

“Accreditation News” Issue 65

Third Quarter 2013

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ENAC from the inside

Certificates and Accredited Scopes. New security features

These enable the assessment service users to be assured of the accreditation's validity and so contribute to increase confidence in the accredited bodies' activities and eradicate unlawful actions to the greatest possible extent which represent unfair competition for these bodies and so discredit the entire system.

Generating confidence in both the market and the authorities for the accredited assessors activity is probably the primary goal of any accreditation body. To achieve this, in addition to establishing rigorous assessment procedures, it is essential that the accreditation certificates and their technical annexes, which support this assessment, also provide a high degree of confidence in its validity and legitimacy.

As the market demands more accreditation so certificates and technical scopes that have been manipulated or, specifically, falsified are detected more often. This is a problem found not only in Spain but worldwide, so much so that the international accreditation organizations ILAC and IAF are beginning to consider taking possible measures to combat it.

At ENAC, with the aim of increasing the information security we offer to the market and in order to make these practices as difficult to do as possible, we have implemented various measures.

Therefore all accreditation certificates and the technical annexes include a digital signature, guaranteeing the receiver of the document that it has been issued by ENAC and that it has not been modified since its issuance, making it easier for unsigned documents to be seen as "suspect", thereby achieving a substantial increase in security.

The Certificates and Technical Annexes also include a security code which enables the validity of the accreditation to be checked in real time, to see if the accreditation is active at that time or if it has been suspended or withdrawn. To do this you only have to click on the electronic validation code in case of a digital document or, in the case of paper documents, introduce it in the relevant place on our web page.

The **paper accreditation certificates** issued since last year include a hologram with ENAC's logo in order to distinguish the original documents, making them easily identifiable and so any document without the hologram is treated as a copy.

All of these actions enable accredited assessment service users to make use of these tools in order to ensure the accreditation is valid so that they can trust and contribute to increasing confidence in the accredited bodies' activities and eradicate the unlawful actions to the greatest extent possible which represent unfair competition for these accredited bodies and so discredit the entire system.

For more information: soporte_sgd@enac.es

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ENAC from the inside

ENAC strengthens its internal structure

Recently, new professionals have joined ENAC coming to help strengthen the services provided in various areas.

Sergio Sancho Barrio

An Agricultural Engineer, with a degree in Environmental Sciences and 13 years professional experience. He has extensive experience in consulting and auditing for product certification and agri-business companies. He joins the Product Inspection and Certification Area from the Agri-food and BPL Department.

Natalia Dalmau Tortosa

An Honours Chemical Engineer with additional training in instrumental analysis, treatment and recycling engineering as well as environmental and quality management. She has more than 8 years of professional experience in centres of industry and technology. She joins the Department of Laboratories and Product Certification.

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ENAC from the inside

Agreement between ENAC and the "Origin Spain" Association

This agreement enables the Protected Designation of Origin and Protected Geographical Indications to participate in ENAC's technical work and so increase the efficiency and transparency of their contribution.

ENAC and the Spanish Designation of Origin Association "Origin Spain" have recently signed an agreement to formalize their collaboration and coordinate their work.

"Origin Spain" is a private non-profit organization formed by the Spanish Protected Designation of Origin (PDO) and Protected Geographical Indications (PGI). Its objectives are to promote the recognition of its essential role, promote the exchange of knowledge and experiences as well as to defend these quality brands differentiating between the national, community and international organizations, the relevant authorities, consumers and the general public.

For ENAC the priority is to rely on the participation of all interested parties, especially on the technical developments. The collaboration with the Conformity Assessment associations constitutes an efficient and transparent way to organise this participation.

Products covered by PDOs and PGIs must be certified in accordance with the UNE-EN 45011 standard (recently replaced by the ISOIEC 17065 UNE-EN). Therefore, "Origin Spain" brings together numerous product certification bodies, many of which are already accredited and others are on the way to being accredited.

This agreement enables the PDOs and PGIs to be involved in and collaborate with ENAC's technical work and to spread and promote accreditation and the benefits it brings to the market and to the Administration which relies on accredited assessment.

General Assembly of Origin Spain

The agreement was signed in the Association's 5th General Assembly, held from the 26th to the 28th of June in Mahon. It brought together numerous PDO and PGI agri-food product Regulatory Councils from all over Spain and was attended by representatives of the Ministry of Agriculture, Food and Environment, the Menorca Island Council, the Spanish Patent Office and ENAC.

