“Accreditation News” issue 43

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Óscar Recuero, Head of Department

NEW ENVIRONMENT DEPARTMENT

The Environment Department was set up in February 2008. It will take care of the accreditations of testing laboratories and inspection bodies which carry out their activities in the environmental area. Likewise, in view of the importance that acoustic pollution is taking on in the environment, testing laboratories and inspection bodies have also been included that carry out conformity assessment activities in the acoustic field.

The decision to set up this new department is based, on the one hand, the need to meet the growing demand for applications related to the environment and, on the other, to be able to undertake effectively the development of the specific technical aspects of conformity assessment in this area.

The department has come into being with a clear orientation towards ENAC clients, laboratories and inspection bodies accredited in this sphere and their users which will be embodied in different courses of action aimed at improving the efficacy of ENAC activities and their assessment. There will also be a search for greater specialisation in the auditing personnel for the purpose of encompassing the specific features of the sector in greater depth and thereby improving the effectiveness of the assessments carried out.

APPOINTMENTS

ELENA BABADILLA

A chemistry graduate with broad accredited environmental chemistry laboratory experience, has joined the Department of Laboratories and Product Certification.

ÓSCAR RECUERO

An industrial engineer, specialised in chemistry, with wide experience in laboratory and company quality management as a senior ENAC auditor, takes up the post of Head of the Environment Department.

NEW ACCREDITATIONS

TESTING

The new bodies accredited by ENAC (December-February 2008) are set out below:

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN.

IMMUNOLOGY SERVICE CLINICAL DIAGNOSIS LABORATORY

Immunology 619/LE 320

ENVIRONMENTAL RADIOACTIVITY LABORATORY. UNIVERSIDAD POLITÉCNICA DE VALENCIA

Radioactivity tests 620/LE1050

DIRECCIÓN DE ENSAYOS DEL CENTRO TECNOLÓGICO DE AUTOMOCIÓN DE GALICIA

Motor vehicle, accessory and component testing 621/LE1230

EPOCHE AND ESPRI, S.L. (Unipersonal)

Tests for evaluating the safety of information technologies and communications 622/LE1399

FONOTEL INGENIEROS, S.L.

Building acoustics tests 623/LE1293

LABORATORIO DE SALUD PÚBLICA DE CÁDIZ

Physicochemical, microbiological and toxicological analyses of food products 624/LE569

LAVENOR ACÚSTICA, S.L.

Building acoustics tests 625/LE1346

LABORATORIO DE ANÁLISIS CLÍNICOS DE LOS DRES. F. LEMA and J. BANDÍN, S.L.

Physicochemical and microbiological analyses of water, fishery and agricultural products and ready-cooked meals 626/LE1271

CENTRO MUNICIPAL DE ACÚSTICA DEL AYUNTAMIENTO DE VALLADOLID (CMA)

Industrial acoustics tests 627/LE1371

UNIVERSIDAD DE EXTREMADURA ENVIRONMENTAL RADIOACTIVITY LABORATORY (LAUREX)

Environmental radioactivity tests in water 628/LE1260

LABORATORIOS BIOTEST, S.L.

Physicochemical analyses of water and microbiological analyses of foods and water 629/LE1262

HOSPITAL UNIVERSITARIO "PRÍNCIPE DE ASTURIAS". SERVICIO DE ANÁLISIS CLÍNICOS – EMERGENCY LABORATORY

Biochemistry 630/LE1377

FUNDACIÓN CENTRO TECNOLÓXICO DO GRANITO DE GALICIA

Natural stone tests 631/LE1350

MUNICIPAL LABORATORY OF BENIDORM

Physicochemical analyses of water 632/LE1195

CONSORCIO HOSPITAL GENERAL UNIVERSITARIO DE VALENCIA. ENVIRONMENTAL HEALTH LABORATORY.

Legionella testing in water 633/LE1222

HOSPITAL UNIVERSITARI DE BELLVITGE LABORATORI CLINIC

Biochemistry and Haematology 634/LE1378

NATIONAL INSTITUTE OF TOXICOLOGY AND FORENSIC SCIENCE. MADRID DEPARTMENT

Toxicological and forensic analyses 297/LE1367

Physicochemical analyses of water 297/LE1366

CALIBRATION

ENDESA GENERACIÓN, S.A.

