"Accreditation News" issue 61 Third Quarter 2012

NEW ACCREDITATIONS

TESTING

Environmental Testing CANAL DE ISABEL II GESTIÓN, S.A. - 287/LE2015, 287/LE2016 BUSINESS RESEARCH ASSOCIATION TECHNOLOGY CENTRE OF MARBLE AND STONE - 373/LE1944 FCC ÁMBITO, S.A. - 990/LE1950 INSPECCIÓN AMBIENTAL CANARIAS, S.L. - 997/LE1916 GRUPO HESPÉRIDES BIOTECH, S.L. - 1000/LE1975 **Agri-Food Products** LABORATORIO PECUARIO PROVINCIAL DE ALBACETE (LPPAB) - 991/LE1863 LABORATORIOS APINEVADA, S.L. - 995/LE1935 FUNDACIÓN CONSEJO REGULADOR DE LA D.O. QUESO MANCHEGO - 996/LE1945 Acoustics VIBRACUSTIC, S.L. - 999/LE1800 **Meter Verification** CANAL DE ISABEL II GESTIÓN, S.A. - 287/LE2017 **Drug Abuse Confirmation** LABORATORIO DR. F. ECHEVARNE ANALISIS, S.A. - 511/LE1947 **Non-destructive Testing** SERVICONTROL, S.L. - 992/LE1931 **Used Mineral Oil** GESTIÓN DE ACEITES USADOS DE ARAGÓN, S.L. (Unipersonal) - 993/LE1877 **ATP Vehicles (Transport of Perishable Goods)** METALWORKING AND TRANSPORTATION FOUNDATION TECHNOLOGY CENTRE -994/LE1951 Determination of Fluids, Human Tissues and DNA Identifiers UNIVERSIDAD DE SANTIAGO DE COMPOSTELA. INSTITUTO DE CIENCIAS FORENSES LUIS CONCHEIRO. SERVICIO DE GENÉTICA FORENSE - 998/LE1900

CALIBRATION

Fluids

LABORATORIO DE ENSAYOS METROLÓGICOS, S.L. (LEM) - 93/LC559 IBERDROLA GENERACIÓN, S.A. (Unipersonal) - 205/LC545 **Time and Frequency** TECNICAS REUNIDAS DE AUTOMOCIÓN, S.A. - 201/LC554 **DC and Low Frequency Electricity** IBERDROLA GENERACIÓN, S.A. (Unipersonal) - 205/LC544

INSPECTION BODIES

Industrial Area

ASESORÍA DE SERVICIOS DE INGENIERÍA Y GESTIÓN MEDIOAMBIENTAL S.A. -261/EI454 Environmental Inspection ENXEÑEIROS E ARQUITECTOS CONSULTORES IDOM, S.A. (Unipersonal) - 263/EI440 ARGANO ASESORES, S.L. - 264/EI462 INSPECCIÓN AMBIENTAL CANARIAS, S.L. - 265/EI447 AGUAS MUNICIPALIZADAS DE ALICANTE, EMPRESA MIXTA - 266/EI434 Technical Service for Vehicle Modifications INSTITUTO DE INVESTIGACIÓN SOBRE REPARACION DE VEHICULOS S.A. (CENTRO ZARAGOZA) - 262/EI445 Road Vehicle Inspection INSPECCIÓN TÉCNICA DE VEHICULOS VALDEMORO, S.L. - 60/EI/ITV074

PRODUCT CERTIFICATION

Agri-Food Products CONSEJO REGULADOR DE LA D. O. P. LES GARRIGUES - 102/C-PR242 CONSEJO REGULADOR DE LA D.O.P. TORTA DEL CASAR - 103/C-PR221 Railway Rolling Stock LLOYD´S REGISTER ESPAÑA, S.A. - 81/C-PR215

CONTROL BODIES

Legal Metrology

EUROCONTROL, S.A. - OC-I/271 INSPECCIÓN TÉCNICA DE VEHICULOS VALDEMORO, S.L. - OC-I/268 SUPERVISION Y CONTROL, S.A. - OC-I/254 INSPECCIÓN TÉCNICA DE VEHÍCULOS MACO, S.L. - OC-I/285 **Industrial Safety of Facilities Regulation** ADD, ENTIDAD DE INSPECCIÓN Y CONTROL, S.L. (Unipersonal) - OC-I/279 AB-AUCATEL INSPECCIÓN Y CONTROL, S.L. (Unipersonal) - OC-I/282 QUALICONSULT - OC-I/241 **Mining** I.P.CONTROL, S.L. - OC-I/263

GOOD LABORATORY PRACTICE Studies of Plant Protection Products SIPCAM IBERIA, S.L. - 35/BPL052

Accreditation, a tool in the support of government- driven trade liberalization measures.

