the services, hallmark

of our teacher Dr. Felicitas Mateos, also made easier by the decentralization gasometrics project (point-of-care-testing) led by the same A&E laboratory.

In terms of the benefits it can bring to the institution, we could consider the contribution of a useful response time that has improved the organization of some services, mainly the emergency services, day hospitals such as the Oncology one and critical patients' units. A useful response time clearly affected the activity of these services, and provided monitoring for this indicator as well as many improvements after the ISO 15189 standard was introduced. It is certainly one hallmark of our activity, all without being detrimental to quality results.

In terms of the benefits that the standard can provide for personnel working in the laboratory, being aware that is the most important heritage we have, I would stress first of all a higher technical level and knowledge thanks in part to the established qualification, assessment and continuous training procedures carried out at the heart of the ISO 15189 standard. They know that they are competent, as the standard suggests, for the work carried out. This gives them safety, confidence and outcomes in improving the quality of the results. A lot of effort has been made to improve the working climate taking into consideration, as I mentioned before, the difficulties involved in a laboratory with 3 continual work shifts. Technical and medical staff working in an orderly environment, with well-organized tasks where nothing is subject to improvisation and this again leads to a better service for our patients.

Finally, in economic terms, although it involves a disbursement by means of direct costs for items such as record maintenance or document management systems, and still not being possible to document it objectively, my opinion is that it contributes clearly to saving material resources, optimizing human resources and rationalizing the physical spaces. Improvements in purchased product controls, expiration date controls or regulated preventative maintenance of analysers provide better use of resources. Furthermore, regular monitoring of the performance of all the purchased items. Better staff training about analysers decreases the percentage of unnecessary repetitions, calibration errors of measurement methods or incorrect actions depending on results of analytical quality control.

#### **Do you consider that accreditation is sufficiently valued by health authorities and users?**

The answer to this question in my opinion is a clear no. Firstly, because the clinical laboratory believes that in regards to the public it is a relatively transparent area within health organizations. Patients have contact from the time of sample taking, basically giving blood, but they are unaware of how the laboratory is operated and organized. The clinical services in general also do not know how we work except in specific specialties and in certain areas. I have always argued that an important part of the responsibility for this situation is ours given that we have failed to get close enough to our partners or establish collaborations at the scientific society level. On this basis, the laboratory quality management systems are even more unknown. One example is that, in the opinion of many people, concepts such as certification and accreditation are quite comparable and are used interchangeably. In our experience, almost the only time when we are asked or required for these matters is when asked to provide so-called quality certificates at the heart of clinical trials.

At the health authority level I believe that, apart from exceptional situations in our country such as what occurred in Aragon where again ignorance was widespread, both for the current situation and differences in concepts. Despite the fact that in the clinical laboratory, we have years of advantage in relation to other clinical specialties in everything to do with concepts of quality and quality management systems, this is what we have not been able to make valued. I

think that many specific efforts have been made, but there is a lack of planning at the health authority level in this regard and I suppose also of recognizing and assessing the pluses an accredited laboratory can provide for the care of patients.

I think it is important to highlight also international recognition. The scenario whereby this advantage can positively affect our daily life is in principle remote, however, without a doubt it can be an added advantage to be able to demonstrate technical competence through compliance with the requirements of the standard in the international environment. We have had some examples while participating in international multi-centre studies that have shown what it means to make determinations in an accredited laboratory.

### **How do you rate these 9 years as an accredited laboratory?**

Well, without a doubt the assessment is very positive in general. As I have said previously, achieving accreditation by the ISO 15189 standard was a big effort in 2005. But no less important is the effort carried out to maintain this achievement over the years, having even expanded its scope in 2009. It has without a doubt helped the backbone of laboratory activity and has decisively improved the workers' scientific and technical quality and therefore can be seen in the patients' results and reports. It has also led to a reputation that we are certainly proud of.

This huge task was initially led by Dr. Teresa Contreras and in the last 8 years by Dr. Pilar Fernandez Calle, both as quality coordinators of the service. I have to thank them both for their work and also for the efforts of many other people over these 9 years.

I would also like to point out that over the years, from a teaching point of view, there are many professionals who have had the opportunity to train in our Service, our own residents and from other hospitals who have come specifically to see first-hand how to work in a laboratory accredited by the ISO 15189 standard. This has enabled us to pass on some specific culture, vocabulary and best practices to these professionals which, as in any case we know, have been taken to other centres.

