

“Accreditation News” issue 63

First Quarter 2013

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ENAC from the inside

New standard of accreditation for Product Certification

The ISO/IEC 17065 standard, applicable worldwide, replaces the European UNE-EN 45011 standard used so far by ENAC and the rest of the European accreditation bodies to accredit this activity

Accredited product certification is present in different activity sectors -industry, agriculture and animal husbandry, energy, construction, health, transport, telecommunications and so on- generating confidence in the quality brands of a variety of industrial products and consumption processes and services.

This new version has been completely revised to align with the current approach to the rules laying down the evaluators' technical competence framework of conformity, ISO standards of the 17000 series.

Although the difference between the UNE-EN 45011 standard and the current UNE-EN ISO/IEC 17065 standard is substantial, a large proportion of the new points added to the latest standard were already considered guidelines in IAF documents, the international organization of accreditation bodies, and so they were included in ENAC's documentation and are already being used as references in accreditation processes.

With this in mind, the differences resulting from this change of standard can be in practice summarized as a better definition of the requirements of impartiality, clarifying the aspects which pose a threat and establishing different mechanisms to be used to safeguard it; and the requirement of a certification agreement to be legally executed between the client and the certification authority which guarantees both parties responsibilities.

Regarding the certification process, the minimum content which must include an application and the aspects to be considered for review is added, incorporating a review process of the evaluation results prior to decision making. Finally, internal and external resources which can be used by an organisation are distinguished, specifying clear requirements for both.

Transition

ENAC has established and published the Transition Plan which is to be applied in order to set up the new standard. The Plan conforms to the 3-year period established by the International Accreditation Forum IAF.

In the [Document Section](#) of our web site you can consult and download the document.

To help the accredited certification bodies adapt their systems to these changes, ENAC has had an information session on the main aspects and requirements of this standard and its implication on accreditation processes.

For more information: direcciontecnica@enac.es

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ENAC from the inside

New additions

To keep on providing the best service, ENAC continues adapting its resources to increase and diversify accredited activities.

Recently, two technicians have joined the Inspection and Control Bodies Department in order to strengthen activities in the control body and automotive fields:

Marta González

Agricultural engineer, with extensive experience in conformity assessment activities (testing, inspection and certification), as well as in the development of research projects, she joins the team of technicians in the Inspection and Control Bodies Department

Dolores Díaz-Velasco

Industrial Engineer, she joins the Automotive Area of the Inspection and Control Bodies Department, bringing broad experience to the area as head of Periodic Technical Inspections for motor vehicles and their trailers, as well as in the development of vehicle modification projects

Interview

Interview with María Luisa Poncela, Director General of Innovation and Competitiveness

Prior to this interview, Poncela was appointed General Secretary of Science and Technology, she will continue promoting this collaboration as, in her words, "ENAC's participation in the IDi field's evaluation process is very valuable".

1. What, in general terms, is the role of the Director-General of Innovation and Competitiveness?

The Director-General for Innovation and Competitiveness, DGIC's fundamental objective is to boost company's competitiveness through innovation. Likewise, it is the companies' organ for relating to other science, technology and innovation bodies in the Spanish System of Science and Innovation and serves as a forum for inter-agency meetings on matters of innovation.

The role of the DGIC is to boost private investment in innovation and to promote business demand by supplying new knowledge generated by the Science, Technology and Innovation System. Our function is to sensitize sectors to promote the transfer of technology in both directions; between economic sectors and between regions. We develop this work through different mechanisms: through support for public/private cooperation in such a way to produce a transfer of bi-directional technology between companies and research organizations; through the development of joint projects or through innovation clusters such as technology platforms; by promoting the incorporation of human resources trained in innovation into businesses; by working with all Administrations to gradually introduce innovation through demand using a tool as powerful as the Innovative Public Purchase; or by bringing the Singular Scientific Infrastructure Techniques to the productive sector. These are some examples of the means to achieving our final goal, which is that companies innovate.

In addition, the Secretary of State for Research, Development and Innovation on which the DGIC relies in matters of Research and Innovation, is the organ related to the other bodies of the central and regional Administrations allowing them to jointly achieve the established social challenges.