The Royal Decree-Law 192012 examines the performance of accredited assessment bodies.

Both the companies interested in gaining accreditation and the Councils who wish to make use of this tool can meet the criteria that ENAC is going to apply in this field.

On the 26th of May, the Official Bulletin of the State published The Royal Decree-Law 192012 of the 25th of May, on urgent measures to liberalize trade and certain services; eliminating the need for prior authorization to provide certain commercial services and replacing it with a declaration of responsibility or prior notice.

It is replacing, therefore, the traditional "a priori" control of an authorization system with one when the veracity of the presented declaration is verified as being exercised in accordance with the regulations in force "a posteriori" to the start of the activity.

To achieve greater agility in checking the corrections of prior notices and declarations of responsibility, the Royal Decree-Law lays out that local corporations may make use of legally accredited assessment bodies, which will act on a competitive basis and will totally or partly manage the checking of the veracity of the said information contained in such declarations of responsibility and if it is subject to the legislation in force.

In the same way it establishes that the interested parties; for the purposes of assessing the requirements expressed in their declarations of responsibility, or in their prior notices, may freely decide to use or not use the services of the said bodies.

ENAC, aware of the importance of implementing these liberalizing measures quickly and effectively for the economic recovery of our country, has already made a document available on our webpage www.enac.es which sets out the accreditation criteria of these assessment bodies so that both, the companies which might be interested in gaining accreditation and the Councils wishing to make use of this tool, will know the criteria to be applied by ENAC in this plan.

For more information: <u>direcciontecnica@enac.es</u>

(Pages 6/7) Report

The ENAC accreditation in the field of organic production

Spanish organic production has experienced a tremendous growth in recent years, in both the acreage and volume of these transforming industries, with the large export volume of both raw materials and organic products being especially relevant.

It is therefore a sector of growing importance in which the ENAC accreditation brings the necessary confidence to the administration and to the consumers.

Organic production is a general system of farm management and food production that combines the best environmental practices, a high level of biodiversity protection, the preservation of natural resources and the implementation of high standards of animal welfare and production in accordance with certain consumers' preference for products obtained from natural substances and processes.

Regulation and control of organic production

In Europe, organic farming is regulated by Council Regulation (EC) 834/2007 on organic production and labelling of organic products.

This regulation, in addition to establishing the requirements which operators must meet in order to be able to say that their products are eco-friendly, it regulates labelling and limits the use of the terms "ecological" and "biological" as well as derivatives or abbreviations, such as, "eco" and "bio" to only products that meet these requirements.

The regulation also defines the control system to ensure compliance with the requirements for operators and establishes the need for inspection bodies to be accredited according to the European Standard EN45011.

In Spain, the control and certification of organic farming production is conducted through Organic Farming Control Bodies, agencies dependant on the respective Ministries or Departments of Agriculture, or directly through the Directorate General attached to the same agencies. However, some autonomous communities (Andalucía, Aragón and Castilla-La Mancha), have authorized private agencies to carry out these functions. There are currently 25 authorities and control bodies, of which 11 are private certification bodies.

Presently 10 organizations carrying out organic product control have the ENAC accreditation, 7 of them are private bodies and 3 are public control authorities. Also, there are 3 organizations which have applied for the certification plan accreditation.

The controls that these organisms carry out include, on numerous occasions, tests to verify that the products meet the European regulation requirements. These trials must be performed in compliance with the applicable requirements of ISOIEC 17025. For this reason many laboratories accredited by ENAC work serving organic production control bodies.

Collaboration with the European Commission

The Council Regulation (EC) 834/2007 along with its application regulations are complex documents which require interpretation in many cases. This is why EA (European Cooperation for Accreditation), an organization that integrates European Union and EFTA accreditation bodies, created a specific work group for this certification scheme, in which ENAC has participated very actively.