### **What do you consider to be the challenges facing clinical laboratories in the future?**

The clinical laboratory has experienced great progress and development in recent years, on one hand due to important technological and automation advances, and without a doubt it has also been influenced by the economic constraints which we are subjected to. The changes experienced by society such as an aging population, increased immigration or a change in the pathology profile to study, together with the need for a sustainable health care system have no doubt influenced the new laboratory organization models. As some authors have expressed, the Darwinian evolution of the laboratory moves towards more integrated and consolidated processes. Improving our efficiency by creating laboratory partnerships, integrations and networks by taking advantage of information technology will be necessary but not enough to guarantee success.

We must apply ourselves to get more involved in creating, applying and distributing the laboratory's knowledge for proper patient care. We have to worry more about an efficient use of laboratory testing and less about the numbers. It should be an absolute objective to optimize relations with different clinical services which act as real consultants both for proper test application and their correct interpretation. Therefore, we have had to provide added

value that enables the laboratory, in the words of Dr. Fernando Cava, to become a "value-atory" instead of a "result-atory".

On the other hand, carrying out testing beyond the confines of the laboratory will be a safe growth area. Everything about point-of-care-testing shall be more highly developed than it presently is. The laboratory has to lead projects that assist in its proper development, being clear that our contribution can clearly impact the patient.

New emerging technologies such as mass spectrometry must gently incorporate clinical laboratories with welfare purposes and we will have to learn how to transfer this knowledge to clinical practice. The laboratory's role in personalized medicine, genomics and so-called other "omics", will also be safety development areas. It is certainly desirable that these activities could be performed with the highest scientific and technical quality and it is here where standards such as the ISO 15189 should encourage us and help us to provide the best patient service.

In short, it is a world of challenges and opportunities. As Winston Churchill said, a pessimist sees difficulty in every opportunity, and an optimist sees opportunity in every difficulty. I hope that we know how to be cleverly optimistic and seize the opportunities that we have before us with the clear objective of positively affecting the health of the population.

## **Interview with Begoña Cristeto, the Secretary General of Industry and Small and Medium-sized Businesses**

**"ENAC is a trusted partner of the Administration availing a set of safe, reliable, and competent assessors on issues that directly affect public safety"**

**In your opinion, what role do accreditation and ENAC play in improving the competitiveness of Spanish companies?**

Accreditation is an important tool in the processes of competitiveness and internationalizing industry. So, both the Governments of Europe and the rest of the world have understood that accreditation is the best means to ensuring the products and services that companies put on the market are reliable and secure.

Using assessors accredited by ENAC provides businesses with confidence in the technical capacity of these organizations, knowing that they have been assessed through a rigorous process based on international standards.

The ENAC mark is a guarantee that an assessor is technically competent to carry out the task in Spain and in the 70 countries which recognize and accept the mark, thanks to the Recognition Agreements signed by ENAC and their accreditation bodies.

ENAC's accreditation brings the added trust needed for companies to operate unfettered in the national and international market.

If companies opt for an accredited assessor, it will decrease the risk of possible litigation as they can demonstrate that they have used assessors internationally accepted as competent, it will reduce paperwork (there will still be a need to audit companies or test their products in



new markets) and it will increase its differentiation and leadership in the market by showing credible evidence of good practices.

*Since the start, ENAC's relationship with the Administration has been very close, how do you value this relationship?*

The Administration increasingly sees ENAC and accreditation as a tool for implementing its policies. Certain control tasks that have traditionally been carried out by public authorities have been delegated, for various reasons, to external organizations. Accreditation being, in these cases, an indispensable prerequisite to ensuring the competence and integrity of the organization for the work entrusted to it. Currently, ENAC accreditations are demanded or accepted in numerous areas of the Administration, both centrally and regionally in very different sectors (industrial safety, drinking water quality, environmental control, official food control, etc.)

Collaboration is close and fruitful. ENAC is a trusted partner of the Administration availing a set of safe, reliable, and competent assessors on issues that directly affect public safety, it is a support to its management and transparently simplifies administrative procedures with full international recognition.

*Last July the Council of Ministers approved the Agenda for strengthening industry in Spain, What does it consist of and how is the Secretariat involved?*

The Agenda consists of a set of specific and well-defined action proposals, carrying them out in the short term will enable the conditions which develop industrial activity in Spain to be improved thereby helping industry to grow, be competitive and increase its weight in the GDP.

This Agenda includes the Ministry of Industry, Energy and Tourism's conduct as well as other ministerial departments and public bodies, aimed at making the business environment more favourable to developing our industrial fabric.

It is in line with the 2014 National Reform Programme and the Government's economic agenda and brings together industry's most relevant actions for the Plan of measures (for growth, competitiveness and efficiency) approved by the Government in order to boost present and future growth and competitiveness of the economy and business financing.

The Agenda is made up of 97 measures, grouped around ten lines of action, and structured into three main blocks depending on its scope and sphere of action.