2. In your opinion, what are the main benefits of collaborating with ENAC?

Since the time of setting up the quality and industrial safety infrastructure, ENAC has played a key role in both the regulated and the voluntary spheres. As a State-level accreditation organization, ENAC's ultimate aim is to transmit confidence to all affected parties, relating to the reliability of product or service assessments and certifications which ENAC's accredited assessment bodies perform. And this accreditation role has proved to inspire confidence when working with the organization.

This has been possible due to ENAC's nature and qualities: impartiality, independence and transparency, relying on its governing bodies working with all interested parties in the process (the organizations accredited by ENAC, the industry users of their services and Administrations).

On the 17th December, the collaboration with ENAC was strengthened by Royal Decree 1715/2010, which refers to the National Accreditation Entity (ENAC) as a national accreditation body in accordance with Regulation (EC) nº 765/2008 of the European Parliament and Council, 9th July 2008, by establishing the requirements for accreditation and market surveillance relating to product marketing, to such an extent that the activity of ENAC extends to practically all economic sectors in both the voluntary and regulated spheres: industry, telecommunications, health, agriculture, construction and the environment.

3. What advantages are there for companies making use of Accredited Certification Bodies? And especially, what benefits do you believe will it grant to the sector?

The advantages are those inherent to certification; that certification is carried out by a third party whose quality is accredited by ENAC with all the quality requirements that this implies. The fact that an organization is accredited by ENAC undoubtedly adds value and creates confidence in the procedures. Not only accredited companies are valuable elements, but also ENAC's participation is valuable in the evaluation process in the RDI field. ENAC's recognized merit is having identified a set of top level Technical Experts belonging to different institutions with specific knowledge in every area of knowledge transfer. The use of qualified personnel in the evaluation processes, for example, gives security and creates confidence in a job well done.

4. In relation to the system of tax relief for RDI activities, how would you rate it in terms of improving the accredited certification experience so far?

Positively. According to the latest published report on tax deductions and motivated reports (2010), the quality is very high and only 9% of technical reports issued by technical qualification bodies are rejected by this Administration. The fact that the degree of acceptance has risen in comparison to the previous year, together with the increase in the figures, highlights the quality of the certifying bodies' work, and hence the usefulness of the technical report for the relevant Administrations.

These data are consistent with such a strict, objective and guaranteed system. This must be so, because it is linked to AEAT, so it is vital that the exercise of this jurisdiction is rigorous and aligned to the tax regulations emanating from the Tax Director General and maintains the confidence of that body. Precisely because of this, only applications involving a high level of knowledge and certainty about their qualification are presented. In addition, the procedure involves a double or even triple filtering system. It first passes the filter of the consultants and advisers, in his case, the Certification Bodies supervised by ENAC, and then the Ministry, that to date studies each and every one of the records, which is known by the agents involved.

5. What is the expected future of RDI project certification and the continuity of tax relief?

In view of the experience developed since the beginning of the motivated reports (R. D. 1432/2003) and the growing demand by companies, there's no doubt about continuing to count on the technical report as a binding document to provide a motivated report application, unless there is some exception.

In terms of continuing the tax deductions, this Administration defends the role of tax incentives for the RDI, particularly in the current context of tight public spending.

In connection with the above, currently the RDI Commission of the CEOE is conducting a questionnaire in order to be able to generate interest, value and efficiency of this RDI business tax incentive for companies.

6. Do you foresee promoting other ENAC-related action and/or accreditation in the future?

Possibly the statement of "Young Innovative Company", which regulates the Science, Technology and Innovation Law, will incorporate a business plan evaluation part for such firms and other considerations for which the certification system within the system accredited by ENAC is very appropriate. We are not thinking it to be the Ministry who evaluates the applicant companies but only for making the most of a mechanism that has demonstrated a good performance in other fields.

7. In relation to the concept of innovative SMEs, do you think that introducing RDI management systems may be a way to improve their competitiveness?

It's not yet final, and they are considering ways to obtain the "SME innovative" seal, one of them being the introduction of an RDI management system. Obviously, the benefit would be double, associated to the advantages the above-mentioned seal could offer, as well as the intrinsic benefit of introducing an RDI management system which means working systematically, planned and orderly, to create records and manage information.

