

# **“Accreditation News” issue 42**

Fourth Quarter 2007

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## **ENAC from the inside**

### **NEW EDITION OF THE AUTONOMOUS COMMUNITY FORUMS. ROAD VEHICLE INSPECTION ENVIRONMENTAL AND CONTROL BODIES CONVENED THEIR ANNUAL MEETING**

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As has become regular practice in recent years the Autonomous Community Road Vehicle Inspection (ITV) Forum was held during the month of November, with the participation of representatives of eleven autonomous community. In addition to the fixed points on the agenda, where the present state of accreditations is reported on and various matters relating to Autonomous Community-ENAC communications are discussed, notable features are the proposed modification of the scopes of accreditation (breakdown of non-periodic inspections, mobile stations, etc), as well as the favourable attitude of the Autonomous Community towards the appearance of the new Non-Periodic Inspection Manual that will be published by the Ministry of Industry Tourism and Trade (MITYC).

Similarly, the Environmental Inspection Forum was held, with the participation also of 11 Autonomous Community representatives and the Ministry of the Environment. In this case, not only technical but also matters relating to the evaluation processes were addressed, without overlooking normal subjects relating to the ENAC-Autonomous Community information mechanisms. It was made clear that there is a growing need by the different authorities for bodies accredited in an increasingly larger number of fields (e.g. atmosphere, soils, waste, noise, etc.) to carry out control and surveillance activities, besides the needs explained by the authorities that could involve the development of new patterns of accreditation (IPPC, etc) and the necessary cooperation in these activities too between ENAC and the respective partners from the relevant administrative echelons.

In the same line the III Control Bodies Forum was held, attended by representatives of 15 Autonomous Communities. One of the subjects that raised most interest during the conference was the treatment of the “delegations” in the scope of accreditation. ENAC

informed the representatives of government of the significance of a delegation appearing in the scope or not and the effect that this fact has on the evaluation. Also noteworthy are the remarks relating to the excellent results achieved in the qualification and training of the Low Voltage inspection personnel as a consequence of G-ENAC-10 “Guide to technical competence requirements of inspectors” arranged between ENAC and the Public Administrations at the previous Forums. In the opinion of the autonomous community representatives the guide is extremely useful, so it was decided to organize a new working party to set the qualification requirements in the fields of Fuel Gases, Liquefied Petroleum Gases and Gas Appliances.

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## **NEW APPOINTMENTS**

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### **Emma Alconero**

Graduate in Chemistry and Food Technology, with broad experience in Management System Certification and Environmental Verification, she joins the Department of Certification and Verification.

### **Francisco Ollero**

Holding a Diploma in Statistics, with broad experience as a calibration laboratory technical supervisor, he has cooperated as a Technical Expert for ENAC and joins the Department of Laboratories and Product Certification.

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## **NEW ACCREDITATIONS**

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### **TESTING LABORATORIES**

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**RYMOIL, S.A.**

Testing of insulating fluids 602/LE1229

**LABORATORI DE SALUD PÚBLICA DE PALMA**

Physical and chemical analysis of food products 603/LE1307

**FOOD PROCESSING WASTE ANALYSIS LABORATORY  
OF EXTREMADURA**

Physical-chemical analyses of water, manures and fertilizers, dairy products and oils and microbiological analyses of water 604/LE1182

**FOREIGN TRADE INSPECTION AND QUALITY  
CONTROL CENTRE**

Physical-chemical analyses of food products and ceramic materials in contact with them 605/LE1287

**ANALAQUA, S.L. - LABORATORIO DE CONTROL DE  
LA CONTAMINATION (CIC)**

Physical-chemical analyses of water 606/LE1341

**LABORATORIOS ANABIOL, S.A.**

Microbiological analyses of foods 607/LE1070

**FUNDACION LACE**

Testing of electromagnetic compatibility: Emission 608/LE1305

**LABORCONTROL GEOSINTÉTICOS, S.L.**

Testing of geosynthetics 609/LE1351

**CENTRO MILITAR DE FARMACIA DE LA DEFENSA.  
LABORATORIO DE REFERENCIA DE DROGAS**

Toxicology tests 610/LE1261

**NORESGA, S.L.**

Physical-chemical analyses of water 611/LE1269

**UNIVERSITY OF VIGO. FACULTY OF SCIENCE.  
DEPARTMENT OF FUNCTIONAL BIOLOGY AND  
HEALTH. MICROBIOLOGY AREA**

Physical-chemical and microbiological analyses of water microbiological analyses of food products 612/LE1141

