Multi-Country Workshop on Accreditation and Conformity Assessment for Mediterranean Neighbouring countries

INT MARKT 53084

Best practices of Italian Notified Bodies operational under New approach Directives

Important operational issues for notified bodies

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TOPICS EXAMINED

- The evolution of the accreditation of notified bodies after regulation 765/2008.
- Italian notified bodies: typology and activities.
- The role of the associations of conformity assessment bodies.
- Sources and modalities of information for notified bodies, their duties and prerogatives.
- Standards, New Approach directives and CE marks.
- The free movement of products on the market.

SITUATION IN ITALY BEFORE 2009

Certification and Inspection Bodies accredited by SINCERT

Testing Laboratories accredited by SINAL

Calibration Laboratories accredited by SIT

Testing Laboratories for Food Safety accredited by ISS/ORL

Notified bodies for the CE mark: authorized by the competent ministries and notified at the European Commission

Following its creation, Accredia takes over the accreditation of certification and inspection bodies, testing laboratories, testing labs for food safety and calibration laboratories

Following the entry into force of Regulation (CE) n. 765/2008 of the European Parliament and Council on July 9, 2008, Accredia becomes (at the end of 2009), the sole national accreditation body. Subsequently, in accordance with EU directives, a number of ministries delegated accreditation to Accredia for the purposes of notification

THE EVOLUTION OF ACCREDITATION FOR NOTIFIED BODIES

- The situation of Italian NBs changed following the entry into force of **Regulation (CE) n. 765/2008 of the European Parliament and Council on July 9, 2008**, which establishes standards regarding accreditation and market surveillance concerning the marketing of products and replacing Regulation (CEE) n. 339/93, setting out "*the requirements for the organization and functioning of the accreditation of CABs in undertaking conformity assessment activities", applicable to "accreditation, both mandatory and voluntary, regarding conformity assessment, independently of the legal status of the body in question*."
- Each member state designates a sole accreditation body.
- If accreditation is not performed directly by the public authorities, the member state may task its national accreditation body to carry out accreditation as public authority activities, giving it formal recognition.
- With the decrees of December 2009, the Ministry of Economic Development designated Accredia as sole accreditation and market vigilance body.
- From mid-March, 2011, **a number of Ministries delegated to Accredia the accreditation of notified bodies, whilst others have not yet done this**.

EFFECTS OF THE REGULATION 765/2008 ON NOTIFIED BODIES

On the basis of Regulation 765/2008:

- 5.1 - A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect.
- 5.2 - When a Member State decides not to use accreditation, it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonization legislation in question.

In the case of 5.1 the notification takes place by attaching Accredia's accreditation certificate and is usually concluded successfully within 15 days.

In the case of 5.2 the notification should be concluded within 2 months, but often it gets blocked by queries by the Commission or by member states.

NOTIFIED BODIES OPERATING IN ITALY

- It's difficult to say exactly how many there are which operate against some 34 directives, regulations and decisions, involving 8 ministries, either individually or collectively.
- The official source should be the EU's NANDO database, where about 230 are currently registered for a total of 337 notifications; many operate under more than one directive.
- However a large number of bodies are not NANDO registered due to the fact that they are waiting for accreditation or notification, especially in cases covered by 5.2, without an Accredia accreditation certificate.
- The directives and the Italian notified bodies are given in the following slide.

ITALIAN NOTIFIED BODIES REGISTERED IN NANDO

Direttiva	n° ON in Nando	delega Accredia
89/106/EEC Construction products	65	NO
2009/23/EC (ex-90/384/EEC) Non-automatic weighing instruments	98	SI'
95/16/EC Lifts	32	SI'
97/23/EC Pressure equipment	24	SI'
2006/42/EC Machinery	19	SI'
89/686/EEC Personal protective equipment	15	SI'
2000/14/EC Noise emission in the environment by equipment for use outdoors	14	SI'
2009/105/EC (ex-87/404/EEC) Simple pressure vessels	13	NO
2004/108/EC Electromagnetic compatibility	11	NO
2004/22/EC Measuring Instruments Directive	10	SI'
93/42/EEC Medical devices	9	NO
94/9/EC Equipment and protective systems intended for use in potentially explosive atmospheres	9	SI'
94/25/EC Recreational craft	8	NO
2006/95/EC (ex-73/23/EEC) Low voltage directive	8	SI'
2009/48/EC Safety of toys	8	SI'
2009/142/EC (ex-90/396/EEC) Appliances burning gaseous fuels	8	NO
2010/35/EU Transportable pressure equipment	7	SI'
96/98/EC Marine Equipment	6	NO
2008/57/EC Interoperability of the rail system within the Community (Recast)	4	NO
92/42/EEC Hot-water boilers	3	SI'
99/5/EC Radio and telecommunications terminal equipment	2	NO
2000/9/EC Cableway installations designed to carry persons	2	NO
90/385/EEC Active implantable medical devices	1	NO
Decision 2009/750/EC (impl.Dire. 2004/52/EC) - Interoperability of Electronic Road Toll Systems	1	SI'
93/15/EEC Explosives for civil uses	0	NO
98/79/EC In vitro diagnostic medical devices	0	NO
2007/23/EC Pyrotechnic articles	0	NO
Regulation (EU) No 305/2011 - Construction products	0	NO
Regulation (EC) No 552/2004 - Interoperability of the European Air Traffic Management network	0	NO
29	**377**	