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Current News

ENAC's Accreditation in Algeria

The laboratory of la Société de l'eau et de l'Assainissement d'Oran (SEOR) becomes the first Algerian water company to obtain the ISO 17025 accreditation.

The laboratory of the Algerian company Société de l'eau et de l'Assainissement d'Oran (SEOR), responsible for supply and water sanitation in the Algerian city of Oran, has obtained accreditation according to the UNE - EN ISO/IEC 17025:2005 standard, in recognition of their technical competence to carry out chemical and microbiological tests in waste and drinking water. With this accreditation, ENAC's first in Algeria, SEOR becomes the first accredited Algerian company in the water sector.

ENAC's accreditation process was developed in parallel with the Algerian Agency of Accreditation, ALGERAC.

On the 22nd of March, in celebration of the World Water Day, ENAC's Head of the Department of Environment delivered the Laboratory Accreditation Certificate to the Director-General of SEOR.

For more information: orecuero@enac.es

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Current News

Neonatal screening for sickle cell disease detection

The Bilbao Public Health Normative Laboratory is the first ENAC accredited laboratory for these tests.

Sickle cell is an inherited disease, caused by a mutation in the chromosome 11, affecting haemoglobin, and which means red blood cells become deformed and acquire an abnormal sickle-shaped or half moon appearance (instead of the normal round shape or disk). This alteration in the morphology of the cells causes a high risk of obstruction of the blood vessels, causing intense pain, strokes, serious infections, as well as chronic anaemia.

Carriers of this mutation are prevalent in sub-Saharan Africa, therefore due to the increase in immigrants from these regions in recent years, there has been a rise in the incidence of the disease in our country, and this has led to its inclusion in neonatal screening programs in some autonomous communities.

This is the case in the Basque Country, where the clinical chemical unit, belonging to the Bilbao Public Health Normative Laboratory, has been the first laboratory accredited for its detection.

The test is to identify haemoglobin variants by high performance liquid chromatography in blood samples obtained by tapping the heel of newborns.

In addition to sickle cell disease, the clinical chemical unit is accredited for the detection of other diseases included in the Screening Programme, such as cystic fibrosis, congenital hypothyroidism, phenylketonuria and MCADD (Medium Chain Acyl-CoA Dehydrogenase Deficiency).

For more information: ccorral@enac.es

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Current News

Historic Vehicles Inspection

A vehicle considered historic must pass a preliminary inspection by an Official Laboratory designated by the competent body of the Autonomous Region. ENAC has already granted the first accreditation for this activity in Zaragoza.

Collecting is a hobby that has been practiced throughout the history of mankind. The car is considered one of the revolutionary inventions of the 20th Century which has been the most active era for collecting, and therefore what can be referred to as the birth of "historic vehicles", took place during the first half of this Century. This boom in collecting has run in parallel with economic development, especially in Europe and the United States, and has now become a source of economic activity: vehicle sale, restoration workshops, original component manufacturing, management of documentation, etc.

Of special importance in this market is the definition of what should be considered a historic vehicle, as well as the set process for these to be properly catalogued, guaranteeing at the same time the necessary safety measures and restrictions that must be set for movement.

The conditions for historic vehicles' cataloguing and use in Spain are contained in the RD 1247/1995, which approves the Regulation of Historical Vehicles, setting preliminary inspection by an Official Laboratory designated by the competent body of the autonomous community as a condition for a vehicle to be considered historic.

Specifically the Autonomous Region of Aragon has established, for Official Laboratories acting in its territory, that they have the ENAC accreditation according to the requirements of the UNE-EN ISO/IEC 17020 standard.

ENAC has already initiated the accreditation processes in this field by granting the first accreditation to the Automotive Laboratory of the Department of Mechanical Engineering at the University of Zaragoza.

For more information: fjbarroso@enac.es

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Current News

Accreditation in the European Regulation framework on waste

ENAC already has the necessary accreditation system to evaluate the technical competence of certification bodies of quality management system of producers and suppliers of scrap metal and glass.

Waste generated by industry and consumers in Europe is increasingly transformed into secondary raw materials and new products, rather than sent to landfills.