During the Assembly, the ENAC's head of the Agri-food and BPL Department gave a presentation on the new aspects of the UNE-EN ISOIEC 17065 standard and the transition plan established by ENAC.

We are convinced that this agreement will provide many opportunities for both the "Origin Spain" Association and ENAC in the future.

For more information: egredilla@enac.es

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In depth

Railway Sector Accreditation

The increasing safety and vehicle comfort requirements, together with the specific characteristics of the design and production processes, as well as national and international development of rail infrastructures and services have created the need for accredited conformity assessment services.

The safety inspection accreditation for risk evaluation and assessment has been incorporated into services accredited by ENAC.

The formation of an integrated railway area where trains, passengers and goods must be able to circulate freely, has led to the development of the European Rail Traffic Management System (ERTMS), a project which aims at eliminating rail borders thereby encouraging markets to open up, establishing a safe and operable system for all companies.

This has led to the technical regulation developed with common safety requirements and solutions as well as the interoperability of structural and functional subsystems which comprise the railway network. These are required to rely on the accredited conformity services, such as the ETCS trials, infrastructure certification, rolling stock, control, commands, signalling and energy, etc., and more recently, safety inspection for evaluation and assessment of risk.

In Spain, the FOM/233/2006 order and its corresponding Technical Specifications for Homologation (ETH), set out the requirements for railway rolling stock to circulate on the General interest Railway Network guaranteeing, among others, both the safety of the railway circulation and interoperability of the material and the infrastructure.

Currently the Spanish railway sector is present in more than ninety countries. According to the Spanish Institute of Foreign Trade, in 2012 the railways ranked second place in the top ten sectors to most increase their sales abroad, with a 21.2% in 2011.

The sector currently includes various testing, certification and inspection services that are accredited by ENAC:

- Carrying out ETCS Testing, aimed at verifying compliance with the Technical Specifications for Interoperability (TSI), ensuring that these information transmission elements will communicate correctly with the train equipment regardless of whoever manufactures either equipment.

- Testing of railway vehicles, such as structural strength tests, static tests, emitted noise and interior noise measurements or passengers travel comfort measurement.
- Infrastructure Certification; Rolling Stock and Control Command and Signalling and Energy in accordance with the Technical Specifications of Interoperability (TSI) of the Trans-European High-Speed Rail System.
- Certification of carriages, self-propelled units, locomotives, railcars and auxiliary rolling stock according to the Technical Specifications for Homologation (ETH).
- Independent safety assessments (ISA) of structural and functional safety systems.
- Inspection of railway rolling stock according to specifications of the client and/or manufacturer.

Safety inspection for risk evaluation and assessment.

A new activity that joins ENAC's accreditation.

The Implementing Regulation (EU) 402/2013 of the Commission of 30th April 2013, concerning the adoption of a common safety method for risk evaluation and assessment, in accordance with the directive on the safety of the community's railways (2004/49/CE). It establishes that when there is a significant change, with an impact on safety, an independent safety assessment (ISA) report is necessary.

Such changes may be technical, operational or organisational and can affect any of the structural subsystems: infrastructure; energy; control; command and signalling; rolling stock and functions: traffic operations and management; maintenance; telematic passenger service applications and freight transport – all which make up the railway system.

These assessments are essential, too, to validate the systems related to safety, especially rolling stock and signalling and control systems or if the relevant technical specifications for interoperability (TSI) require a risk assessment for the structural subsystems and those applicable under the 200857CE Directive.

The ISA carry out an independent competence assessment of both the application of the risk management process and also its results according to the CENELEC norm (EN50128, EN50126 and EN50129). There are currently accredited bodies, conforming to the provisions of these rules, to act as independent assessors.

In order to ensure the competence of the assessors, the Regulation opts for requiring accreditation by the National Accreditation Body (paragraph 14), in accordance with the criteria set out in the ISO/IEC 17020:2012 standard (ANNEX II).

ENAC is ready to offer this activity's accreditation to companies that request it. All the necessary information is on our website.

For more information: shuerta@enac.es

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Current News

First laboratory accredited for internal personal dosimetry

The first accreditation awarded by ENAC in this field at the biological structure level (chromosomal alterations in peripheral blood lymphocytes).