In this way, it is possible to distinguish between actions aimed at the national level, international actions and transversal actions.

It is necessary to point out that currently the 70 measures have already started, which certainly shows strong momentum being carried out in this field.

*What support may be provided by ENAC's accreditation here?*

The ENAC accreditation is an important tool for opening up foreign markets. It represents an unquestionable support for Spanish companies in order to help them overcome technical

trade barriers, derived constraints from the lack of recognition for certificates or approvals obtained in Spain, among other aspects.

Certificates marked ENAC will not have any problem being accepted and recognized in all EU countries thanks to the Recognition Agreements which ENAC has signed with its respective bodies in other countries. This acceptance also exists outside the European Union, thanks to the Multilateral Recognition Agreements at the heart of international accreditation organizations. There is no doubt that ENAC's accreditation constitutes a "Passport" which eases access to markets.

### **Professional career**

Begoña Cristeto Blasco graduated in business and economics from the Autonomous University of Madrid in 1984. She belongs to the Technical Trade and State Economists' Body.

She has been delegated Minister to Enisa and to Invest in Spain, General Secretary of the Spanish Agency of International Cooperation for Development and Economic and Commercial counsellor in Spain's Economic and Commercial Office in Miami during the period 2000-2004. Previously, she served as Executive Director for the Centre for Establishment, Support and Communications of the Economic and Commercial Office Network, and Director of the Information Systems Division of ICEX.

She has served on the following boards of Directors: Mercagalicía, Mercamadrid, Mercasa, IFEMA, ICEX, Invest in Spain, SEPI, CDTI, ENISA, Navantia.

She is currently the Secretary General of Industry and Small and Medium-sized Businesses, in the Ministry of Industry, Energy and Tourism.

*“The ENAC accreditation brings the added trust needed for the company to operate unfettered in the national and international market”*

*“The Agenda, which is made up of 97 measures, will help industry grow, be competitive and increase its weight in the GDP”*

## **Metrological traceability: guaranteeing reliability of measurements**

*ENAC is developing a series of actions targeting calibration laboratories and their clients, as well as certification bodies all aimed at bringing clarity to the market and making it easier for calibration users to be able to discriminate between those calibration certificates that guarantee metrological traceability and those which do not.*

Companies need to be certain that the results their measuring equipment provide them with are correct, since they are usually employed in key activities such as quality control and process, product or service safety, in order to have the necessary information to analyse correctly and make informed and technically justified decisions.

If the results of these measurements are unreliable, mistakes can be made, products or services can be offered which do not meet designed specifications that the client requires, or is

not in accordance with certain regulatory requirements. Therefore, it is necessary to have strict controls of measuring equipment and these must include an adequate use and maintenance and undergo a calibration plan which guarantees metrological traceability.

Metrological traceability is based on a continuous and documented chain of calibrations using measurement procedures that enable the results to relate to a reference (in general, to the corresponding unit in the International measurement System, IS) and with a measurement uncertainty.

For the calibration sequence to be effective, each of the calibrations should:

- have been carried out by staff with the necessary training and technical qualification;
- have been carried out with equipment ensuring the proper state of calibration and maintenance.
- have been made with an appropriate measurement uncertainty for the purpose;
- be documented so that all the necessary information is provided clearly.

In short, each of the calibrations should have been developed with the necessary technical competence, in an internationally recognized way to ensure the calibration performance's technical competence is compliant with the ISOIEC 17025 standard as well as with accreditation, the guarantee of compliance.

Obviously the fact of guaranteeing metrological traceability, with the breadth of topics and with all established requirements, could not be practiced satisfactorily without an efficient and global support structure.

This structure consists of the following bodies, procedures and agreements established over time:

- The International Bureau of Weights and Measures (BIPM), which has the mission of establishing worldwide measurement uniformity, the General Conference of Weights and Measures, which has overall responsibility for the International System of units (SI), which is maintained by the International Committee of Weights and Measures (CIPM);
- The National Metrology Institute (NMI) of each State (in Spain the Spanish Metrology Centre and its associated laboratories) which perform, maintain, perfect and circulate the international system's units which fall under such international organizations as the International Committee of Weights and Measures (CIPM), the framework which unambiguously shows the equivalence between the realizations of IS units in the various National Metrology Institutes.
- National Accreditation Bodies (in Spain, ENAC), which accredit the technical competence of calibration laboratories in accordance with the international ISOIEC 17025 standard.
- The international organizations of accreditation bodies: EA in the European case and ILAC worldwide enable mutual recognition of accreditations and, therefore, of the calibration certificates accredited by the signing of Multilateral Recognition Agreements (ILAC MRA).