Currently this group works closely with the unit responsible for ecological farming at the Agriculture General Management of the European Commission, defining policy to be followed in assessing this certification plan, with the objective of further harmonization of certification body assessments working within the framework of the aforementioned Regulation.

We are confident that the effort being made in the drafting of this document will be for the benefit of all those involved in organic production.

How to identify organic products

So that the consumer can distinguish organically-farmed products, the packaged units; along with its own brand and some of the aforementioned specific terms of organic farming, must include the community Organic Farming logo.

In addition, products must be printed with the authority code and control body, or a specific logo with the name and code of the control body mentioned above.

This ensures that the product attains to the quality supposed by the consumer and complies with the established rules.

For specifically accredited certification bodies and more information visit our web site: <u>www.enac.es</u>

(Pages 8/9) Sectors

<u>Accreditation in the field of the common infrastructures of telecommunications</u>

The services accredited by ENAC, the highest level of trust both for the administration and the users of the telecommunications services

In the last few years, the development of communications and information technologies; along with the process of liberalization that has been carried out, has led to different operators offering important new telecommunications services. The new technologies' ultra-fast access developments also allow these services to become increasingly more powerful, fast and reliable.

Some of these services require, in order to be provided to citizens, the updating and improvement of the telecommunications' common infrastructures on the inside of buildings and, consequently, of the technical standards which regulate them.

In this regard, the publication of the Royal Decree 3462011, on the 11th of March; which approves the regulatory Rule of the telecommunications' common access infrastructures for the services of telecommunication in the interior of buildings, already examines the access networks, based on fibre-optics, in line with the objectives of the 'Digital Agenda for Europe" established by the European Commission. Among the action fields studied in this "digital agenda", fast and ultra-fast Internet access and deployment promotion of NGA (Next Generation Access) networks are highlighted, in order to ensure that by 2020 all Europeans will have access to a much faster Internet speed, and to increase the use of fibre-optics in the home.

This regulation aims to guarantee citizens the right to access the offers of new telecommunications services, removing the obstacles that prevent them from being able to

freely contract these services, as well as developing effective competition between operators, ensuring that they have equal opportunities for their services to reach the customers.

The regulation promotes likewise the telecommunications infrastructure, which every day is more complex, that will be installed in the buildings, to be properly maintained by their owners in order to ensure, to the best extent possible, the continuity of the telecommunications services the inhabitants receive and enjoy. Stressing the need for them to be designed in such a manner which is easy to evolve and adapt contributing to the process of coming together with housing in the concept of a «digital home», and the benefits this provides to its users: greater security, savings and energy efficiency, accessibility, etc.

For the purposes of ensuring compliance with the established technical standards, this regulation defines the participation of accredited third party compliance assessors who have the means and the necessary technical training to carry out the prescriptive technical project verification, as well as the necessary independence regarding the implementation of the projects.

In this way, the ENAC accreditation is established as the highest level of trust both for the administration and the users of the installations or of any person or institution that, for one reason or another, could be involved as they can recognize, in the work undertaken by the accredited verification bodies, the guarantee of an independent and impartial assessment of the competence of their performances.

For more information: <u>Imrodriguez@enac.es</u>

(Page 10) Sectors

ENAC strengthens its collaboration with the aerospace sector

In 2002, ENAC was appointed by the Spanish aerospace industry association (TEDAE) to accredit in the Industry controlled other party scheme (ICOP), being at that time the first European deployment operating plan.

The Spanish plan, including the work of the accreditation body, has since been subject to annual monitoring by the international organization governing the plan (IAQG), reaping more than favourable results in each edition.

In January 2012, a new version of the EN 9104 standard was approved; by the European sectoral standardizer ASD STAN, identified as prEN 9104-1: 2012 "Aerospace series - Quality management systems - Part 001: Requirements for Aviation, Space, and Defence Quality Management System Certification Programs". It recognizes new requirements for the accreditation body in addition to other agents of the plan.

At the last meeting of the Certification Bodies Management Committee (CBMC) of the Spanish aerospace certification plan, held last June, ENAC was confirmed as the accreditation body of the plan in Spain, after having been evaluated in respect to these new requirements.