**UNIVERSITY OF VIGO. FACULTY OF SCIENCE.  
DEPARTMENT OF FUNCTIONAL BIOLOGY AND  
HEALTH. MICROBIOLOGY AREA**

Physical-chemical analyses of waste water 612/LE1437

**ENERGY TO QUALITY, S.L.**

Wind turbine testing 613/LE1315

**CALIDAD Y GESTIÓN CIENTÍFICA, S.L.**

Environmental acoustics and building testing 614/LE1357

**NEIKER - INSTITUTO VASCO DE INVESTIGACIÓN Y  
DESARROLLO AGRARIO**

Physical-chemical and microbiological analyses of feeds and raw materials and immunological analyses of animal serum 615/LE1321

**CEDEMA ESTUDIOS AMBIENTALES, S.L.**

Building acoustics testing 616/LE1388

**LABORATORIO AGROALIMENTARIO INDUSTRIAL, S.L.**

Sensorial analysis of virgin olive oil 617/LE1203

**BIONOSTRA, S.L**

Biomolecular analyses for identification of fish species, detection of animal origins and transgenic material 618/LE1267

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**CALIBRATION LABORATORIES**

**SPARESAIR, S.L.**

Fluids - Pressure 174/LC434

**MCV, S.A.**

Temperature - Humidity 175/LC438

Fluids - Flow 175/LC444

**GRUPO DE EMPRESAS TEMPER, S.L**

DC Electricity and Low Frequency 176/LC461

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**INSPECTION BODIES**

**AVALUA, S.L.**

Environmental Inspection 149/EI237

**CERTIFICACIÓN CALIDAD AGROALIMETARIA, S.L.**

Food Processing Inspection 150/EI158

**AMBIENTAL EIC, S.L.**

Inspection of plant with legionella risk 151/EI239

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**PRODUCT CERTIFICATION**

**GARANTIZA CALIDAD AGROALIMENTARIA, S.L**

Optional beef labelling 46/C-PR073

Report

EVALUATION SYSTEM MODERNISATION

ENAC is undertaking a process of adaptation, improvement and modernisation of its service by increasing the commitments and responsibility of the agents involved and simplifying management in order to respond to a market in which clients and users are looking for better performance and calling for closer contact and a service more in line with their needs.

In the last few years there has been considerable development in the Spanish conformity evaluation sector in which ENAC provides its services. From an atomised market dominated mainly by companies operating primarily on a single plane (testing, calibration, inspection or certification), usually medium and small-sized (with the exception of the regulatory inspection sector), we have gone to another totally different one, where the phenomena of concentration and internationalisation of activity have taken place, with the appearance and consolidation of large multinational groups (especially in the certification sector and also, albeit to a lesser extent, the laboratories and inspection sector) and an increasingly larger number of companies operating on various planes.

ENAC is now facing a market characterised by the maturity of the companies and the conformity evaluation sector in general, with a significant increase both in the number and size of the organizations composing it. This, together with an unceasing increase in the interest for accreditation, is leading to a continual rise in the number of companies accredited.

All this has brought about a more demanding market, where both the clients and the users look for better performance, call for closer contact and a service in keeping with their needs, and take part in the definition of the processes so that their expectations may be met more fully.

In this environment, ENAC has to go on advancing in the process of adaptation, improvement and modernisation of the service in the search for tools to meet market needs and requirements in order to enhance the value and trust in the organisations accredited.

In order to offer a response to these needs ENAC has implemented the “Evaluation System Modernisation Plan-ADAPTA”, which will be developed in the period 2008-2009 with the aim of providing an efficient, modern, flexible evaluation system that will meet current market needs, that will heighten the commitments and responsibility of the agents involved, and that will simplify management.