- The accredited calibration laboratories, in all scales, in all measurement fields and, at all levels of accuracy, which have properly demonstrated their metrological traceability competence to an accreditation body, for both the intended purpose and to all users requiring it.

It is this international structure for recognizing measures which enables reliable, robust, and internationally accepted comparable measurements to be carried out, in each one of the steps, providing necessary evidence and which allows users to have confidence in the validity and acceptability of the measurement results.

In response to the existence of this international system, it shall be considered that an instrument or measurement pattern makes metrological traceability available for national or international patterns when the calibration process has been done by an accredited calibration laboratory. Issuing an accredited calibration certificate, which include the accreditation mark is proof of what it is.

Aware of the technical complexity of all this international framework which many organizations at different levels are involved in, ENAC is developing a series of actions aimed at bringing clarity to the market and making it easier for calibration users to be able to discriminate between those calibration certificates that guarantee metrological traceability and those which do not.

*To this end, two complementary actions have been undertaken:*

One of them is aimed at their own calibration laboratories and their clients: setting limitations on issuing certificates without the ENAC mark by accredited laboratories and strengthening reporting requirements that a laboratory must provide to its client in the case of doing so. On the other hand, a document is being prepared that will insist on some of the concepts mentioned in this article and that will also clear up the inaccuracy of certain practices such as using terms like "ENAC traceability" or "ENAC patterns" which, in addition to being technically incorrect, can be misleading and should not be used by accredited laboratories nor be accepted as good by clients from non-accredited calibration laboratories.

And other action aimed at certification bodies and certified companies. ENAC has just published the Technical Note 62 "Certification Bodies: Metrological Traceability Assessment of measurement results". The purpose of this document is to establish the criteria applied by ENAC to determine the correct assessment by certification bodies for measurement traceability requirements that some standards, such as ISO 9001, include and it insists on the concepts stated above which should be taken into account by certification bodies in their audits.

## **First accreditation for load testing and software performance**

ENAC credited the first laboratory in Spain and one of the few that exist in the world for this type of software testing.

ENAC has accredited the testing laboratory of the company Software Quality Systems S.A. SQS for carrying out load testing and application performance. Since that time, SQS has become the first laboratory in Spain to be accredited for conducting this type of software testing and one of the few that exist in the world.

In all software development projects, the testing is a crucial part of ensuring the application's expected quality as well as offering a robust error-free software. Testing provides information about the behaviour of the system in various aspects and, therefore, gives the key to improving it.

You can make different types of tests based on the information you are looking for. Load and performance testing consist of submitting the system to high workloads, simulating the real activity of the future users of the system. These tests help to predict the system's behaviour and to understand the degree to which it has been designed to carry out the functions without loss of service and with a stable and optimal response time.

Specifically, load testing indicates and validates the application's response when subjected to a load of users and/or expected transactions once in a production environment (for example: checking that the application's response in face of a simultaneous discharge of 1000 users is correct) and performance testing measures the application's response to different expected load volumes (for example: knowing the response speed when processing the entry of 20, 200 and 2000 users simultaneously). Those load and performance tests which exceed the limits set to real user activity are known as stress testing and enable it to establish the volume of data (or time) and when that application is no longer able to respond to requests as expected.

These tests are an indispensable requirement if a system has performance problems, when there is an increase in the number of users of an application, if there is a migration or change in software or hardware components, etc. In any case, it is always advisable to perform this type of testing to provide maximum information about the system's behaviour. Users dissatisfied with the system's performance may never return, badly affecting business.

Testing is a crucial part of ensuring the expected application quality as well as offering a robust error-free software.

## **Quality of breast cancer screening services**

**The European Co-operation for Accreditation (EA) collaborates with the European Commission to contribute to developing a quality assurance scheme for breast cancer care services. ENAC takes part in the working group in charge of developing this scheme.**

Breast cancer affects a large proportion of the European population, being the most common cause of death by cancer in women. Incidence, prevalence and survival rates vary widely within and between Member States. These differences are closely related to the variability in providing services for prevention, early diagnosis, treatment, rehabilitation and palliative care in different countries.

Since 2003 the Council of the European Union has been encouraging Member States to develop strategies and plans for comprehensive cancer screening, while inviting the European Commission (EC) to explore the development potential of European quality assurance scheme volunteers for cancer screening and appropriate follow-up of lesions detected.

Therefore, the European Commission has launched a project to develop a quality assurance scheme (QA) at the European level whose objective is to ensure that processes directly related to breast cancer health care can demonstrate that they comply with an agreed standard and provide a high degree of trust to both the patients and health services managers, regardless of the country and the organization that provides it.

