

“Accreditation News” issue 60

Second Quarter 2012

NEW ACCREDITED BODIES

TESTING LABORATORIES

Acoustics

EPTISA SERVICIOS DE INGENIERÍA, S.L. - 89/LE1922
INGENIEROS ACÚSTICOS CONSULTING, S.L.P. (Unipersonal) - 985/LE1943

Agrifood Products

LABORATORIO DE ANÁLISIS Y SERVICIOS AVANZADOS LTDA - 975/LE1905
ANÁLISIS, INVESTIGACIÓN, DISEÑO Y ENSAYO, S.L. - 977/LE1849
LABORATORIO DE SALUD PÚBLICA DE FUERTEVENTURA - 982/LE1937
CANATEC 35, S.L. - 988/LE1903
SOCIEDAD COOPERATIVA GENERAL AGROPECUARIA ACOR - 983/LE1930

Environmental Testing

INDROPS LABORATORIO DE ANÁLISIS Y CALIDAD MEDIOAMBIENTAL, S.L. - 658/LE1987
MANCOMUNIDAD DE MAIRAGA-ZONA MEDIA <>ERDI ALDEA - 973/LE1889
GEOTECNIA 2000, S.L. - 976/LE1821
CANAL DE ISABEL II - 287/LE1923
GESTIÓN Y TÉCNICAS DEL AGUA, S.A. - 981/LE1909
INGENIERÍA MEDIO AMBIENTAL IMA, S.L. - 986/LE1526
LABORATORIO HIMALAYA, S.L. - 987/LE1426

Wind Energy

CENTRO DE INVESTIGACIONES ENERGETICAS, MEDIOAMBIENTALES Y TECNOLOGICAS (CIEMAT) - 144/LE1926

Clinical Laboratories (UNE-EN ISO 15189)

SERVICIO ANDALUZ DE SALUD. HOSPITAL MÁLAGA - AXARQUÍA - 916/LE1952
LABORATORI DE REFERENCIA DE CATALUNYA, S.A. - 978/LE1940
FUNDACIÓN CENTRO NACIONAL DE INVESTIGACIONES ONCOLÓGICAS CARLOS III - 984/LE1911 y 984/LE1873
CATLAB-Centre Analítiques Terrassa, A.I.E. - 989/LE1956

Radiation Safety

CENTRO DE ESTUDIOS Y EXPERIMENTACION DE OBRAS PUBLICAS (CEDEX) - 82/LE1955
CENTRO DE INVESTIGACIONES ENERGETICAS, MEDIOAMBIENTALES Y TECNOLOGICAS (CIEMAT) - 144/LE1836