Electricity – High Voltage 177/LC394

P & B INSTRUMENTS, S.C.P.

Mechanics – Mass 178/LC337

BRÜEL AND KJAER SOUND & VIBRATION MEASUREMENT A/S

Acoustics 179/LC483

UNIVERSITY OF CÁDIZ. INDUSTRIAL METROLOGY CENTRE

Dimensional 180/LC486

INSPECTION

FISHERIES AND AQUACULTURE DEPARTMENT. DIRECTORATE-GENERAL FOR FARMING AND FISHERIES OF MURCÍA

Food Processing Inspection 152/EI1248

SYSTEMS AND ELECTRONIC ENGINEERING DIVISION (DSIE) OF THE UNIVERSIDAD POLITÉCNICA DE CARTAGENA ELECTRONIC TECHNOLOGY DEPARTMENT

Industrial Inspection 153/EI1277

ECA ITV RIOJA ALTA, S.L. (Sole trader)

Industrial Inspection 154/EI1266

EFICIEN, S.A. (Sole trader)

Industrial Inspection 155/EI1271

TECHNICAL VEHICLE INSPECTION

ITV OCAÑA, S.A.

Technical Vehicle Inspection 42/EI/ITV053

MANAGEMENT SYSTEM CERTIFICATION

IBUREAU VERITAS CERTIFICATION, S.A. (Sole trader)

Certification of Food Safety Management Systems 4/C-SG021

Certification of Forestry Management Systems 4/C-SG026

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Report

ENAC CONTRIBUTES TO ASSURING THE QUALITY CONTROL OF WATER

ENAC activity in the field of water has increased considerably as a result of the great interest aroused both amongst consumers and the different levels of government in all aspects relating to its quality.

The concept of water as a limited resource is one of the features of our society today. Concern for its management and use and knowledge and control of the impact of all activities on this asset cause the public to demand greater and more effective controls by the authorities to prevent all abuse and its degradation.

The regulation sought by control and surveillance in every single process of the integrated water cycle, from its collection to its return to the natural environment, in order to offer greater protection to people and the environment against the adverse effects stemming from any kind of water contamination is bringing about a greater demand for accredited analysis and inspection services.

The activity of over 263 laboratories and 23 inspection bodies accredited in this field contribute to the control and surveillance in every one of the integrated water cycle processes.

WASTEWATER AND QUALITY OF THE RECIPIENT SYSTEM

Order MAM/985/2006 of 23 March, implementing the legal status of the water authority partner bodies in the area of control and monitoring of water quality and management of wastewater discharges to the public hydraulic domain, requires accreditation under UNE-EN ISO/IEC 17025, if the sphere of action is testing, and UNE-EN ISO/IEC 17020, if it is inspection, to be authorised as a partner entity by the Ministry of the Environment.

Its function is to provide the required information to grant, renew or modify the authorisations for discharge. This information has to assure the water authority that the treatment plants and the control elements are in line with the water quality standards and objectives and the qualitative and quantitative conditions these wastewater discharges. These bodies may also undertake other activities in support of the water authority, such as carrying out wastewater control programmes and programmes for monitoring or checking compliance with the environmental quality objectives and standards laid down for the recipient system.

DEVELOPMENT OF ACCREDITED ACTIVITIES

This quantitative increase in laboratories and accredited inspection bodies has been accompanied by an evolution with regard to the types of activities, ranging from the most traditional - physicochemical and microbiological water analyses - to the most innovative, such as analyses of radioactivity in water, legionellosis prevention and control analyses, toxicity analyses, or those required by the Water Framework Directive (WFD).

This directive, which represents a basically environmental Community framework for the protection of water, establishes the "ecological state" concept as an expression of quality and functioning of the aquatic ecosystems and the use, together with the already traditionally applied physicochemical indicators of various biological components for the classification of the ecological state of rivers, including amongst these the composition and abundance of invertebrate benthic fauna, for the determination of which the first accreditations have already taken place.