During the scheme's development the European Quality Assurance Guidelines will be revised to screen and diagnose breast cancer (European Quality Assurance Guidelines for Breast Cancer Screening and Diagnosis), and set accreditation, in accordance with Regulation (EC) 765/2008, as the foundation to ensure its soundness. The quality assurance scheme (QA) must cover all aspects - diagnosis, surgery, treatment, nursing care, palliative care - and its main objective will be the quality of patient care.

The scheme must be very flexible, in order to guarantee the inclusion of different health systems across Europe. And to ensure its effectiveness it must make use of and combine different standards, tools and techniques.

The EA's Mission is to provide a comprehensive guide for the different agents of the scheme, i.e. national authorities, professional associations, national accreditation bodies, as well as conformity assessment bodies. Thanks to its experience the EA may provide the framework, tools, processes and procedures for accreditation.

A working group composed of six experts of the national accreditation bodies of different Member States, including ENAC has been established to develop the project. Isabel de la Villa, Head of the Department of Health, is ENAC's representative in this group.

It is planned for autumn 2016, a pilot project will start up so that associate EA members can test the BCS accreditation system in practice for accreditation activities in accordance with the scheme's requirements.

## **Inspection of wooden packaging. First ENAC accreditation**

### **Independent inspection body accreditation for inspecting wooden packaging generates confidence in pest control for safe trading**

Free trade and the movement of goods has increased the risk of introducing and spreading pests. Wood packaging used for transporting goods may represent a means of propagation. A very sensitive example is pine wood packaging, which can lead to nematodes entering the pine wood, which constitutes a serious threat to trees in the destination country, and could therefore involve borders' closing to domestic trade in order to prevent the spread.

In 2002, to ensure wooden packaging's phytosanitary safety, the FAO (Food and Agriculture Organization of the United Nations) adopted the International Standard for Phytosanitary Measures ISPM No. 15 concerning the regulation of wood packaging used in international trade.

The Ministry of Agriculture in the AAA4582013 Order defines the responsibilities of the independent control agencies, which are in charge of verifying compliance with the requirements of this order and the ISPM15 for standard wood packaging operators. In particular, its function is to inspect the operator's facilities in order to ensure the correct heat treatment of wood and its mark, which identifies how plague-free the packaging is.

Such institutions must be accredited under the UNE-EN ISO/IEC 17020 standard and comply with independence requirements as a body type A, meaning a totally independent third party. This ensures the technical competence and independence of the parties involved, offering a reliable and traceable service.

ENAC has granted accreditation to Formaset, a leading inspection body accredited for wood packaging control operators in order to ensure a safe market of pest-free packaging.

## **Accreditation of reference material producers**

**Last November, ENAC awarded the first accreditation of the Reference Material Producers scheme according to the ISO 34 Guide**

Reference materials are an essential tool for making the work of testing and calibration laboratories reliable. They are used for calibrating, validating methods, estimating uncertainty, checking the proper operation of a given method and for routine quality control. Taking into account the definitions of reference materials and certified reference material included in the ISO Guide 30 and JCGM 200:2012, International vocabulary of metrology, we can conclude that the following properties will be important in reference material and it will be necessary to determine the degree of compliance depending on what it will be used for:

- **Homogeneity:** it is a necessary property in any reference material. The lack of homogeneity should be reflected as a component of uncertainty.
- **Stability:** it is also necessary for any type of reference material in its useful lifespan.
- **Traceability:** this property is reserved for certified reference materials. It is convenient to take into account what is the traceability (final reference) position which can be a specific method or a specific item to the International System.
- **Assigned value of a certain property:** this is a required property only for certified reference materials. In this case it is essential that it is accompanied by its uncertainty.

The previous notes allow us to infer the fundamental differences between "reference material" and "certified reference material" which are summarized in the following observations:

- Reference material is a generic term that is sometimes used to describe a reference material that is not certified.
- A reference material is useful for determining the accuracy of a method. Only if it is certified may it serve to additionally determine its veracity.
- For a reference material to be appropriate for calibrating, it is necessary, in addition to the property value and its associated uncertainty, to provide the necessary traceability, that is to say, a certified reference material will be needed.

The ISO Guide 34 document defines a reference material producer as the body that assumes full responsibility for planning, management, decisions on allocating the property value and its uncertainty and issuing reference material certificates or other statements that it produces. That said, the figure of a reference material producer is part of the conformity assessment bodies and is a key piece in assuring test and calibration quality.

The growth of reference material producer accreditation experienced in the international field in recent years and ILAC's intention to sign a Mutual Recognition Agreement (MLA) for

accreditation of reference material producers led ENAC to open this new pilot accreditation scheme in 2011.