This modernisation process involves the adoption of innovative management systems that focus their attention on the analysis, follow-up and ongoing evaluation of the processes and results and on endowing the organisation with greater flexibility and capability to respond to the needs of clients and users.

BASIC PRINCIPLES INSPIRING THE ADAPTA PLAN:

- Modernisation utilising the advantages offered by the new Information and Communication Technologies.
- Efficacy and efficiency of the service that ENAC offers to clients and to the market in general.
- Flexibility to adapt to the features and new needs of the clients.
- Permanent participation of all the agents with an interest in accreditation.
- Communication and transparency, facilitating the development of channels for transmitting and sharing information.
- Simplification and rationalisation of the administrative processes.
- Commitment and responsibility, increasing the involvement and accountability of each individual agent who has an interest in accreditation (auditors, clients, users).

STRATEGIC OBJECTIVES SET FOR THE IMPROVEMENT PROJECTS:

1. Facilitate understanding of the accreditation process and access to accreditation by simplifying the structure and content of the application forms.
2. Improve the pre-audit processes so as to offer a more flexible service and increase the efficacy of the evaluation process (application review, audit planning and preparation).
3. Enhance the efficiency of audits by means of specific strategies for the evaluation of technical competence.

- 4. Reduce the administrative load attached to the handling of deviations.
- 5. Simplify and modernise the report drafting process.
- 6. Increase the efficiency of follow-ups and extensions by fomenting the evaluation of critical processes and risk analysis and examining alternative evaluation channels.
- 7. Raise efficiency in the evaluation of key clients, defining new models of evaluation adapted to their features.
- 8. Improve the level of public information to the market and interested parties and modernise the information preparation and transmission mechanisms.
- 9. Take maximum advantage of the capability offered by the Information and Communication Technologies so as to simplify and streamline administrative formalities, facilitate communication and, in short, enhance and increase the efficiency of the service.

**SIMPLIFICATION OF THE HANDLING OF THE DEVIATIONS DETECTED IN AUDITS.**

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**First Action Steps of the Adapta Plan**

The new system will assist compliance with accreditation times and offer a better solution to the key aspects.

In December 2007 Operational Note NO-11 “Deviations: Classification and Handling”, developed under the Evaluation System Modernisation Plan (ADAPTA), was adopted in order to simplify the handling of deviations and heighten the efficiency and transparency of the whole process.

The document was adopted after a pilot stage involving the participation of bodies from the different accreditation schemes and assessors, whom we thank for their cooperation and enthusiasm.

The new system sets out to increase the auditee's responsibility and commitment in the resolution of the problems detected during the ENAC audits, requiring him to remedy the most serious deviations in a quick and effective manner, but leaving him the responsibility for resolving the less serious ones without the necessary prior involvement of ENAC.

This new system is expected to produce a significant reduction in the post-audit formal work

load, which will be greater (possibly even being eliminated entirely) the better the audit results are. This will facilitate compliance with the accreditation process times and better resolution of the problems as both auditees and assessors will concentrate their attention on the major deviations.

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**Sectors**

**GLP**

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**ENAC’S DESIGNATION FOR GLP CERTIFICATION OF INDUSTRIAL CHEMICALS**

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ENAC has been designated by the Ministry of the Presidency at the suggestion of the Ministries of Health and Consumer Affairs, Industry, Trade and Tourism, and the Environment as the Good Laboratory Practice (GLP) assessment and certification body in the non-clinical trials of industrial chemicals, which include the biocides and the substances governed by the European Regulations relating to the registration, evaluation, authorisation and restriction of chemical substances and preparations (REACH).

This Set of Regulations specifies the obligation of the manufacturers to register the substances produced or imported into the EU in order to assure responsible management of the risks that chemicals have for human health and the environment. Specifically, REACH reforms the conditions of the marketing of chemicals by introducing a system of Registration, which involves the Evaluation of certain products, the Authorisation of those arousing most concern, and restriction in certain cases. As regards evaluation, it is stipulated that in the cases when it is necessary to run toxicological and ecotoxicological tests, these have to be performed in compliance with the principles of Good Laboratory Practice (GLP)

The principles of GLP, which were approved by the OECD and later adopted by the European Union through various directives, are applied to the health and environmental safety studies of chemicals of various kinds, normally associated with regulatory authorisation/registration processes and they set out to provide trust in the quality and validity of the data obtained in these studies.