Drinking water

In the case of drinking water, the current standard (RD 140/2003) requires the participation of both public and private laboratories to carry out analytical control, establishing that the laboratories that perform these activities and exceed 5000 samples a year should be accredited under standard UNE-EN ISO/IEC 17025

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Interview

Gonzalo Sáenz de Samaniego, Secretary of Agriculture, Fisheries and Food of the Government of the Basque Country

"ENAC ACCREDITATION GENERATES CONFIDENCE AND PEACE OF MIND IN CUSTOMERS AND CONSUMERS"

1. What role does ENAC accreditation play and in what activities carried out by your department is it used?

For the Department of Agriculture, Fisheries and Food, accreditation is an essential tool for generating trust in the quality and characteristics of the products and services that are offered to the consumer and to customers.

Naturally, it is not only that we are using it, but also we are promoting it, since we consider it to be a valid tool.

On the one hand, there are directives for the official control of food products, which more and more predetermine our use of laboratories whose determinations are accredited. Therefore, following an order of priority in which the different determinations are carried out, the laboratories that come under our Department (Azti, Neiker and Lekumberri) are compiling with the specified accreditations. Furthermore, this

Department has been one of the sponsors of accreditation in product certification with seals of quality and origin, through promoting Fundación Kalitatea, an entity set up amongst other reasons for the purpose of assuring the consumer of the origin, quality and authenticity of quality products of the Basque Country, where faith has been pinned in the accreditation of the certification systems ever since their establishment.

2. What is your opinion of the recent accreditation of Kalitatea as the certifying entity of the three protected designations of origin of Txakoli?

The obtaining of accreditation for the three designations of origin of Txakoli is recognition of the great effort made by wine-growers, vintners and the actual Basque government, along with Fundación Kalitatea, in order to demonstrate compliance with the technical regulations, their good practice and the implementation of systems that assure the authenticity and quality of the Txakoli labelled.

This department set up the foundation in 1998 so as to guarantee the quality and origin of products with Basque Country seals, and in this way assure the reliability and consistency of the control and certification of food products. We are not only therefore satisfied, but also proud of this new recognition, as we consider that it is once again the outcome of a job well done and the consolidation of a bold decision to offer food companies a guarantee of impartiality, independence and technical competence.

This accreditation, awarded to Fundación Kalitatea, is the first accreditation that certifies a Designation of Wine Origin, and for this entity, which continues to be the only accredited product certification agency in Euskadi, it is a matter of great merit to be able to offer customers the utmost trust and assurance in its services.

3.What advantages do you think that working with accredited conformity assessment organisations brings the food processing sector?

For the food sector of the Basque Country attached to voluntary quality specifications (Designations of Origin, Eusko Label, Organic Agriculture, etc.) the advantages of working at this time with accredited assessment organisations may be condensed into trust and peace of mind. It is the best way of upgrading and assuring customers and consumers of the quality of the products so as to lay down consistent assessment criteria on a global level and as a key tool for facilitating domestic and international trade through its contribution of the removal of barriers.

At this time and in particular for the three Txakoli designations through being pioneers in the wine sector, it is also a specimen of innovation and ongoing improvement as it is a step ahead of the Community regulations on this matter.

4. How do you consider that ENAC accreditation contributes to assuring the consumer of the control and safety of foods?

The consumer and satisfaction of his needs and requirements has become the centre of the food production chain. Consumers more and more assurance that what they are buying corresponds exactly to what they have been offered, and more so in those products a quality differentiated at source as is the case of protected designations and distinctives, where product control and certification tasks are essential. Accreditation for these therefore represents maximum guarantees of control, greater transparency and clarity in the whole process and the maximum level of self-requirement on the part of food companies in compliance with standards.

"It is not only that we use ENAC accreditation, but we are promoting it through considering to a valid tool"

First accreditation of a Designation of Wine Origin

Last February, Fundación Kalitatea was granted the first accreditation to certify a Protected Designation of Wine Origin, the Txakolí D.O. of Getaria, Álava and Vizcaya.