The opening of the scheme means a competitive advantage on two levels. On one level, for Spanish reference material producers; as this is conformity assessment activity with a large worldwide market, they cannot afford not to adapt to new demands. On the other, for testing and calibration laboratories; as they may rely on reference materials manufactured by accredited producers and so comply with reference standard requirements and as a result the more established selection and use guidelines.

### **FIRST REFERENCE MATERIAL PRODUCER ACCREDITATION**

Last November, ENAC awarded the first accreditation of the reference material producer scheme in accordance with the ISO Guide 34 to the company IELAB CALIDAD S.L.

IELAB's accreditation scope includes the production of different reference materials used in microbiological and chemical testing. When it comes to good interpretation of the scope, it is important to point out that, as indicated earlier, only those materials which are indicated as "certified" provide assigned values for the specified properties, uncertainties and associated traceability, meaning they are the only ones that can assess the bias.

The microbiological property reference materials that IELAB produces and sells are classified into three groups for different applications, one is qualitative which certifies the identity of the microorganism supplied, another is quantitative which certifies the present amount of the organism and the third where the microorganism's present amount is not certified but is useful as a repeatability method control.

In terms of chemical property reference material, reference materials with value certificates for the amount of certain metals are presented in the scope, specifically in mud.

## **ENAC responds**

*We are a small company and we need to perform certain tests on our product. We have employed an accredited laboratory, but upon receiving the test report we see that it does not bear ENAC's mark and they have told us that it is no good without the mark. Is that true? Is it important that the report bears the mark? Can the laboratory issue reports with or without the mark? The truth is that we are a little overwhelmed by all this and need your help.*

*How do I know if a report or a certificate is covered by ENAC's accreditation?*

Results from an accredited activity should be in reports or certificates that include ENAC's mark, as using it is the way accredited organizations publicly declare they have fulfilled all accreditation requirements.

A report or certificate that does not include the mark does not guarantee compliance with these requirements and, therefore, may not benefit from the advantages of accreditation, in particular, its international recognition.



### *Can an accredited organization issue certificates or reports without the mark for activities that it has accredited?*

No, it must always issue certificates and reports with ENAC's mark when it performs an activity within its accreditation scope, except if the client explicitly accepts this beforehand.

In this case, the accredited organization must inform the client that a report or certificate without the mark will be considered for all purposes as "uncredited". This is especially relevant if the applicant is obliged by law or by contract to make use of accredited bodies, since the applicant would be in breach of this requirement. Or if it wants the report or certificate to be valued in foreign markets, as unmarked documents are not accepted as equivalent by the accreditation body signatories of the multilateral agreements.

### *What should I do if I receive a report without the mark which includes testing the laboratory is accredited for?*

Accredited organizations must inform customers in advance of the situation as well as the consequences and seek its acceptance. If it doesn't, it has failed to fulfil the accreditation requirements. Ask him to issue a report with the mark and in case of failure to do so, please contact ENAC using the complaint section of our web.

### *Why do accredited companies sometimes offer "unmarked" services at lower prices?*

These services, uncovered by accreditation are not supervised by ENAC's audits so they can do them without the accreditation guarantee, implying that the result has an unknown reliability and whoever contracts the service does not know how it has been done.

This practice, if it is not performed with absolute transparency to the customer is considered by ENAC to be bad practice, and we recommend that companies do not accept those proposals. And if it is considered that the accredited organization has not been clear in explaining the consequences of receiving certificates and non-accredited reports then do not accept this proposal and let us know using the complaint section on our website.

## **In 2014 ENAC continued strengthening the homogenization of their auditors**

### **27 homogenization workshops of Chief Auditors and technical experts in 2014**

ENAC, convinced of the important role played by external auditors in the quality of accreditation processes, continues strengthening the homogenisation criteria for Auditors' accreditation, by investing time and resources for both Auditor Chiefs as well as technical experts. So, throughout 2014 a total of 27 workshops were carried out with more than 500 attendees from practically all accreditation schemes.

These meetings were an important opportunity to improve the progress of the accreditation processes, providing a forum for participating, discussing and sharing experiences where ENAC's Chief Auditors and technical experts, the technical floor staff and the Body's management all worked together to resolve various aspects of the auditor's daily activity.

Therefore, these workshops were a key tool for putting together all aspects of the auditor's daily activity that were liable to be analysed or improved, for harmonizing the technical criteria which raised doubts when applied and for submitting new documents and procedures that affect the Auditors.