ASSOCIATIONS OF CONFORMITY ASSESSMENT BODIES

There are many associations of CABs operating in Italy. The 8 in the list below are **Accredia members** and 3 are members of the Board of Directors; one of these is a member of Accredia's Executive Committee. There are other smaller associations which operate, for example, in accordance with single directives.

Sigla	Nome	Tipologia di Soci
AIOICI	Associazione Italiana Organismi Indipendenti Certificazione e Ispezione	Tutte le tipologie di soggetti Accreditati
AIZS	Associazione Istituti Zooprofilattici Sperimentali	Laboratori di Prova Statali
ALA	Associazione Laboratori Accreditati	Laboratori di Prova Accreditati
ALPI	Associazione Laboratori di Prova ed Organismi di Certificazione e Ispezione	Tutte le tipologie di soggetti Accreditati
Ascoteco	Associazione per il Controllo Tecnico delle Costruzioni	Organismi di Ispezione settore costruzioni
CISQ	Certificazione Italiana dei Sistemi Qualità Aziendali	Organismi Di Certificazione Sistema
CONFORMA	Associazione Organismi Certificazione Ispezione Prove Taratura	Tutte le tipologie di soggetti Accreditati
UNOA	Unione Nazionale Organismi Accreditati	Organismi Di Certificazione Sistema

TASKS OF THE ASSOCIATION OF CONFORMITY ASSESSMENT BODIES

The associations perform a number of useful tasks for notified bodies, such as the following, taken from the statute of ALPI:

- To promote the culture of quality.
- To raise awareness among institutions, businesses and consumers.
- To contribute towards the continuous improvement and technical competence of associated bodies.
- To increase coordination of the activities of associates, the exchange of information, also by creating working groups.
- To collaborate with the public authorities and other public bodies which have competencies in the field of conformity assessment.
- To contribute, both at national and international levels, to the development of horizontal standards in conformity assessment.
- To represent Italian CABs in Europe and other countries which are active in the field of accreditation and conformity assessment, including the maintenance of relations with coordination groups for notified bodies at the European Commission, in accordance with recommendations issued by the Commission.

TASK OF THE ASSOCIATIONS OF BODIES

ALPI Technical section of notified / authorized bodies

- Specialist group ON – notified bodies (general matters)
- Specialist group ASC– lifts
- Specialist group MAC – machinery
- Specialist group PED – pressure equipment
- Specialist group T-PED – transportable pressure equipment
- Specialist group DM – medical devices
- Specialist group RUM – noise emission
- Specialist group DPI – personal protective equipment
- Specialist group CPD-CPR –construction products - specialist group in steel structures
- Specialist group VIT – ground installation verifications/audits
- Specialist group article 71 – periodical audits

INFORMATION SOURCES FOR NOTIFIED BODIES

- EC directives
- EC guidelines
- Coordination and EC working groups
- Decrees enacting directives in national legislation
- Ministerial decrees with requirements for notified bodies
- Accreditation standards and Accredia regulations
- Technical standards and working groups on technical standards at the national AB
- Internal working groups at the associations of notified bodies
- Comparison with the associations of producers

INFORMATION MODALITIES OF NOTIFIED BODIES

- Availability of legislation (EU and national).
- Attendance of coordination groups, either directly or through national delegates appointed internally within the associations.
- Discussions with the accreditation body and the ministries, also submitting requests for interpretations/opinions.
- Discussions among notified bodies as part of the technical working groups of the associations.
- Training and informing inspectors and technical officers, also by means of regular updates and meetings.
- Participation at round robin tests for directives which provide for a large amount of laboratory testing activities.