The system includes inspections of all the vineyards (varieties and control of yields) and audits, with collection of samples at the wineries attached to the designations of origin, verifying all the requirements stipulated in the regulations.

This new accreditation joins the accreditations that Kalitatea already possessed for the inspections carried out for the regulating council of the designation of origin of Idiazabal cheese and for certification of the optional labelling of the beef brand.

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Sectors

HEALTH

GENERAL CLINICAL LABORATORY ACCREDITATION CRITERIA

In March ENAC published the document "General

Clinical Laboratory Accreditation Criteria" (CGA-ENAC-LCL). This document sets forth the clarifications or explanations of the contents or interpretation of certain sections of standard UNE-EN ISO 15189 when this is going to be used in an accreditation process and which should be taken into account by the laboratories as criteria to be met in order to obtain or maintain ENAC accreditation.

The criteria set out in this document are the result of the experience acquired in the processes of accreditation of clinical laboratories carried out to date under this standard, of ENAC participation in international forums and, above all, of the cooperation of clinical laboratory professionals through scientific societies.

EXPERIENCE IN THE ACCREDITATION OF CLINICAL LABORATORIES

Since 2005, when the first accreditations were awarded to clinical laboratories, ENAC has gone on gathering experience in the application of the standard for the assessment of these laboratories. In these years laboratories of different branches (immunology, biochemistry, genetics, microbiology, haematology) and of different levels of specialization have been evaluated, from national reference centres to basic routine or emergency laboratories. This necessary experience has acted as the basis for the establishment of the CGA criteria.

PARTICIPATION IN INTERNATIONAL FORUMS

ENAC takes part in international discussion forums on standard ISO 15189 and its use in accreditation processes. Of particular interest was the participation in the EA Working Group for Clinical Laboratories, where representatives of the European accreditation organisations work together on an ongoing basis with representatives of laboratory professionals and the companies producing in vitro diagnostic materials on the most critical aspects of the standard and on those that need clarifications, in order that EA members may adopt a consistent attitude during assessments.

COLLABORATION IN SCIENTIFIC SOCIETIES

Since publication of standard ISO 15189, ENAC has considered that scientific societies should play a fundamental role in the establishment of criteria. For this purpose, cooperation agreements have been made with the scientific societies of all branches in the course of these years.

AEBM (Spanish Association of Medical Biopathology

AEDP (Spanish Association of Prenatal Diagnosis)

AEFA (Spanish Association of Pharmaceutical Analysts)

AEHH (Spanish Association of Haematology and Haemotherapy)

SEAP (Spanish Society of Pathological Anatomy)

SEI (Spanish Society of Immunology)

SEIMC (Spanish Society of Infectious Diseases and Clinical Microbiology)

SEQC (Spanish Society of Clinical Biochemistry and Molecular Pathology)

All the societies have taken part in the process of reviewing this document, but this cooperation has been kept active in many other necessary aspects, such as expression of the scopes of accreditation, the minimum criteria of technical competence for certain fields, preparation of other accreditation supporting documents, etc.

CONTENTS OF THE CGA-ENAC-LCL DOCUMENT

This document qualifies aspects affecting various sections of the standard, especially in the technical side, where all its sections are subject to clarification or interpretation.

Amongst the aspects that required further definition of criteria are the pre-analytical procedures. On the one hand, the pre-analytical stage is a critical process in clinical laboratories and, in fact, the need to define requirements for it was one of the main reasons for the preparation of a specific ISO standard for this activity. On the other, there is a wide variety of situations in the different clinical laboratories in relation, primarily, to responsibility in obtaining samples in their handling. Thus, there are samples obtained outside the laboratory, under the responsibility of the laboratory in some cases and in others under that of the applicant services or centres.

In addition, some types of samples, as is the case of surgical samples or different biological liquids (cephalo-rachidian, amniotic, synovial, etc), are obtained by professionals of branches different from those of the clinical laboratory. This variety of situations has to be taken into account in the accreditation processes as, whatever the organisation and structure of a clinical laboratory may be and the type samples and their origin, the laboratory has to show technical competence for these activities such that sample quality is assured. The document prepared by ENAC lays down the criteria for evaluating the technical competence of laboratories at the pre-analytical stage, irrespective of the type of clinical laboratory.