## **EA assesses ENAC**

**The audit team of the European Organization EA has valued ENAC's technical competence and the technicians' knowledge very positively, as well as the auditors and external technical experts ENAC relies on.**

Last October, ENAC was visited by the designated EA assessment team to carry out reassessment in order to determine if ENAC will continue as a signatory of the recognition agreements in EA: for testing, calibration, certification systems, product and persons, inspection and Greenhouse Gas Emission Trading Right inspection as well as the corresponding Environmental Inspectors who act within the framework of the EMAS Regulation.

The EA assessment was conducted by an audit team made up of 9 Auditors led by Chief Auditor, Christina Waddington-Walden, from the Finnish Accreditation Body (FINAS) supported by eight auditors from the accreditation bodies of Italy (ACCREDIA), Czech Republic (CAI), United Kingdom (UKAS), France (COFRAC), Romania (RENAR), Belgium (BELAC), Greece (ESYD) and Switzerland (SAS).

Likewise, and as has happened in the past, the assessment of ENAC was chosen by the international accreditors organizations ILAC and IAF for developing the EA supervision, which is based on the international recognition agreements, monitoring was carried out by a representative of each of these organizations.

During their stay the EA audit team conducted a detailed investigation of the whole accreditation system, assessed support documents as well as activity records, interviewed various staff members and made accompanied visits with ENAC audit teams in their audits. Their findings will be useful for improving our processes.

In the final meeting the audit team gave some very positive feedback on ENAC's technical competence and the technicians' knowledge as well as the auditors and external technical experts.

The final report, prepared by the head assessor, includes the corrective actions submitted by ENAC. Next April it will be studied by the MLA Council, an EA body in charge of decision-making, which represents all the Accreditation Body signatories of the agreements.

That is why we are pleased with the outcome as it confirms "the excellent assessment" we have traditionally received in EA assessments, and which reaffirms our commitment to remaining a leading body in Europe and the rest of the world. Being aware that, more than just the pride that this represents for those working in ENAC, they have a clear influence on the confidence of ENAC-accredited conformity assessors' work.

### ***International assessment process: Foundation of the Mutual Recognition***

The Mutual Recognition Agreements, MLA, constitute an essential element for achieving one of the basic accreditation objectives; the reduction or elimination of technical barriers.

With their signatures, the accreditors ensure the equivalence of their accreditation systems, and therefore, the accredited organizations' activities, promoting cross-border trust and acceptance of the information provided by conformity assessors, regardless of the country in which they are accredited.

To be able to sign the MLA, accreditation bodies must successfully pass a rigorous evaluation process, called peer evaluation, which checks the equivalence.

*The audit was done by 9 auditors from the 27th to 31st October and covered 15 accompanied visits and assessed more than 40 accreditation records.*

## **General Assembly of ILAC and IAF**

*From the 8th-17th October, the city of Vancouver became the headquarters of the Assembly General of the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC).*

Beatriz Rivera, General Director of ENAC, and Ignacio Pina, Technical Director, attended the joint General Assembly of ILAC and IAF on behalf of ENAC, which dealt with activities carried out by these organizations in order to continue promoting the harmonization of the accreditation systems of different countries, the collaboration between all interested parties and the confidence in the accredited conformity assessment.

At this international meeting, which was attended by around a 210 representatives from more than 80 countries, including representatives of accreditation body signatories of the ILAC and IAF recognition agreements. There, they analysed and approved technical documents, strategic plans of these organizations, the relationship between regional accreditation groups (EA: Europe, IAAC: America, APLAC and PAC: Asia Pacific, AFRAC: Africa, ARAB: Arab countries, SADCA: countries of southern Africa), the use of the mark as well as the signing up of new members to the IAF and ILAC agreements.

### *ILAC Multilateral Recognition Agreements: new signatories*

New accreditation bodies have been integrated into the Multilateral Recognition Agreements:

Argentina (OAA): inspection  
Colombia (ONAC): testing and calibration  
Cyprus (CYSAB): calibration  
Egypt (EGAC): testing (ISO 15189) and inspection  
Romania (RENAR): inspection  
Tunisia (TUNAC): inspection  
Ukraine (NAAU): testing (ISO/IEC 17025) and calibration.

IAF Multilateral Recognition Agreements: new signatories

Kazakhstan (NCA): product certification (ISO/IEC Guide 65/17065)  
Sri Lanka (SLAB): product certification (ISO/IEC Guide 65/17065), and management systems certification (ISO/IEC 17021).

### *New activities in the MLA*

The ILAC General Assembly agreed to extend the scope of the Multilateral Recognition Agreement to include accreditation of proficiency testing providers. The assessment activities of accreditation bodies joining the Agreement will start in the near future.

At the same time, the IAF General Assembly agreed to include greenhouse gas inspection accreditation in the MLA.