Metallic Material

UNIVERSIDAD REY JUAN CARLOS LABORATORIO DE INTEGRIDAD MECÁNICA (LIM) - 380/LE1961

Medical Product Sterilization

BIOTECNAL, S.A. - 408/LE1969

Electrical Safety

IDNEO Technologies, S.L. - 827/LE1906

Plastic Materials

FUNDACIÓN ANDALTEC I+D+i - 974/LE1899

Graffix Arts

INSTITUTO TECNOLÓGICO Y GRÁFICO TAJAMAR, (ITGT) DEL CENTRO CULTURAL Y DEPORTIVO TAJAMAR, S.A. - 979/LE1921

Automobile Components

GKN DRIVELINE ZUMAIA, S.A. - 980/LE1925

CALIBRATION LABORATORIES

Fluids

ALFEJO LABORATORIOS, S.L. - 202/LC546

Chemical Concentration of Gases

INSTRUMENTACIÓN Y SERVICIOS DE CALIBRACIÓN, S.L. - 203/LC551

Optics

INSTITUTO TECNOLÓGICO Y GRÁFICO TAJAMAR, (ITGT) DEL CENTRO CULTURAL Y DEPORTIVO TAJAMAR, S.A. - 204/LC543

INSPECTION BODIES

Mining

LABORATORIO OFICIAL J.M. MADARIAGA (LOM) - 23/EI437

Vehicle Reform Technical Service

DESARROLLO AUTOMOVILIDAD, S.L. (Unipersonal) 254/EI362

LABORATORIO DE MOTORES TÉRMICOS DE LA ESCUELA SUPERIOR DE INGENIEROS DE LA UNIVERSIDAD DE SEVILLA - 255/EI456

ASOCIACIÓN DE INVESTIGACIÓN Y COOPERACIÓN INDUSTRIAL DE ANDALUCÍA "F. DE PAULA ROJAS" - AICIA - 258/EI439

LABORATORIO DE VEHÍCULOS. Universidad Miguel Hernández de Elche - 259/EI446

Environmental Inspection - Soils

GARRIGUES MEDIO AMBIENTE, CONSULTORÍA TÉCNICA Y DE GESTIÓN INTEGRADA DEL MEDIO AMBIENTE, S.L.P. - 256/EI316

GEOTECNIA 2000, S.L. - 260/EI452

Agri-food sector – Animal Health

COLEGIO OFICIAL DE VETERINARIOS DE MADRID - 257/EI408

Road Vehicle Inspection

ENTIDAD IDV MADRID, S.L. - 59/EI/ITV068

PRODUCT CERTIFICATION

Agrifood Products

CONSEJO REGULADOR DE LA DENOMINACIÓN DE ORIGEN PROTEGIDA "MAHÓN-MENORCA" - 96/C-PR179

COMITÉ DE AGRICULTURA ECOLÓGICA DE LA COMUNIDAD VALENCIANA - 97/C-PR135

CONSEJO REGULADOR DE LA DENOMINACIÓN DE ORIGEN CALATAYUD - 98/C-PR238

ASOCIACIÓN ESPAÑOLA DE ENTIDADES DE CERTIFICACIÓN AGRARIA Y ALIMENTARIA (CONSECERT) - 99/C-PR185

INGENIERÍA TÉCNICA AGRÍCOLA CERTIFICADORA AGROALIMENTARIA, S.L. - 101/C-PR223

R&D Projects

TÜV RHEINLAND IBERICA INSPECTION, CERTIFICATION & TESTING, S.A. - 100/C-PR240

Concrete products

ASOCIACIÓN ESPAÑOLA DE NORMALIZACIÓN Y CERTIFICACIÓN (AENOR) - 1/C-PR002.079

Fired Clay Ceramics

ASOCIACIÓN ESPAÑOLA DE NORMALIZACIÓN Y CERTIFICACIÓN (AENOR) - 1/C-PR002.034

MANAGEMENT SYSTEMS CERTIFICATION

Health and Safety

DET NORSKE VERITAS BUSINESS ASSURANCE ESPAÑA, S.L. (Unipersonal) - 3/C-SG051

CERNE AUDITORES DE PREVENCIÓN, S.L. - 37/C-SG036

CONTROL BODIES

Industrial Safety Facilities Regulation

ECA, ENTIDAD COLABORADORA DE LA ADMINISTRACIÓN, S.A. (Unipersonal) - OC-/I259

GISCE-INGENIERIA, S.L. (Unipersonal) - OC-/I255

Legal Metrology

FUNDACIÓN TECNALIA RESEARCH & INNOVATION - OC-/I235

ITVERSIA GESTIÓN, S.L. - OC-/I258

ENTIDAD IDV MADRID, S.L. - OC-/I244

Building Products Directive

OCA Instituto de Certificación, S.L. (Unipersonal) - OC-P/250

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ENAC from the inside

Participation and collaboration with stakeholders

For the accreditation system to function properly, it is essential to maintain a high level of collaboration and communication with all stakeholders.

Therefore, this year, ENAC has continued its collaboration with Governments, business organizations, professional and technical associations and other stakeholders; thereby helping to keep up a regular exchange of information between ENAC and the various organizations that make use of the accredited services.