As stated in standard UNE-EN ISO 15189, a feature of clinical laboratories is the inclusion of interpretations and recommendations in the Laboratory Report. Due to the wide variety of tests that are performed and the continuous changes and introduction of new methods, it is necessary in some cases that the laboratory report should include the interpretation of the findings or results, so that the information set forth in the report is comprehensible to the applicant physician, who is gong to base his clinical decisions on these reports. Therefore, the CGA establishes in what cases and in what conditions such comments ma be included in the report. The validation of the analytical methods is also the subject of clarification in the CGA. The criteria set out in the document are those accorded at European level in the above-mentioned Clinical Laboratory EA Work Group. The content of this document does not add new requirements for the laboratories, so ENAC will apply it in its assessments as of its publication.

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SECTORS

ADAPTA Plan

NEW MODEL OF ASSESSMENT FOR INSPECTION BODIES WITH MULTIPLE SITES

NT- 41 "Inspection bodies with multiple sites", recently approved and prepared in the framework of the ADAPTA Plan "Modernisation of the assessment system" is applicable to inspection bodies and control organisations which have standard UNE-EN ISO/IEC 17020 as the basis for their accreditation and which possess more than 7 sites covered by the accreditation.

It lays down the new model of assessment and the requirements that have to be met by the bodies that wish to be attached to it. This model takes into consideration of the special features of bodies of this type which have to assure a high level of centralised control of the key processes of the inspection activities that they perform and lay special emphasis on the need to increase the commitment on the part of the bodies in their control processes.

The objectives of the model proposed are condensed in the following points:

- Increase the efficiency of the assessment process making all the agents who take part in the process concentrate on the assessment of the critical aspects of the activity performed by these bodies, eliminating the possible inefficiency associated with the repetition of actions.
- Ensure that the bodies exercise the proper degree of control of the activities that are performed at the different emplacements.
- Seek simplification of the assessment processes and increase their value added.
- Reduce the structural costs of the assessment process.

The new model will be set into operation for its validation at a pilot roll out stage which will be carried out in the period April 2008-March 2009. At the end of this stage the model will be confirmed with the adjustments considered necessary, with the participation both of the bodies and of government.

In the course of this process the lines of improvement adaptable to inspection bodies with a smaller number of sites will be identified.

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HIGHLIGHTS

EA ADOPTS ITS POLICY ON CROSS-BORDER ACCREDITATION

At its last General Assembly held in Cyprus, European Cooperation for Accreditation – EA - adopted document EA-2/13 "Policy of cooperation on EA member cross-border accreditation"

"EA member accreditation organisations are established to offer their services to their local market and to operate non-profit accreditation for non-commercial reasons. It is EA policy that its members should not promote or offer their accreditation in the countries of other EA members. EA members shall not compete with other EA members. EA members shall only consider offering accreditation services to countries or economies of other EA members in cooperation with the EA accreditation organisation, unless the local accreditor refuses to cooperate, in which case the EA member could continue with the process".

On that basis the document defines the following basic concepts:

1) Compulsory cooperation between EA members, who should subcontract the assessment of the organizations situated in countries or economies of another EA member from the local accreditor.
2) Exchange of information between the local and foreign accreditor relating to applications, suspensions, claims, etc.

3) Adaptation to the local market establishing that follow-up and re-assessment periods have to be established by the local accreditor.

4) Transparency, with the creation of an EA data base containing the accreditation activities of each of the members abroad.

5) Control in EA assessments of the effective application of their obligations by members.

At ENAC we have always defended attitudes similar to those now laid down in EA policy and we are, therefore, delighted with the adoption of this policy document, which will, in our view, bring great benefits to accreditation in Europe.

The document rests on the concepts of "cooperation" and "non-competition"

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HIGHLIGHTS

3rd FORUM WITH THE AUTONOMOUS COMMUNITIES ON FOOD PRODUCE CERTIFICATION

In March the 3rd Food Processing Forum was held. It was attended by all the Autonomous Communities and the Ministry of Agriculture, Fisheries and Food.