In this way, the relevant authorities are entrusting ENAC to evaluate and certify that the laboratories that carry out these studies have done so according to GLP principles, thereby complying with the European directives governing this activity. But beyond this, the



designation covers a gap existing hitherto in Spain in this respect, which is going to provide the Spanish laboratories performing non-clinical trials of chemical substances with access to a certification essential for the recognition of their work. This will, in turn, redound to the benefit of the companies in the chemicals sector, which will be able to conduct the required trials of the substances required on a mandatory basis in Spain.

At ENAC we receive this designation not only as an opportunity to offer a new service to the Spanish laboratories, but also as a recognition of the role they have been performing in this field since the Ministry of Agriculture, Fisheries and Food designated us as an evaluation body for the testing of health protection products.

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**HEALTH**

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**FIRST ACCREDITATION FOR INSPECTION OF PLANTS WITH LEGIONELLA RISK**

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In October ENAC conferred the accreditation for this activity to the environmental company EIC, S.L. It is a case of the first accreditation in this scheme developed by ENAC in close collaboration with the Health Authorities.

The adoption in 2003 of RD 865/2003 for the prevention and control of legionellosis represented a major advance in the prevention of this disease. Thus, a series of hygiene and health measures are laid down that have to be applied at the plant where Legionella might potentially proliferate and be disseminated. These measures include the need to carry out specific maintenance activities for each type of plant at risk.

It falls to the Health Authorities of the Autonomous Communities to ensure compliance with the requirements of this legislation. In this respect, the health departments of some Autonomous Communities have laid down the requirement that the review of compliance with the stipulations of the above-mentioned Royal Decree should be carried out by bodies that have shown their technical competence for such activities under standard UNE-EN ISO/IEC 17020 and possess the respective ENAC accreditation. This is the case of the Generalitat de Catalunya (Decree 352/2004) and of the Government of Aragón (Decree 136/2005).

Since the publication of these regulations, ENAC has cooperated very closely with the officials of the Department and Office of Health of both autonomous communities to define the criteria to be applied in these evaluations and to meet their needs.

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**HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN**

**FIRST LABORATORY ACCREDITED IN CLINICAL IMMUNOLOGY TESTS**

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In December, ENAC conferred accreditation on the Immunology Service Clinical Diagnostic Laboratory belonging to Hospital General Universitario Gregorio Marañón.

The scope of the accreditation, first in this field, includes the bulk of the processes that act as the basis for the study of the multiple pathologies in which the humoral components of the immunological system are involved. These include tests as immunoglobulins, light chains, IgG subclasses, paraprotein typification in serum and urine, complement factors, total IgE and IgE specific to different allergens and other immunoproteins of biological and clinical importance for the diagnosis and treatment of the patient with immunological system pathologies (immunodeficiencies with a humoral component, paraproteinemias, allergic diseases, monitoring of substitute therapy with gammaglobulins, amongst others).

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**REVIEW OF STANDARD UNE-EN ISO 15189:2007, REFERENTIAL FOR ACCREDITATION OF CLINICAL LABORATORIES**

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In September 2007 the new version was approved of standard UNE-EN ISO 15189, the Spanish version of the reference standard in the accreditation of clinical laboratories, which overrides and replaces the version of 2003.

The purpose of this review is to align the standard with the second edition of standard UNE-EN ISO 17025, published in 2005. In this case, the alterations introduced are minimal and do not

involve changes in the technical requirements. It only includes some modifications in the terminology and in the regulatory references and includes an additional qualification referring to internal communication.

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**First accreditations**

**R+D+i**

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**ACCREDITATION FOR CERTIFICATION OF RESEARCH STAFF R+D+I**

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In October the first accreditation was conferred for the Certification of Research Staff R+D+i activity on the Research, Development and Technological Innovation Accreditation Agency (AIDIT).