The European Commission is preparing a set of regulations designed to ease re-entry into the production cycles of certain by-products previously considered to be "waste", in accordance with European regulations. Consideration as "waste" greatly limited not only use but the handling and movement of any substance.

Given that there is market and demand for these by-products; recovering for use as raw materials in the industry, a regulation mechanism has been established so that materials and their producers must comply with requirements, to ensure a high level of environmental protection and human health, satisfying the specifications of purity for different industries.

So far, two Regulations have been published dealing with three different by-products: ferrous scrap, steel and aluminium (Regulation No. 3332011 and (EU) Regulation No. 11792012). While paper, plastic and copper are at the advanced draft stage of publication.

One of the process's key requirements applies to producers and suppliers of by-products, since it stipulates that they must issue a conformity declaration of the parts' characteristics and rely on a management system certified by an accredited body capable of ensuring the established criteria for waste recovery.

Especially in the latest drafting of these regulations, there is an obvious need for those by-products to move between different Member States without any kind of administrative burdens, this has stressed the need for the required accreditation which has successfully passed the assessment required by Regulation (EC) n ° 7652008.

ENAC is open to any interested applicant and has developed the accreditation process for the management system certification of producers and suppliers operating within the framework of these regulations. The new NT-59, available on the ENAC's website, establishes the specific requirements for accreditation in this field.

ENAC will be expanding the accreditation scheme in these fields as new regulations are published.

For more information: egago@enac.es

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Highlights

Quality Service Assessment, ENAC 2012

For the fourth consecutive year, ENAC has commissioned a survey to assess the quality of their service, to know the effect of the implemented improvements and to identify those areas to keep working on.

95.8% of surveyed customers appear to be satisfied or very satisfied with the service.

One of ENAC's strategic lines is the management of the accreditation system, following guidelines of effectiveness; adapting to customers' needs; providing a value-added service; a guarantee of integrity and competence, all constituting distinguishing features in the market.

In this context, quality service evaluation by the customer constitutes an essential tool for knowing the effects and outcomes of the improvement projects by developing and identifying the areas of action which should continue to be worked on.

Therefore, for the fourth consecutive year, quality service evaluation surveys have been carried out by the accredited organizations. In 2012, there were 1132 surveys, of which 571 responses were received which still represent a good level of participation (50%).

According to the results obtained, 95.8% of surveyed customers said they were satisfied or very satisfied with the service. And 60% of customers considered that it has improved in the last two years.

The results show a high degree of satisfaction with key aspects of the service, such as the rigorous accreditation process, the professionalism of ENAC's staff, the competence and behaviour of auditing teams, the impartiality of the evaluation or how easy it is to agree on the date of the audit. In addition to these, other service aspects such as how straightforward it is to contact ENAC's staff and the quality of information, care and treatment received.

Similarly, helpful information has been collected on some aspects, such as accreditation process deadlines, which, although they were positive in the customer evaluations, they still need to be worked on in accordance with the proposed improvement projects.

Once again we want to thank all the accredited organizations for participating in these surveys in order to help develop and improve the service.

At www.enac.es you can find more information about the results.

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International

Advances in the MLA concerning Greenhouse Gases Emissions Verification

ENAC has already submitted the application to join this Multilateral Recognition Agreement. The EA has appointed 8 experts, among them two technicians from ENAC, who will draw up the process details and tools to evaluate the National Accreditation Bodies.

The Commission Regulation EU 600/2012, of June 21st, establishes the obligation that National Accreditation Bodies granting accreditation to verifiers within the European Greenhouse Gases Emissions Trading System must successfully pass the peer-evaluation organised by the European Co-operation for Accreditation (EA). In this way the system ensures free movement of inspection based on the recognition of equivalent service by the different member States.

In the EA, they are working hard on developing and launching this new MLA so that it is operational in the shortest possible time. That is why accreditation bodies, as in the case of ENAC, wanting to join the agreement from the first moment had to submit the application before the deadline of the 1st of August, 2012.

Since then, the EA has established three groups of National Accreditation Bodies to fix the assessment activities depending on their situation within two parameters:

- demonstrated experience in granting accreditation with regard to the ISO 14065 standard
- date of the next periodic EA evaluation

ENAC is in the experienced group of organizations and whose periodic evaluation has taken place recently prior to the publication of the regulations, for those who have established the following evaluation activities:

- evaluation of the submitted documentation
- a direct observation of how it evaluates an inspector (witnessing visits)
- optionally, depending on the result of previous activities; an office audit.