For more information: <u>rgonzalez@enac.es</u>

(Page 11) Sectors

New version of the accreditation standard for personnel certification bodies: ISO 17024: 2012

In the first week of July the new version of the standard ISO/IEC 17024: 2012 "Conformity assessment - General requirements for bodies operating certification of persons" was approved and published. This version contains an in depth review of the drafting of the standard in order for it to be up-to-date and aligned with other standards whose application scope is the accreditation of certification in other plans, such as the ISO 17021: 2011.

The most important changes include the new requirements relating to management of impartiality, training and qualifications, scheme development and security. Also, it has modified the requirements applicable to the owners of the personnel certification schemes and the supervision conditions of such plans; a principles section has been included as an informative annex.

The international agencies involved - IAF and ISO - shall adopt, in short, measures that will organize the transition from the existing accreditations to the new standard. These measures, which will be announced before the end of the year, will probably set a period of two years, starting from the publication, for it to be definitively implemented.

When this happens, ENAC will promptly inform the accredited bodies and in the process of the details needed to comply with these international commitments.

2012. A year of changes in the ISO standards

Along with the recent adoption of the new version, the standard mentioned above and the approval last March of the new revision of the ISO/IEC 17020 standard which lays out the criteria used for the inspection body assessments, also this year other changes in the standards applicable to accredited organizations are expected.

The standard ISO/IEC 17065, used as a criteria to evaluate and accredit product certification bodies will replace guide ISO 45011 65EN. Upon completion of the voting period in July, the English version was published. The Spanish Edition is expected before the end of year.

Regarding the review of the ISO 15189 standard on particular quality and competence requirements of clinical laboratories, it is expected to be adopted by the end of year.

(Page 12) Highlights

<u>Control bodies for the assessment of transportable pressure</u> <u>equipment</u>

The transport of goods by road and rail is an everyday element in our lives. Part of this transportation is carried out by pressure equipment; which is an added risk, so the safety requirements demanded for this equipment are critical to ensure the safety of persons and property.

Due to the free movement of such transport in the internal market, the European Commission has developed different policies affecting both the transportation of dangerous goods and the transportable pressure equipment, which Spain has incorporated into its national regulations.

The Royal Decree 1388/2011, on the 14th of October, transposed Directive 2010/35/UE (16th of June, 2010) on transportable pressure equipment, taking into consideration both the developments in transport safety and the content of Directive 2008/68/CE of the European Parliament and Council (24th of September 2008), which expanded the scope of the provision application of certain international agreements so that they would apply to domestic traffic in order to harmonise the conditions throughout the European Union, under which dangerous goods are transported by road, rail and inland waterway.

The Directive 2010/35/UE, which supersedes previous Directives on the subject, aims to prevent conflicts of Standards in particular what it refers to as the requirements for conformity, conformity assessment and conformity assessment procedures, applicable to transportable pressure equipment.

Focusing on the most relevant aspects, the regulation lays down the obligations of the economic operators (manufacturers, those authorized to be responsible, importers, distributors, owners and users), the technical requirements for the conformity of the transportable pressure equipment and the aspects relating to the notification process, including the necessary requirements of conformity assessment bodies.

In the last case, and as it is customary in the regulatory documents that are responsible for ensuring aspects relating to the safety of persons and property, it examines the participation of the Notified Bodies, which must have the status of Control Bodies, and participate in different conformity assessment processes.

From the accreditation point of view, the publication of the new regulation has meant a significant job of homogenizing the development of the Control Bodies' assessment process that has requested the extension to the new document. ENAC has already begun the proceedings and granted the first accreditations for this new regulation.

For more information: lmrodriguez@enac.es

(Page 13) Highlights

Publication of the Accreditation and Verification Regulations for the emissions trading scheme

Last July the Accreditation and Verification Regulations for trading of emission allowances was published, which set out, among other questions, that for emissions verifiers to be able to operate in this plan they must be accredited by the corresponding National Accreditation Body designated in each member state under Regulation (EC) No. 765/2008. In Spain, therefore this activity will continue to be performed by ENAC.

Furthermore, the regulation established the EN ISO 14065 Standard "Greenhouse Gases - Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition" as a reference for this accreditation.