Some examples are listed below:

- Collaboration with the Spanish Office of Climate Change on the adaptation of the Greenhouse Gases Emissions Verification Scheme within the new European Regulation for Accreditation and Verification.
- Collaboration with the Ministry of Economy and Finance on different aspects related to the R&D, such as the so-called "Patent box", a tax incentive associated with the transfer of technology.
- Meetings with both the Committees on Occupational Risk Prevention and on Quality and Environment of SEOPAN companies.
- Participation in the Basque Government's Forum on the prevention and correction of soil contamination, groundwater and landfill sites.
- Participation in the revision and harmonization work of the GLP inspection criteria of the three national Performance Programs, within the framework of the Technical Inspection Committee of the Spanish Drugs and Health Products Agency.
- Collaboration with the forensic and scientific police services on the implementation of the Framework Decision 2009/905/JAI on the accreditation of forensic service providers which carry out laboratory activities (DNA and fingerprints).
- Developing the calibration and verification criteria required for the equipment used in the Road Vehicle Inspection, in cooperation with the Spanish Management Collaboration Bodies Association of the Road Vehicle Inspection AECA-ITV.
- Collaboration with the Ministry of Industry, Energy and Tourism for the accreditation of the Laboratories of Cataloging historical vehicles.
- Contact with Professional Bodies and Associations (Official Quantity Surveyors Association of Madrid; General Council of Official Industrial Engineers Associations; Technical Association of Roads,...).

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Interview

ENAC's Interview with Cayetano López, Director General of the Energy, Environment and Technology Research Centre, CIEMAT

"Accreditation has meant an improvement in the management of the service, and a greater control of technical processes"

CIEMAT is a Public Research Organisation focussed mainly on energy, environment and the related technology fields. Because of their intermediary position in the chain that runs from the creation of basic knowledge all the way to the industrial application, its activity seeks to serve as a bridge between the R&D and social interest objectives.

Its mission is to contribute to the sustainable development of Spain and the citizens' quality of life through the generation and application of scientific and technological knowledge, while maintaining a position as a centre of excellence in scientific and technical areas where it develops its activities.

What activities are developed at the newly-accredited Radiation Dosimetry Service (RDS) of CIEMAT's Environmental Department?

RDS performs tests which determine the radiation doses from internal and external exposure. The techniques or methods used in the RDS include the determination of the Personal Dose Equivalent $H_p(d)$, through the use of personal thermoluminescent dosimeters (TLD); the determination of the Environmental Equivalent Dosage $H(10)$, by way of environmental dosimeters and thermoluminescent area; the allocation of the Committed Effective Dose ($E(50)$), due to the incorporation of radionuclides, based on direct methods (body radioactivity metre) and indirect methods (means of excreta) for determining the incorporation of radionuclides in the human body.

Who are the users of this Service?

Workers exposed to ionizing radiation, both those that develop their professional work at CIEMAT and in other public institutions, such as ENRESA; the public body responsible for the management of all radioactive waste generated in Spain, ENUSA advanced industries, S.A.; which is responsible for the design, manufacture and supply of fuel to Spanish and international exchanges, in addition to the users who request the RDS provided services.

What kind of laboratories, in addition to the RDS, offer this service at the national level?

There are other dosimetry services in Spain, some of them accredited for external personal dosimetry testing or environmental dosimetry testing and those areas. But none of them has the wide range of internal and external personal dosimetry testing methods, which are included in the scope of accreditation of the RDS.

How does accreditation contribute to the work of the RDS?

It has meant an improvement in the management of the service, as well as a greater control of the technical processes which are carried out. The accreditation which is obtained shows the RDS's technical competence in radiation dosage testing, which ultimately translates into user-confidence for the quality of the results reported.

By obtain the accreditation, the RDS has been consolidated as a reference centre in Spain in the field of radiation dosimetry.

CIEMAT already had the ENAC accreditation for some of the activities carried out, are they intending to extend accreditation to new activities in the future?

The Environmental Radiology Division aims to extend the accreditation, to include new environmental radioactivity and dosimetry testing. In addition, different departments of CIEMAT are working on the implementation of quality systems for the accreditation of its activities.

What relation does the RDS have with the Nuclear Safety Council (NSC)?

Since 1992, the NSC has awarded the express authorization to the External and Internal Personal Dosimetry Services that make up the RDS for the individual monitoring of workers exposed to ionizing radiation, as established by the Health Safety Against Ionizing Radiation Regulation, Royal Decree 783/2001. By virtue of this authorization, the NSC performs periodic inspections to verify compliance with the conditions of authorization.

The RDS also acts as a laboratory of technical support to the NSC when required.