The Biological Dosimetry Laboratory, belonging to the Radiation Oncology Service at the Gregorio Marañón General University Hospital, has obtained accreditation according to UNE-EN ISOIEC 17025 standard for radiation dosage estimation by cytogenetic analysis of dicentric chromosomes in blood samples.

Ionizing radiation affects cells biologically and is detected by studying their genetic material. The damage induced in the cells causes the appearance of some very distinctively shaped chromosomes recognizable under a microscope; the chromosomes with two centromeres or dicentrics. These chromosomes appear with a very low frequency in individuals unexposed to radiation so that by studying its frequency in an exposed person the absorbed radiation dosage can be estimated using dose-effect calibration curves generated in vitro.

This biological dosimetry analysis is used in the health and safety of workers exposed to ionizing radiation, as well as in the event of radiation incidents which could affect places and individuals not subject to personal and environmental radiation protection programmes. This laboratory is expressly authorized by the Nuclear Safety Council to carry out these analyses, as required in the Regulation on Health Protection against Ionizing Radiation (RD 783/2001). In addition, the laboratory belongs, along with other Spanish laboratories, to the European Consortium RENEB (Realising the European Network of Biodosimetry), designed for managing radiation emergencies.

The laboratory also complies with the criteria laid down in ISO 19239:2004 standard (Radiation protection - Performance criteria for service laboratories performing biological dosimetry by cytogenetics) for laboratories which perform this service.

For more information: lanorbe@enac.es

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Current News

Good Manufacturing Practice (GMP) compliance assessment of raw materials for medicines

ENAC has established the outline for accreditation in this activity, which has recently been awarded the first accreditations.

The manufacture of medicinal products in the European Union is subject to a number of directives aimed at safeguarding public health. This affects all the ingredients used and the medicines at all stages of manufacturing.

Currently many of the ingredients (active and inactive or excipient) used for manufacturing come from third countries (China, India,...) so that measures have been established to ensure that these cases meet EU requirements.

In the case of the active ingredients of medicines for human use, besides other requirements laid down in European legislation, the drug manufacturer is obliged to verify by triennial audits that the supplier manufactures the active ingredients in accordance with the Good Manufacturing Practice (rules set out in the International Conference on Harmonization - ICH Q7).

In many cases the manufacturers do not have the necessary resources to carry out these audits on their own either individually or jointly with other European manufacturers, so external evaluation firms are used to carry out GMP compliance audits.

This assessment system, in operation in the pharmaceutical sector over recent years, has been strengthened by including, like an element of added confidence, accreditation in accordance to the ISO/IEC 17020 standard. For this reason, ENAC has outlined accreditation for this activity which has resulted in two important Spanish companies in the sector recently gaining accreditation from ENAC: Forum Auditorías (accredited in May 2013) and Auditgmp Pharma S.L. (accredited in July 2013).

For more information: ivilla@enac.es

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Current News

ENAC accreditation for measurement of Noise Generated by Vehicle's Tyre

Safety and the Economic and Environmental Efficiency of Road Transport.

Michelin's Experiment Centre has obtained accreditation from ENAC for testing tyre noise emissions.

The 1222/2009 Regulation of the European Commission requires that all affected tyres manufactured after June 2012 and on sale in the European Union from November 2012 should include their noise classification in the labelling.

The Regulation aims to increase safety and the economic and environmental efficiency of road transport, promoting safe and fuel-efficient tyres with low noise levels. In addition, it establishes a framework for harmonizing the supply of information throughout the industry on tyre energy-efficiency performance, wet-surface braking and exterior noise levels which will enable end users to choose better, and with more criteria, tyres that fit their and their vehicle's needs.

It is the responsibility of providers (manufacturers and importers) to indicate tyre characteristic classifications (fuel consumption, safety, and environmental noise) in the technical promotional material (manuals, brochures and catalogues).

Noise classification is related to the type-approval limits of the European Union, which are different depending on the size and category.

The Michelin Experiment Centre of Almería (CEMA), has been accredited to perform the "Coast-by" test (track edge measurement, with the vehicle in neutral and the engine off), the tyre's rolling noise emission. All of this is for classes C1 (tourism); C2 (trade); C3 (truck).