To carry out these evaluation activities the EA has appointed 8 experts, among them two technicians from ENAC, who met for the first time on the 5th and 6th of March in Brussels to draw up the process details and assessment tools.

It is expected that the first MLA will be signed at the Multilateral Agreement Council (MAC) meeting taking place in the Autumn of 2013 or Spring of 2014.

For more information: comunicación@enac.es

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International

World Accreditation Day

On the 9th June, the World Accreditation Day is celebrated, a global initiative jointly established by the IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation), to raise awareness about the importance of accreditation-related activities.

Reflecting the strategic goal of both organizations, this year's main theme is "Accreditation: easing global trade".

Today globalisation means that most of us enjoy and rely on numerous products and services that come from other countries. International trade accounts for a significant part of the GDP of most countries. According to the latest data from the World Trade Organization, in 2011 the global goods trade amounted to \$18.2 billion and exports of services to \$4.2 billion.

At the same time, in different countries and activity sectors there has been a rise in the number of both regulatory and voluntary regulations, standards and procedures for testing, inspection and certification. These are normally established to meet the quality and safety requirements demanded by consumers, companies, administrations and other organizations of goods and services, regardless of the country of origin.

That products and services can cross borders, according to global demand, without causing health and safety risks to people or to the environment, is something vital not only for individuals and organizations but also for the economy both nationally and internationally.

You can consult the full text of the joint statement of ILAC and IAF on our website: http://www.enac.es/web/enac/world_accreditation_day_2013

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Agenda

NATIONAL MEETINGS

XXVI CONGRESS OF THE SPANISH SOCIETY OF INTERNATIONAL ACADEMIC- PATHOLOGICAL ANATOMY (SEAP-IAP)

From the 22nd to the 24th of May, 2013 in Cadiz

Representing ENAC: I. De la Villa

QUALITY MANAGEMENT COURSE FOR TESTING AND CALIBRATION LABORATORIES

The 29th and 30th of May, 2013 in Madrid

Representing ENAC: C. Corral

FOOD ANALYSIS REFERENCE DAYS. EDITION 2013

From the 5th to the 7th of June, 2013 in Madrid

Representing ENAC: E. Gredilla

5th SPANISH METROLOGY CONGRESS

From the 12th to the 14th of June, 2013 in Madrid

Representing ENAC: J.L. Borrego, R. Porres, M.J. Cotarelo, I. De la Villa y C. García