OBLIGATIONS OF NOTIFIED BODIES

- To respect the directives and national laws resulting from such, the accreditation standards and the Accredia regulations. Of particular importance are the criteria of independence and impartiality.
- To communicate or make available to the ministries the list of certificates issued.
- To communicate all certification refusals so that they are known by all other notified bodies.
- To make sure that staff are kept updated from a technical point of view and that clients are informed regarding changes to the state of the art regarding standards and laws.

STANDARDS AND DIRECTIVES

European standardization works in close collaboration with the EU in order to make available the standards which set out shared rules (on how to plan, make, verify a product etc.).

HARMONIZED STANDARD

Standards begin as voluntary, but they can assume a legislative character when they are published in the Official Gazette of the EU, with the status of “harmonized standard”.

HARMONIZED STANDARD

- Compliance with a harmonized standard involves conformity under the law.

- The list of reference harmonized standards for the various directives is available at:

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

NEW APPROACH - PRINCIPLES

- The EC directives are legal documents addressed to member states which must create national laws for their implementation.
- EU regulations are applicable directly to all interested bodies and legislation is not necessary.

NEW APPROACH - PRINCIPLES

- Products covered by the directive cannot be issued on the EU market without the CE mark on them.

- It is also not permitted to put the CE mark on products which specifically do not require it.

NEW APPROACH - PRINCIPLES

- Directives which are known as the “New Approach” will carry the CE mark following procedures which vary depending on the directive and the type of risk related to the product.
- The approach to conformity follows a module scheme depending on the category of risk related to the product.

NOTIFIED BODIES

- The modalities to follow for the CE mark are based on the risk factor.
- For higher classifications of risk the intervention of a notified body is necessary for the application of the CE mark on the product.

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NOTIFIED BODIES

The assessment modules generally include:

- approval of a type or model, also by means of tests and inspections;
- approval and audit of the producer's quality system;
- periodical inspection of products made.

NOTIFIED BODIES

On the basis of the modules the notified body ensures that the producer has:

- defined the end use of the product;
- evaluated all the potential risks and taken the necessary action to minimize risks.
- The producer means any person, physical or legal, who is responsible for the design and manufacture of a product to be placed on the market under his/its name.

NOTIFIED BODIES

On the basis of the modules the notified body ensures that the producer has:

- designed the device taking into consideration the results of the risk analysis;
- demonstrated respect for relevant safety requirements, making use, where possible, of harmonized standards (product, testing).

NOTIFIED BODIES

On the basis of the modules the notified body ensures that the producer has:

- described and documented the characteristics of the product;
- defined the process of production and control of the product;
- activated a quality system which ensures product conformity over time.

NOTIFIED BODIES

On the basis of the modules the notified body ensures that the producer has:

- defined instructions for the installation of the product and the equivalent requirements of competence of the installer;
- defined and documented the instructions for the use and maintenance of the product.

Marcatura CE – responsabilità e ruoli

NOTIFIED BODIES

The notified body, before granting CE certification:

- evaluates the completeness and conformity of the technical leaflet;
- evaluates the conformity and strength of the producer's quality system.

NOTIFIED BODIES

Following granting of the CE certification, the notified body:

- evaluates any possible changes contained in the technical leaflet;
- periodically and systematically checks that the producer behaves consistently, keeping active an adequate quality system.

MODULE B

- Provides for the approval of a type, by means of the examination of the documents of planning and inspection of a prototype with the possibility of doing conformity tests.
- This is usually done in association with other modules with the exception of the Machines Directive annex IX, where no other module is applicable.

MODULE F

- Associated with module B, providing for the verification of each sample to ensure conformity with the approved type.

MODULE D

- Associated with module B, providing for the verification of the production quality system to ensure continuity of the productive process and products which are in conformity with the approved type.

MODULE G

- Applied to single samples, providing for the examination of the technical project documentation, the modalities of manufacture and the verification of the single sample, without advanced approval of the “type” in accordance with module B.

MODULE H

- Providing for the “total” verification of the producer’s quality system, including the planning processes.
- It normally provides for the verification of a technical leaflet to identify the range of products which come within the certification issued by the notified body.

FREE MOVEMENT OF PRODUCTS

- The recognition by EA of the certifications issued under the accreditation of accreditation bodies signatory to the EA agreements has now been achieved.
- The free movement in the EU of European or non-European products with the CE mark has now been achieved.
- The free movement of products with the CE mark for non-European countries but signatory to the MLA agreements is still a distant aim, due also to national legislation.