CIEMAT's Radiation Dosimetry Service accreditation

The RDS is one of the first services of dosimetry to be accredited at the national level for internal dosimetry testing and the first for the allocation of internal dosage due to the incorporation of radionuclides. It is also the first Spanish personal dosimetry service accredited for the carrying out of dosimetry of limbs by means of ring dosimetres.

The Radiation Dosimetry Service (RDS) of the CIEMAT's Environmental Department has obtained the accreditation according to the UNE - EN ISO/IEC 17025:2005 standard, in recognition of their technical competence for **testing of radiation dosages**.

The accreditation scope includes **external dosimetry testing** for determining Personal Dose Equivalent Hp (d) using personal thermoluminescent dosimetres (body, abdomen and ring) and for determining Environmental Equivalent Dosage H (10), by way of environmental dosimetres and area thermoluminescents.

In the field of **internal dosimetry**, and within the accreditation scope, trials are conducted for the allocation of the committed effective dose E (50) due to the incorporation of radionuclides in the human body and which include direct methods, by means of gamma spectrometry with the detection systems LEGe, NaI (TI) and Fastscan, as well as indirect methods by urine and faeces sample analysis after radiochemical separation processes and measured by alpha spectrometry, scintillation spectrometry in liquid phase and laser-induced kinetic phosphorimetry.

A specialist of the Division of Radiation, Transport and Waste Safety for the **International Atomic Energy Agency (IAEA)**, joined the audit team to ensure the correct assessment of such a specific activity with such highly-technical content as this.

For further information: orecuero@enac.es

First accreditation for the Energy Star programme Efficient Energy Consumption

In February 2011, ENAC was officially recognized by the United States' Environmental Protection Agency (EPA) to accredit laboratories carrying out tests on products seeking the ENERGY STAR certification.

ENERGY STAR is a joint program by the EPA and the United States Department of Energy which was created in 1992 to promote energy efficient electrical products, thereby reducing the greenhouse gas emissions of power plants.

It began as a program of voluntary labelling designed to identify and promote energy efficient products; computer products were the first to be labelled. Since then it has expanded to include office equipment, lighting, electrodomestic appliances and so on.

LGAI Technological Center S.A. is the first laboratory accredited by ENAC for testing under the specifications of this programme. Specifically, the accreditation obtained is for the testing of the operational mode (OP) in order to quantify the energy consumption of printers, scanners, copiers and multifunctional devices.

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ENAC hosts the EA General Assembly

On the 23rd and 24th of May the General Assembly of the European Co-operation for Accreditation (EA) was held in Madrid, with the participation of representatives of accreditation agencies from more than 40 countries, from the European Commission and also numerous European and international organisations.

This year, among the attendees were the European national accreditation bodies, representatives of the European Commission, the European Free Trade Association (EFTA) and the Eurasian Economic Commission (EEC); the organizations of Asia-Pacific regional accreditors (APLAC) and America (IAAC), agencies and institutions of metrology, professional associations such as the European Federation of Clinical Chemistry and laboratory medicine (EFCC), conformity assessment associations such as the European Federation of Associations of Certification Bodies (EFAC), EUROLAB and European Organic Certifiers Council (EOCC); standards associations and international quality organizations such as the European Organization for Quality (EOQ), and others.

The meetings addressed various issues relating to the collaboration work with the General Management of Industry, Health and Consumer Protection, the Environment, Climate Action and Agriculture and Rural development of the European Commission.

The Jordanian Accreditation Organization (JSMO) and that of Morocco (SEMAC) joined as associate members of EA, taking effect from the 23rd of May 2012.

In addition, the incorporation of the accreditation bodies of Serbia (ATS) and the Former Yugoslav Republic of Macedonia (IARM) to the EA Recognition Agreements were ratified, and the agreement on activities for testing, calibration and certification of management systems with the Ukrainian accreditation body was expanded. With these additions, there are currently 37 countries signatory to these agreements.

During the Assembly, the process for the establishment of a new Multilateral Agreement for the ISO 14065 standard was approved, giving support to the European Emissions Trading System. (EU ETS its acronym in English).

Value of accreditation in economic policy

The meeting received important support from the Government, with Manuel Valle Muñoz, the Director-General of Industry and Small and Medium Enterprise Department of the Ministry of industry, Energy and Tourism's, participating at the welcome ceremony.