To be eligible for this accreditation, as a prerequisite the certification bodies have to have accreditation for the certification of R+D+i projects. The extension to this new accreditation represents a specific evaluation, for the purpose of checking that the certification system developed by the body establishes the appropriate procedures for assuring that the company to be certified has personnel, engaged on a full-time basis in research, development and technological innovation activities, in the terms laid down by current legislation (Law 35/2006 and Royal Decree 278/2007).

As stipulated in the requirements laid down for accreditation, the certification process has to include, amongst other aspects, the identification of the research staff by means of the study of the organizational R+D+i structure of the company to be certified, as well as the evaluation of the research staff and their full-time engagement in R+D+i activities. This process is developed by way of various stages that include: documentary study of the certification process, auditing at its facilities and on-the-spot checking of the performance of auditing team for a real case of research staff certification.

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**LABORATORIES**

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**LUXOMETER CALIBRATION**

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The Official Central Electrotechnology Laboratory (LCOE) is the first laboratory to obtain accreditation for calibrating illuminance meters (luxmeters).

These instruments are normally used by the inspection bodies in different regulatory fields (Electrotechnical Low Voltage Regulations, Lift Regulations, Technical Building Code), for the purpose of assessing whether the illumination levels meet the required illuminance and uniformity limits. They are also used by the industrial risk prevention services when checking that the lighting is appropriate for the type of working activity being carried on.

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**INSPECTION**

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**FIRST ACCREDITATION FOR REGULATORY INSPECTION IN THE FIELD OF FISHERIES AND FISH FARMING**

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Accreditation as an inspection body under standard UNE-EN ISO/IEC 17020 has been conferred on the Fishery and Fish-Farming Service of the Murcia Directorate General for Stockfarming and Fisheries for carrying out regulatory inspections in the area of fisheries and fish farming at fish markets, fish shops, on the road and through aerial inspection.

The Service performs the inspections stipulated in the protocols adopted by Resolution by the Directorate General to assure compliance with EU, state and autonomous community regulations in the area of fisheries and fish farming.

It is a case of a novel accreditation not only through being the first awarded by ENAC in the field of fisheries and fish farming, but also, what is more important, the first accreditation of inspection activities carried out directly by government.

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**CERTIFICATION OF MANAGEMENT SYSTEMS**

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**FOOD SAFETY MANAGEMENT SYSTEMS**

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ENAC has conferred accreditation on Bureau Veritas Certification S.A. for the certification of Food Safety Management Systems in accordance with standard UNE-EN ISO22000:2005.

This is the first accreditation conferred by ENAC for the certification of this standard, which may be applied to

all the organisations forming part of the food chain. In the food-processing sector the publication of this standard aroused great expectations in the food industry operators, who now have an accredited certification body.

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**Points of Interest**

**DEBATE IN THE EA GENERAL ASSEMBLY:  
WHAT IS ACCREDITABLE?**

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The European accreditation organisations exchange ideas on the field of activity and limits of accreditation in order to achieve policies that will develop and consolidate their role in Europe.

On 21 November an International Workshop was held in Nicosia (Cyprus), coinciding with the EA General Assembly, on the subject of What is accreditable?

The aim of the workshop was to awaken discussion and an exchange of ideas as to what the field of activity and the limits of accreditation should be for the ultimate purpose of examining the establishment of policies that will permit the development and consolidation of the role of accreditation in Europe taking into account, in the words of EA Chairman Lorenzo Thione, that “We Accreditation Bodies and the Conformity Evaluation Organisations have to face new strategic challenges together in the near future as a result not only of the new legislative framework that will be prepared by the European Union, but also as a result of the development of the Global Market, the protection of the environment, and integration of the emerging economies”.

The workshop included three papers that addressed the question from different angles. The first was delivered by the UKAS Accreditation Manager, Jane Beaumont, under the title of “Accreditation for the 21st Century. Who will need it and will we be able to supply what they need?”. The second: “Accreditation: Where are the limits?” delivered by the ENAC Technical Manager, Ignacio Pina and; the third paper was given by Hugo Eberhardt Chairman of CEOC International, and its subject was the “Reasonable Frontiers of Accreditation”.

The workshop concluded with a lively discussion in which the attendants explained their different points of view, which will fire an even more open debate not only at European but also at global level.