During this conference a report was given on the present state of the accreditations awarded by ENAC in the voluntary and voluntary-self-regulation area as well as of the different normative documents that are included in the scopes of accreditation granted.

Another of the subjects discussed was the specific communication between ENAC and the relevant authorities responsible for the authorisations of the control agencies established by the various current regulations, as well as the general communication mechanisms.

The situation and provision of ENAC activities with a view to the forthcoming entry into force of Community regulations relating to designations of origin were one of the main specific subjects addressed at this year's forum.

These activities include the forthcoming holding of a conference, organised by ENAC and aimed at regulatory councils, which will be attended by members of the forum.

PRODUCT CERTIFICATION	Accreditations	In process
Extra virgin olive oil	1	1
Free-range poultry (Voluntary labelling)	1	1
Fruit and vegetables		
EUREP GAP	15	3
Naturane	1	2
Natursense	-	1
Controlled Production		
UNE 155000	1	-
Fertilizers	-	3
Industries:		
BRC-Food	10	3
BRC-IOP	1	-
IFS	6	1
FACE(gluten-free products)	2	3
ETG cured ham	6	1
Quality standard for Iberian pork products	-	14
Quality seals	1	3
Animal feed CESFAC	3	-
Organic farming produce	4	8
Integrated production	1-	5
Aquaculture (EUREPGAP)	-	1
Beef		
Optional beef labelling	12	-
Protected geographical indications	1	-
Wine	5	10
Designations of origin and PGIs	2	3

PRODUCT INSPECTION	Accreditations	In process
Designations of origin	3	-
Quality standard for Iberian pork products	4	13
Fisheries and aquaculture	-	1
Animal Produce	1	-
Wine	-	1
Organic farming produce	-	4

FORTHCOMING EVENTS

List of national and international events

NATIONAL MEETINGS

3rd INTERNATIONAL SYMPOSIUM ON CLINICAL LABORATORIES AND QUALITY

17 and 18 April 2008 in Barcelona

ENAC represented by I. De la Villa

UPDATING COURSE FOR INSPECTION ACTIVITY IN THE FIELD OF ENVIRONMENTAL QUALITY AND ASSESSMENT

22 April 2008 in Santiago de Compostela

ENAC represented by F. Ordeig

COURSE ON QUALITY SYSTEMS IN TESTING AND CALIBRATION LABORATORIES

22 and 24 April 2008 in Madrid

ENAC represented by H. González

ENAC COURSE ON STANDARD UNE-EN ISO 15189

8 May 2008 in Seville

ENAC represented by I. De la Villa

EUROPEAN WORK GROUP ON LEGIONELLA INFECTIONS (EWGLI)

12 May 2008 in Madrid

ENAC represented by I. De la Villa

INTERNATIONAL MEETINGS

EA EXECUTIVE COMMITTEE

27 May 2008 in Tallin

ENAC represented by I. Pina

EA GENERAL ASSEMBLY

11-13 May 2008 in Madrid

ENAC represented by B. Rivera / I. Pina

Conference on designations of origin and protected geographic indications

On 10 June the Conference on Designations of Origin and Protected Geographical Indications organised by ENAC will take place in Madrid with a view to disseminating and clarifying the main aspects and requirements of accreditation for the certification of products controlled by (EC) 510/2006 regulations.

The conference, to be attended by representatives from the different autonomous communities with powers in this area, is aimed at the 110 bodies handling the certification of the products that are currently included in the Community register.

The designations of origin and geographical indications constitute the system used in Europe for the recognition of superior quality as a result of innate differential features, due to the geographical environment in which the raw materials are produced, the products are processed, and the influence of the human factor involved in them.

Accreditation-Instilling confidence in the global market

9 June 2008 has been designated as the first International Accreditation Day by IAF, International Accreditation Forum, and ILAC, International Laboratory Accreditation Cooperation.

Accreditation – insofar as it represents stringent independent mechanisms that assure not only technical competence, impartiality and integrity of the control agencies, but also the value and reliability of the corresponding declarations of conformity – enhances confidence in the global market.

ENAC

Entidad Nacional de Acreditación