### *Collaboration with international organizations*

In these meetings, the main new points were presented in collaboration with various international organizations such as the International Electrotechnical Commission (IEC), the International Standardization Organization (ISO), the International Organization of Legal Metrology (OIML), the European Commission (EC), the international telecommunications Union (ITU) and the United Nations Industrial Development (UNIDO).

Also in the framework of the Joint Assembly two memorandums of understanding were signed (agreements between parties), between ILAC and IAF with the International Organization of Legal Metrology (OIML) as well as with the United Nations Industrial Development (UNIDO), which replace those previously signed.

### **Visits by the national accreditation bodies of Nicaragua and Brazil**

#### *ENAC wants to thank the agencies of these countries for the trust shown towards the body as well as the accredited organizations which received us on visits*

One of ENAC's statutory purposes is to promote and circulate accreditation procedures and techniques in Ibero-American countries, which translates into a policy of active support for developing the conformity assessment infrastructure in these countries, by participating in various collaborative projects.

In this context, from the 17th to 21st November, 16 technicians of Nicaragua's National Accreditation Office (ONA) visited ENAC. They were able to learn about the activities developed by ENAC, the accreditation procedure as well as the quality system. The training workshops were completed by participating as observers in conducting audits at laboratories and inspection and certification bodies.

Also in November, and framed in a training project which the "Ministry of Development, Industry and Foreign Trade - MDIC" carried out to strengthen the accreditation activity processes, we received the visit of the Brazilian accreditation body's Head of Laboratories Department, who received a course on ENAC's quality process. It addressed aspects related to the accreditation practice regarding findings, training and supervision of Auditors involved in assessments.

From ENAC we would like to take this opportunity to thank both organizations for the confidence shown in our institution and to all accredited organizations which gave their consent so that the staff of these agencies could attend the audits as observers, making this activity extremely helpful.

## ENAC celebrates its 58th General Assembly

Some of the strategic action lines presented in the General Assembly for next year consist of boosting accreditation as a support element for making Spanish companies more international, as well as developing and implementing a more equitable tariff policy which adapts to each applicant's characteristics and at the same time prevents accreditation costs from being a competitive barrier for micro-enterprises.

On December 17th, 2014 ENAC's Ordinary General Assembly was held when ENAC's President, Mr. José Manuel Prieto, together with the Director-General, Mrs. Beatriz Rivera, presented the forecast budget and Activity Plan for 2015.

With regard to the budget, it set out a similar scenario to 2014 as far as activity is concerned with a similar estimate of activity volume to last year's one. As Beatriz Rivera said, "in 2015 we anticipate a strong growth of new activities because of, among other reasons, new regulations that make accreditation an essential tool to guarantee quality".

Also new rates have been approved for 2015 which aim to meet several objectives of different nature and scope:

Making access to accreditation easier for Spanish micro-enterprises preventing, no matter what, accreditation costs from becoming an insurmountable barrier which would reduce competitiveness.

Establishing a more equitable tariff policy: taking equal treatment into account is a fundamental value of accreditation activity, also in what is referred to as the economic effort, over the next few years a series of changes in the tariff system will be carried out with the following objectives:

- Associating fees to the body's size and complexity so that they are higher for the largest and most complex ones.
- Spreading out travel costs in an equitable basis so that they do not discriminate against customers for their geographical location in respect to the Auditors' place of residence.
- The cost of additional activities affects who receives them meaning that ENAC increasingly tends to charge for services it provides allowing an indiscriminate reduction in quotas.

In relation to the activity plan, during her speech the Director General stressed that one of ENAC's strategic objectives for this year was to strengthen and increase help for Spanish companies' exporting goals as well as for guaranteeing product export success.

For this reason, in 2015 we will make an extraordinary effort to go directly to companies to convey the value of accreditation and as accredited conformity assessors we can help them internationalize and establish products in foreign markets.

In relation also to internationalizing Spanish companies, Beatriz Rivera stressed the importance of ENAC's audit reassessment carried out by the EA due to the signed Mutual Recognition

Agreements. Beatriz Rivera took the opportunity to point out that "the end result has been good for ENAC, the experience was very satisfactory, and a very rigorous and competent audit team has identified very interesting areas of improvement".

In another order of things, the Director also reviewed the developments expected in all accreditation schemes in 2015, including an increase in drinking water laboratory activity, an increased interest in the agro-food industry internal control laboratory accreditation, railway sector developments with EA and the European Railway Agency collaborating together, which is creating a new scheme with ENAC participating, the regulation of electronic signatures, the first accreditation of the FEIQUE scheme, Responsible Care, among other activities. In addition, she recalled that this year, ENAC has been appointed by the Administration to be an assessment and certification body of the Good Laboratory Practices (GLP) of non-clinical trials of feed additives.