**ENAC AND AEGIC SIGN A COOPERATION AGREEMENT**

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Cooperation with the Spanish Association of Business Inspection and Certification Groups foment the involvement of the conformity assessment bodies in the technical work ENAC.

In order to have flexible and versatile channels that will facilitate the involvement of the conformity Assessment Bodies in the technical work of ENAC, a cooperation agreement has been reached with the Spanish Association of Business Inspection and Certification Groups (AEGIC).

This agreement joins those already made with other conformity Assessment Bodies associations: FELAB, the Laboratory Association that groups together EUROLAB Spain and AELI (Spanish Association of Independent Laboratories); ASORCO, the Association that groups together Inspection Bodies and Control Organisations operating in Spain; the Association of Vehicle Inspection Companies (AECA-ITV) and the Spanish Association for Quality (AEC-Certification Body Committee).

By virtue of this Agreement, ENAC under takes to seek the participation of AEGIC in the development of the technical documents that may produce. For their part, the signatory associations undertake to provide ENAC with representatives with the necessary technical competence to take part in the meetings or working parties that may be set up and that will act as representatives of the Association. The documents prepared in this way will indicate this fact.

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**NATIONAL MEETINGS**

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II International Food Safety Congress  
1 March 2008 in Murcia  
ENAC representative: E. Gredilla

Food-Processing Forum  
11 March 2008 in Murcia  
ENAC representative: I. Pina

**INTERNATIONAL MEETINGS**

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Accreditation Bodies of the EAC Certification Committee Work Group  
5 February 2008 Madrid

ENAC representatives: I. Pina and E. Gredilla  
EA Certification and Inspection Committee  
25-27 February 2008 in Athens  
ENAC representative: I. Pina

IAF Technical Committee  
1-7 March 2008 in Bonn  
ENAC representative: E. Gago

ILAC MLA Committee  
5-6 March 2008 in Amsterdam  
ENAC representative: B. Rivera

IAF Executive Committee  
6-7 March 2008 in Germany  
ENAC representative: I. Pina

EA Executive Committee  
17 March 2008 in París  
ENAC representative: I. Pina

EA MLA Committee  
2-3 April 2008 in Warsaw  
ENAC representative: B. Rivera

## **ENAC LEAD ASSESSORS CRITERIA CONSISTENCY CONFERENCES**

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Just like every year, the ENAC lead assessors, the technical staff and the Management of the entity have been able to enjoy a meeting with the aim, as in previous ones, of trying to achieve the harmonisation of the criteria referring to the accreditation processes, with the creation at all times of an atmosphere conducive to discussion and the sharing of experiences

This year the invitation was extended to the lead assessors of all the accreditation schemes at a single workshop,

which will facilitate greater consistency in the actions of all the schemes. In this way, the meeting was attended by some one hundred participants.

Beatriz Rivera, the Managing Director of ENAC, presented the main changes carried out in the company's management model and the balance sheet for the year. From the Assessors Management Department, José Luis Borrego, presented the innovations that have a direct affect on the assessors referring to procedures and forms. The representatives of the Operations Department, Inmaculada Lorente, the Manager, and José Luis Miguel, the Head of Operational Development, presented the main guidelines of the Evaluation System Modernisation Plan (See pages 6/7) . Ignacio Pina, the Technical Manager, focused on the objective of unification of criteria in the work of the assessors, both at the audit management and the technical level.

The queries and suggestions of the auditors closed the workshop, which once again achieved the objective of unifying and harmonising both technical and management criteria.

For further information: [jborrego@enac.es](mailto:jborrego@enac.es)

## **FIRST COURSE FOR INSPECTION LEAD ASSESSORS**

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ENAC convenes the first course for Inspection Bodies Lead Assessors under UNE-EN ISO/IEC 17020, which will be held during 25-29 February 2008.

These instructional workshops form part of the training required for qualification as a Lead Assessors for the evaluation of inspection bodies and will be delivered by ENAC technical personnel qualified as Lead Assessors of inspection bodies.

To refer to the programme, the methodology and the requirements, visit the ENAC portal [www.enac.es](http://www.enac.es); in the training section, where you will also find the pre-registration form.