ENAC has collaborated both in the drafting of the Regulation and in a comprehensive complementary material guide with the Working Group set up by the EA to give support to the Commission's services. Also ENAC is actively involved in the process of reviewing the specific criteria document for verifiers of greenhouse gas reports accreditation (EA-6/03).

At the same time, EA began necessary activities to establish a new European Agreement of Mutual Recognition for this activity, also prescribed in the regulation. ENAC requested to be incorporated and will sign the agreement when the corresponding evaluation processes are completed.

In 2011, to ensure that the verifiers accredited by ENAC were best disposed to address these changes, ENAC launched a transition process for verifiers upgrading their accreditations to the new standard. The adaptation assessments have been conducted throughout the 2011-2012 campaign and, to date, two accreditations have been granted for the Verification of Reports on Trading of Greenhouse Gas Emissions regarding the UNE-EN ISO 14065 Standard.

For more information: <u>ealconero@enac.es</u>

(Page 14) Highlights

First accreditation for the QS Protocol certification in the agri-food field

The QS plan establishes a number of requirements which are intended to ensure the comprehensive food production process, from its origin through processing to its subsequent marketing.

ENAC has recently granted Kiwa Spain, S.L. their first accreditation for the certification of agricultural production in accordance with QS certification for fruits, vegetables and potatoes.

QS is a food sector quality assurance plan, founded in 2001 by leading organizations of the sector in Germany, starting initially in the meat sector and expanding in 2004 to include fruit, vegetables and potatoes. It is a voluntary system of quality assurance that includes all phases of the production process and which implies, among other things, the certification of the operators by QS authorized certification bodies and which should be accredited to this plan with the EN 45011 Standard.

After obtaining the certification and after signing the corresponding contract with the owner of the plan, the operator is authorized to use the QS certification mark according to the requirements of the QS certification mark design catalogue.

Other certification bodies are currently in the accreditation process for this plan, so it is assumed that in the short term the high number of Spanish producers of fruits, vegetables and potatoes who export their products to the European market will have sufficient certification bodies accredited by ENAC.

For more information: egredilla@enac.es

(Page 15) Agenda

ENAC receives the Turkish authorities

On the 12th of July, the office of ENAC received a study visit by the European Commission's technical assistance project which aims to assist the Turkish authorities in strengthening the infrastructure of their country.

The delegation was composed of various representatives of the Ministry of Economy and the Accreditation Agency of Turkey - TURKAK. On behalf of ENAC Beatriz Rivera, the General Director, and Ignacio Pina, the Technical Director, explained in depth how the organization worked and the accreditation activity that has developed into the mark of quality infrastructure in our country.

National Meetings

IBERIAN PIG FORUM 8 October 2012 - Zafra ENAC representative: E. Gredilla

TECHNOLOGICAL INNOVATION AND MANAGEMENT IN CLINICAL LABORATORIES COURSE 15 October 2012 - Sitges

ENAC representative: L. Añorbe

"GLOBALIZATION AND INTERNACIONALIZATION. PROSPECTS AND FUTURE OPORTUNITIES" SYMPOSIUM

18 de October 2012 - Lisbon ENAC representative: I. Lorente

XXI CONFERENCE OF THE SPANISH SOCIETY OF QUALITY ASSURANCE IN RESEARCH (SEGCIB)

18 y 19 October 2012 - Barcelona ENAC representative: M. García

8th MEETING OF THE CANARY ISLANDS CLINICIAL MICROBIOLOGY SOCIETY

19 y 20 October 2012 - Santa Cruz de Tenerife ENAC representative: I. De la Villa

CONFERENCE ON UNE-EN ISO/IEC 17020 (ROAD VEHICLE INSPECTION and CONTROL BODIES)

24 y 25 October 2012 - Barcelona Organized by ENAC

International Meetings

EA COMMUNICATIONS AND PUBLICATION COMMITTEE

10 y 11 October 2012 - Paris ENAC representative: C. Tallés

EA EXECUTIVE COMMITTEE

20 November 2012 - Bratislava ENAC representative: I. Pina

EA GENERAL ASSEMBLY

21 y 22 November 2012 - Bratislava ENAC representative: B. Rivera