INTERNATIONAL CONGRESS OF FOOD SAFETY ACOFESAL 2013

From the 19th to the 21st of June, 2013 in Madrid

Representing ENAC: J. A. García

V GENERAL ASSEMBLY OF ORIGIN SPAIN

The 27th and 28th of June, 2013 in Mahon

Representing ENAC: E. Gredilla

INTERNATIONAL MEETINGS

EA EXECUTIVE COMMITTEE

The 28th May, 2013 in Paris

Representing ENAC: I. Pina

EA GENERAL ASSEMBLY

The 29th and 30th May, 2013 in Paris

Representing ENAC: B. Rivera

EA FOOD WORKING GROUP

The 4th and 5th June, 2013 in Paris

Representing ENAC: E. Gredilla

EA CLINICAL LABORATORIES WORKING GROUP

The 25th and 26th June, 2013 in Frankfurt

Representing ENAC: I. De la Villa

EA EXECUTIVE COMMITTEE

The 10th and 11th September, 2013 in Budapest

Representing ENAC: I. Pina

EA HORIZONTAL HARMONIZATION COMMITTEE

The 24th and 25th September, 2013 in Berlin

Representing ENAC: I. Pina

NEW ACCREDITED BODIES

TESTING

Environmental testing

LABAQUA, S.A. - 109/LE2058, 109/LE2061

LABORATORIS VIDAL, S.L. - 258/LE2069

LA SOCIÉTÉ DE L'EAU ET L'ASSAINISSEMENT D'ORAN - 1023/LE2043

TÜV RHEINLAND IBERICA INSPECTION, CERTIFICATION & TESTING, S.A. - 822/LE2008

Agri-food products

LABORATORIS VIDAL, S.L. - 258/LE2068

DOMINIO DE PINGUS, S.L. (Unipersonal) - 1022/LE2007

LABORATORIOS NICB - 1024/LE2002

IRTAPPLUS, S.L. - 1025/LE1687

CONVET, S.L. - 1026/LE1904

Acoustics

AEMA HISPANICA, S.L. - 1021/LE1998

Reinforced steel for reinforced concrete

DESARROLLO Y CONTROL TECNOLÓGICO, S.L. - 674/LE2014

Non-destructive testing for welded joints of metallic materials

DIAGNOSTIQA CONSULTORÍA TÉCNICA, S.L. - 1019/LE1988

Dispositivos de protección contra sobretensiones y sistemas de seguridad frente al rayo

LIGHTNING RESEARCH INSTITUTE OF CATALONIA, S.L. - 1027/LE2027

Tyre testing

LABORATORIO DE VEHÍCULOS. Universidad Miguel Hernández de Elche - 1020/LE1995

Vehicles and components

AUTOLAB ENSAYOS Y CERTIFICACIÓN, S.L. - 1028/LE1989

QUANTUM INNOVATIVE, S.L. (Unipersonal) - 949/LE2055

Molecular pathology

ALTHIA HEALTH, S.L. - 1029/LE2012

Forensic-identification testing

NEODIAGNÓSTICA, S.L. - 1030/LE1946

CALIBRATION

Mechanical – moments

TORNILLERÍA Y SERVICIOS, S.L. - 210/LC10.158

INSPECTION BODIES

Industrial area

INGENIEROS EMETRES, S.L.P. - 271/EI460

Telecommunications

COLEGIO OFICIAL DE INGENIEROS DE TELECOMUNICACIÓN - 274/EI471

Environmental inspection

EUROESTUDIOS, S.L. - 270/EI467

LABYGEMA, S.L. - 275/EI442

QUIMICONTROL, S.L. - 276/EI425

ENVIRON IBERIA, S.L. (Unipersonal) - 272/EI459

CONSULTORÍA DE TÉCNICAS AMBIENTALES, S.L. - 273/EI453

Technical Service for Vehicle Reform

QUANTUM INNOVATIVE, S.L. (Unipersonal) - 251/EI482

Road Vehicle Inspection

LA CHOZA DE LA HERRERA, S.A. - 64/EI/ITV060

INSPECCIÓN TÉCNICA DE VEHICULOS VILLAVICIOSA, S.L. - 65/EI/ITV082

SERVICIOS TÉCNICOS Y CONSULTORÍA ITV, S.L. - 66/EI/ITV078

ITV PROBUS, S.L. - 67/EI/ITV080

PRODUCT CERTIFICATION

Agri-food products

CONSEJO REGULADOR DE LA DENOMINACIÓN DE ORIGEN PROTEGIDA "UTIEL REQUENA" - 110/C-PR225

AGROCERTIFICADORA, S.L.P. - 111/C-PR250

MANAGEMENT SYSTEMS

Food Safety Certification Management systems

OCA Instituto de Certificación, S.L. (Unipersonal) - 8/C-SG056

CONTROL BODIES

Pressure equipment and Lifts

BUREAU VERITAS CERTIFICATION, S. A. - OC-P/312

OCA Instituto de Certificación, S.L. (Unipersonal) - OC-P/286

State Metrological Control: phase of instruments in service

ITV PROBUS, S.L. - OC-I/301

ATISAE MANAGEMENT & TESTING, S.A. - OC-I/280

INSPECCIÓN TÉCNICA DE VEHICULOS VILLAVICIOSA, S.L. - OC-I/303

SERVICIOS TÉCNICOS Y CONSULTORÍA ITV, S.L. - OC-I/298

Directive 89106 EEC Construction Products

CERTIBERIA EUROPE SOLUTIONS, S.L. - OC-P/292

Industrial safety facilities Regulation

INVERYCA 2011, S.L. - OC-I/275

JOAQUÍN CONTRERAS LÓPEZ (N.I.F.: 34.788.495Y) - OC-I/299