During his speech, Sr. Valle assessed the Ministry of Industry's use of accreditation with relation to industrial safety in the areas within its competence, in both national and European legislation. In this regard he particularly stressed "that for many years already in Spain, where Notified Bodies are concerned, accreditation has been the indispensable base of the notification processes".

At the same time, he also emphasized the value that accreditation has for the export company "it is one of the mechanisms recognized both by the World Trade Organization and the European Union to minimize technical barriers to trade".

The General Director of Industry noted the promotion of the economy based on knowledge, competition, and more specifically on the promotion of the R&D as another aspect that accreditation can play an important role in. "The ENAC accreditation is instrumental in certain specific mechanisms designed by the Government to help companies achieve a more efficient use of certain tax breaks for investments in research and development," said Valle.

In conclusion, he stressed the importance of the existence of a National Accreditation Body that is regarded by the market and society as an independent, serious, professional, rigorous and competent organization "in such a way that the confidence their accreditations inspire within the market come not only from its position as a designated body but, and mainly because, it is perceived as an institution worthy of trust".

"It is precisely the case in Spain," concluded Valle, "something that we in the Ministry of industry say with ostensible pride, since it was at the heart of this Ministry from which arose the first embryo of accreditation in Spain and which some years later opted for a model of accreditation and accreditation body that is virtually identical to that which has been finally sanctioned by European regulation 765".

(Page 12) Sectors

Massive genotyping of SNPs and genetic predisposition

The Laboratory of Human Genotyping of the National Foundation Centre of Oncological Research Carlos III is the first laboratory accredited by ENAC for massive genotyping of SNPs related to the genetic predisposition to develop diseases in the field of nutrition and cardiology.

Only a small portion of the human genome (0.1 approximately) is variable between individuals. SNPs are the more common polymorphisms (variations) and in recent years various technologies have been developed that are able to simultaneously determine a large number of SNPs located in different genes, enabling the study of allelic variations between individuals and their relationship with the genetic predisposition to develop various pathologies.

Therefore, one of the current applications of SNPs genotyping is the predictive diagnosis which allows preventive strategies to be applied to patients (changes in lifestyle, periodic checkups, and so on).

The National Foundation Centre of Oncological Research Carlos III (CNIO), founded in 1998 by the Carlos III Health Institute, is a Spanish public institution dedicated to Cancer research, diagnosis and treatment. In addition to this accreditation, the CNIO has been accredited since April 2012, under the ISO/IEC 17025 standard in the field of histology, including the preparation of stains by conventional histological, Immunohistochemical and molecular techniques, (in situ hybridization).

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Sectors

Sterilization of Medical Devices

The use of sterile medical products is a basic preventive measure in health. The sterilization process is, therefore, essential throughout the whole chain from production to use.

In the manufacturing processes, even those done in accordance with the requirements of quality management system specifications (e.g.: the ISO 13485 standard), the products obtained may contain microorganisms; although in reduced numbers, before sterilization. And in turn, despite the processes of sterilization by physical and/or chemical agents, there is always the possibility that an organism can survive the treatment because of their characteristics (exponential kinetics between the surviving microorganisms and the sterilizing agent's degree of treatment).

Therefore, prior to sterilization, it is necessary that the number of microorganisms is reduced to the minimum. By testing to determine the incidence of microorganisms (ISO 11737-1), it is possible to analyse the product and know their numbers and characteristics (moulds, yeasts and mesophilic aerobic bacteria).

Recently, the first accreditations have been awarded for determining the microbial load: AITEX, for medical textile products, and Biotechna for medical products in general.

Hence, a sterility test is needed to define and validate a sterilization process, determining the presence or absence of viable microorganisms in a device, by using conditions similar to those expected to be used in a routine sterilization. The Biotechna laboratory's accreditation also includes this test (ISO 11737-2).

In addition, the Spanish Medicine and Medical Product Agency has been accredited since 2005 for sterility testing in sterile medicines for human and veterinary use.

For further information: ivilla@enac.es

INTERNATIONAL RECOGNITION OF ILAC/ IAF AGREEMENTS

The United States promotes the acceptance of the MLAs in the World Trade Organization.