For more information: hgonzalez@enac.es

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Current News

Accredited Testing on Glycerine as a bio-diesel by-product

The accredited testing is intended to quantify some of the components that come with glycerol.

Glycerin generated as a co-product of the bio-diesel production process is composed mainly of glycerol (propanetriol), with other components such as water, salts, methanol, etc.

This Glycerin, beyond being able to take advantage of it energetically, can be used for different applications, such as the manufacture of pharmaceutical-grade Glycerin, as a component in the manufacture of animal feed or as a basis for other industrial chemical processes.

Abengoa Bioenergía San Roque, S.A. has obtained the first accreditation from ENAC for Glycerin testing. These tests enable some of the glycerol's co-components to be quantified, providing key information for transforming them into added value products.

Bio-diesel is a fuel (similar to gas oil obtained from petroleum) that can be used in many diesel cycle engines in different proportions (due to its solvent properties some old engines may require modifications), with the advantage of less air pollution as its combustion produces less unburned waste (soot), polycyclic aromatic hydrocarbons, carbon monoxide (CO) and sulphur among other compounds.

For more information: isgarcia@enac.es

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Current News

Storage Equipment Accreditation

ENAC has awarded the first accreditation for storage equipment inspection (metal shelves).

Currently stock control of stored products has become a critical element of management, as it is necessary to minimize fixed assets whilst at the same time guaranteeing supply. In this regard, and as part of the logistics activities, storage must facilitate the movement of

products from their origin to the final consumer, acting as a regulatory element in the flow of goods. Therefore, the warehouse is an area where the products are received, handled, conserved, protected and dispatched, and so it must provide maximum guarantees of preserving and optimizing performance.

Shelves are an essential part of the design and installation of the storage equipment. These may be subject to possible deterioration or shock damage caused by knocks by fork-lift trucks and other maintenance equipment, which ultimately may cause structural collapse and serious injury to people as well as to the deterioration of stored goods.

The UNE-EN 15635 standard "storage in metal racks. Use and maintenance of storage equipment", published in 2010, guarantees the safety of the storage equipment as an objective. Therefore, it not only defines the safety requirements for use of storage equipment, but it also includes the assessment of possibly damaged components. In particular it establishes inspections at strict 12 monthly intervals by adequately trained staff. The planning and carrying out of regular storage equipment inspections is a fundamental process to find faults and damage caused by, as already stated, the use of, or in many cases the shocks caused by, mechanical handling equipment in stores, so that the users of the installation can quickly, properly and adequately find solutions, ensuring safety and that storage equipment is in good condition so as to avoid injury to persons, or damage to stored goods and the facilities.

In October, ENAC awarded the first accreditation for equipment storage inspection (metal shelves) to Noega Systems, S.L., contributing to conveying the necessary confidence to the market in the way the inspections were carried out.

For more information: droman@enac.es

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Current News

Verification of Ultrasound Examination Equipment

The AIMEN laboratory (Northwest Metallurgical Research Association) has received the first ENAC accreditation for the verification of digital examination equipment using pulse ultrasound.

Ultrasound examination is one of the most used non-destructive testing techniques in the industry because of its versatility and its ability to detect different types of defects in different materials. It is an indispensable control tool in the manufacture and inspection processes of metallic materials and welded joints. As this is a non-destructive technique causing no change to the material, it can detect the presence of defects, cracks, or discontinuities unseen at first glance, both on the surface and internal, which if left undetected could compromise the safety of the product or the installation.

To ensure the quality and reliability of these tests, it is essential to properly verify the equipment used in its implementation. Therefore, the UNE-EN 12668 standard specifies methods and acceptance criteria to assess the behaviour of equipment for carrying out non-destructive testing by ultrasound.

This assessment consists of three parts: the first aimed at rating the electrical behaviour of the ultrasound device, the second for verifying the probes, and the third, assesses the behaviour of the full equipment, combined with the probe, as it would be done in practice, with the help of standard pattern blocks.

Last July the AIMEN laboratory (Northwest Metallurgical Research Association) was granted accreditation for periodic verification of digital examination equipment using pulse ultrasound or after it has been repaired, according to paragraph 9 of the aforementioned UNE-EN 12668-1:2010 Standard for verification.

For more information: mjcotarelo@enac.es

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Highlights

Information day on Personnel Certification and its accreditation criteria

This is aimed at accredited organizations and/or any person or institution interested in the personnel certification as a mechanism to guarantee the professionals' knowledge and experience.