US authorities consider that these agreements will aid the creation of a globally solid system which will help to achieve its objectives at the lowest cost to regulators and other authorities while favouring trade and promoting confidence in product conformity.

The World Trade Organization's (WTO) agreement on Technical Barriers to Trade aims to ensure that technical regulations and standards, as well as procedures for testing and certification, do not create unnecessary barriers to trade. Article 9 requires that Members, wherever practicable, formulate and adopt international systems of conformity assessment where a positive assurance of conformity with a technical regulation or standard is required.

Some time ago the Committee on Technical Barriers to Trade recognized that the ILAC and IAF agreements of recognition, of which ENAC is a signatory, were designed to facilitate the acceptance of the results of evaluation, thereby facilitating trade.

Accordingly, the United States delegation has recently submitted the experience of six federal agencies, which have chosen to abide by these agreements, to the Committee: the Consumer Product Safety Commission (CPSC); the Federal Highway Administration (FHWA); the United States Coast Guard (USCG); the General Services Administration; the Environmental Protection Agency (EPA); and the Food and Drug Administration (FDA).

Conformity and interoperability of the information technologies and communications

The International Telecommunications Union (ITU), the United Nations Organization for the information technologies and communication, the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) have signed an agreement which strengthens these organizations' commitment of cooperation and collaboration and will lend further impetus to the development of ITU-T's Conformity and Interoperability (C&I) programme.

The programme seeks, above all, to enable the interoperability of ICT products and services, allowing people access to the Information Society regardless of their location or chosen ICT device.

A key part of this initiative lies in the adoption of test suites applicable to ITU international standards, and in the implementation of accredited conformity assessment activities including the establishment of a global network of regional conformance testing centres – tasked with evaluating products' degree of compliance with ITU's international standards, and thereby assessing the associated likelihood of interoperability.

The recognition agreements established at the heart of the ILAC and IAF, encourage consumer confidence in tested products, increase market opportunities, encourage trade and technology transfer and contribute to the removal of technical barriers to trade.

Therefore the agreement reached by these organizations would contribute greatly to ensuring that the ITU's C&I program objectives are reached.

For further information:

www.itu.int

(www.itu.int/ITU-T/newslog/ITU+Signs+Memorandum+Of+Understanding+With+IAF+And+ILAC.aspx)

www.ilac.es (http://www.ilac.org/itu_iaf_ilac_mou.html)

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Agenda

National Meetings

FIRST INTERNATIONAL CONFERENCE ON FOOD SAFETY

28th and 29th of June 2012 in Barcelona

Representing ENAC: E. Gredilla

ROUND TABLE “RESEARCH INTO SUBSOIL QUALITY AND INSPECTION BODIES”

12th of July 2012 in Madrid

Representing ENAC: O. Recuero

ANNUAL ENAC LEAD ASSESSORS CRITERIA CONSISTENCY CONFERENCES

18th and 20th of September 2012 in Madrid

Organized by ENAC

International Meetings

EA TRAINING DAY ON ISO/IEC 17020: 2012

21st and 22nd of August 2012 in Bern

Representing ENAC: J. Barroso

EA EXECUTIVE COMMITTEE

5th and 6th of September 2012 in Utrecht

Representing ENAC: I. Pina

EA CERTIFICATION COMMITTEE

11th and 12th of September 2012 in Helsinki

Representing ENAC: E. Gago

EA INSPECTION COMMITTEE

13th of September 2012 in Helsinki

Representing ENAC: P. Ordeig

EA LABORATORIES COMMITTEE

19th and 20th of September 2012 in Oslo

Representing ENAC: R. Porres

EA MLA COMMITTEE

26th and 27th of September 2012 in Nicosia

Representing ENAC: B. Rivera

EA HORIZONTAL HARMONIZATION COMMITTEE

3rd and 4th of October 2012 in Brussels

Representing ENAC: I. Pina

The new approved revision of the ISO/IEC 17020

In March, the new revision of the standard which establishes the criteria used for the assessment of the **inspection bodies** was approved.

ENAC has established and publicised the Plan for the transition to the new standard. The Plan fits into the 3-year period established by the International Laboratory Accreditation Cooperation, ILAC.

You can view and download the document from our Document section on the webpage.