Personnel certification is an activity that aims to provide confidence in the professionals' competence to carry out certain activities; 'competence' in this context means: the set of knowledge, experience and skills required and demonstrated for effectively developing the assigned tasks. It is therefore oriented to assess their ability to apply these skills in the professional performance.

Recently a new revision of the international ISO/IEC 17024 standard, applicable to this activity, has been approved. Therefore as usual in these cases ENAC will hold a conference to pass on the most important aspects of the new version.

Taking into account that the personnel certification accreditation is the subject of growing interest, the conference this time has been designed with the additional aim of introducing this type of accreditation to all possible interested parties. It will inform them about the process ENAC follows to grant accreditation and provide attendees with information about requirements and the technical and organizational implications of establishing this type of activity. In addition, new features included in the new revision of the standard will be analyzed in detail.

The Conference, which will be held in Madrid on the 28th of November, is open to both accredited organizations and those in the accreditation process and to any person or institution interested in the personnel certification as a mechanism to guarantee better consumer information on the knowledge and experience of professionals.

For more information: cjimenez@enac.es

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International

ENAC hosts meetings of the EA Certification and Inspection Committees

Among the items on the agenda of these meetings are the harmonization and mutual recognition of the greenhouse gas emission inspection accreditation in the European Directive framework, and the road vehicle inspections within the framework of the European Commission's Road Safety Programme.

From 1st to 3rd October the 26th meeting of the Certification and Inspection Committees of the European Co-operation for Accreditation (EA) were held in Madrid, with the accreditation bodies from more than 30 countries, representatives of the Administration and various European professional and business organizations participating.

These committees were forums for coordinating the different technical aspects which enable the accreditation activities of EA members to be harmonized and promote multilateral recognition agreements.

Certification Committee

In the meeting, along with the work that has been developed on greenhouse gas emissions, the Certification Committee addressed other topics and activities such as those related to the European regulation on ending waste, the policy for organic product certification accreditation, the assessment processes of the management system certification for safety and health at work, or the accreditation of assessors for the certification scheme of service providers being developed by the European Telecommunications Standard Institute ETSI.

Inspection Committee

At its meeting, the Inspection Committee addressed different themes such as accreditation in accordance with the ISO/IEC 17020 standard for crime scene investigations and project inspection in the framework of the European Environmental Technologies Inspection Programme, and the contribution of assessment inspection of product's basic health and safety requirements of European Directives.

Interesting links:

- [EA Media Center](#)
- [ETSI](#)
- [EU Environmental Technology Verification programme](#)

For more information: direcciontecnica@enac.es

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Agenda

National meetings

44 SPANISH CONGRESS OF ACOUSTIC, TECNIACÚSTICA

2nd to 4th October, 2013 in Valladolid

Representing ENAC: O. Recuero

PRESENTING THE NEW UNE-EN ISO 15189:2013 STANDARD

17th October 2013 in Madrid

Representing ENAC: I. De la Villa

INTERNATIONALIZATION AND EXPORT ACCREDITATION CERTIFICATION CONFERENCE

24th October 2013 in Madrid

Representing ENAC: E. Gago

INFORMATION DAY ON "ACCREDITATION: A TOUR OF THE KEY ASPECTS OF THE PROCESS"

7th November 2013 in Madrid

Organized by ENAC

WORLD QUALITY DAY 2013. MADE IN QUALITY, MADE IN SPAIN

14th November 2013 in Madrid

Representing ENAC: B. Rivera

PRESENTATION OF THE NEW UNE-EN ISO 15189:2013 STANDARD

21st November 2013 in Zaragoza

Representing ENAC: I. De la Villa

International meetings

IAF AND ILAC GENERAL ASSEMBLY

From 16th to 25th October in Incheon (S.Korea)

Representing ENAC: B. Rivera e I. Pina

EA INTER-COMPARISONS WORKING GROUP MEETING

29th and 30th October 2013 in Oslo

Representing ENAC: E. González

EA CLINICAL LABORATORIES WORKING GROUP MEETING

19th November 2013 in Brussels

Representing ENAC: I. De la Villa

EA EXECUTIVE COMMITTEE

19th November 2013 in Oslo

Representing ENAC: I. Pina

EA GENERAL ASSEMBLY

20th and 21st November 2013 in Oslo

Representing ENAC: B. Rivera

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New accredited bodies

TESTING LABORATORIES

Ultrasound Equipment Verification

ASOCIACIÓN DE INVESTIGACIÓN METALURGICA DEL NOROESTE. (AIMEN) - 71/LE2056

Agri-food Products

APPLUS NORCONTROL, S.L.(Unipersonal) - 76/LE2042

LABORATORIO DE SALUD PUBLICA DE SEVILLA - 1045/LE2045
CENTRO DE DESENVOLVEMENTO AGROGANADEIRO DEL INSTITUTO OURENSANO DE
DESENVOLVEMENTO ECONÓMICO (INORDE) - 1054/LE1958

Acoustics

INERCO ACÚSTICA, S.L. - 385/LE2102
MINERCONTROL, S.L. (Unipersonal) - 1055/LE2026

Environmental Sector

ODOURNET, S.L. - 1046/LE2024
JECMA CONSULTORIA Y MEDIO AMBIENTE, S.L.L. - 1047/LE2052
CONSORCI D'AIGÜES DE TARRAGONA - 1050/LE2006
INSTITUTO UNIVERSITARIO DE MEDIO AMBIENTE DE LA UNIVERSIDAD DE A CORUÑA -
1051/LE1939

Glycerin Tests

ABENGOA BIOENERGÍA SAN ROQUE, S.A. - 1048/LE2062

Industrial Product (tyres)

MICHELIN ESPAÑA PORTUGAL, S.A. - 1049/LE1991

Petroleum Products

INSPECTORATE ANDALUCIA, S.A. - 1053/LE2038

Molecular Oncology

FUNDACIÓ INSTITUT D'INVESTIGACIÓ ONCOLÓGICA VALL HEBRON - 1052/LE2022

Biological Dosimetry

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN. LABORATORIO DE DOSIMETRIA
BIOLÓGICA, SERVICIO DE ONCOLOGÍA RADIOTERÁPICA - 619/LE2072

CALIBRATION LABORATORIES

Pressure

TÉCNICOS EN CALIBRACIÓN Y MONTAJE, S.A. - 213/LC10.161

INSPECTION BODIES

Raw Materials of Medicines

AUDITGMP PHARMA, S.L. - 288/EI484

Environmental Inspection

CONTROL Y CALIDAD ALIMENTARIA, S.L. - 285/EI472
GENERAL DE ANALISIS, MATERIALES Y SERVICIOS, S.L. (GAMASER, S.L.) - 287/EI480

Agri-food Sector

TRAZA&CONTROL IBÉRICA, S.L.L. - 290/EI465

Railway Sector

SILVER ATENA (SPAIN), S.L. - 286/EI490

Vehicle Reform Technical Service

PYH INGENIERÍA PRADO, S.L. - 289/EI336

Road Vehicle Inspection

ITV JARAMA, S.R.L. - 71/EI/ITV081

ITV ESTACIÓN DE LEGANÉS, S.L. - 72/EI/ITV079

ELECTROMAX 2000, S.L. - 73/EI/ITV086

ITV BERNA, S.L. - 74/EI/ITV076

ITV QUINTAREY, S.L. - 75/EI/ITV071

MANAGEMENT SYSTEM CERTIFICATION

Quality Management System Certification

APCER ESPAÑA, S.L. - 09/C-SC057

Environmental Management System Certification

APCER ESPAÑA, S.L. - 09/C-MA039

PRODUCT CERTIFICATION

Agri-food Products

CONSEJO REGULADOR DE LA DENOMINACIÓN DE ORIGEN PROTEGIDA "QUESO DE LA SERENA" - 116/C-PR178

TRAZA&CONTROL IBÉRICA, S.L.L. - 117/C-PR265

CONTROL BODIES

Transport of perishable goods

COPB LABORATORIO DE CONTROL, S.L. - OC-I/307

State metrological control

ITV JARAMA, S.R.L. - OC-I/304

ITV ESTACIÓN DE LEGANÉS, S.L. - OC-I/300

ELECTROMAX 2000, S.L. - OC-I/315

Heating systems in buildings

AMBIENTAL EIC, S.L. (Unipersonal) - OC-I/296

Power regulation: low voltage

RAÚL DIAZ NAVARRO - OC-I/316