

***Accreditation process for
abilitation/ notification:
experiences and criticalities***

THE REFERENCE FRAMEWORK

The European scenario changes

Regulation 764/2008/EC

Laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC

Regulation 765/2008/EC

Setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing

Decision n. 768/2008/EC

On a common framework for the marketing of products, and repealing Council Decision 93/465/EEC

THE REFERENCE FRAMEWORK

The European scenario changes

Following the entry into force of Regulation 765/08, the Ministry of economic development, together with the following ministries: internal affairs; agriculture food and forestry; environment; land and maritime affairs; infrastructure and transport; labour and social policies; health; education and research, and defence, issued a decree (December 22, 2009 in the official government gazette n. 20 of 26/1/10) designating Accredia, a non-profit association with private legal status, to be the sole national accreditation body in accordance with Reg. 765/2008.

THE REFERENCE FRAMEWORK

The Italian scenario changes

ACCREDIA, in accordance with article 2 of its statute

*«the Body,..... performs the accreditation of bodies performing conformity assessments against technical standards.....the accreditation of bodies performing conformity assessments also takes place in confidential areas (in accordance with the relevant laws and regulations) of the public administrative authorities on the basis of specific mandates and following formal initiatives from such administrative authorities» **has signed agreements with the administrative authorities.***

Agreement: Economic Development Ministry - Accredia

In June 2011 the first agreement was signed between Accredia and the Ministry of economic development to perform the accreditation of bodies for these directives:

- **Directive 2009/48/EC - Safety of toys**
- **Directive 2004/22/EC - MID - Measurement instruments**
- **Directive 1992/42/EC - Boilers and hot water**
- **Directive 1997/23/EC - PED - High pressure equipment**
- **Directive 1994/09/EC - ATEX - Apparatus and protection systems for use in potentially explosible**
- **Directive 2004/108/EC - EMC – Electro Magnetic Compatibility**

Agreement: Economic Development Ministry - Ministry of Labour and Social policy Agreement - Accredia

Also in June 2011, the second agreement was signed between Accredia and the ministries of economic development, of labour and social policies to perform the accreditation of bodies for these directives:

- **Directive 2006/42/EC - Machinery**
- **Directive 1995/16/EC – Lifts**
- **Directive 2006/95/EC – Low voltage**
- **Directive 1989/686/EEC – Personal protective equipment**

Memorandum of Understanding between Accredia and the Ministry of infrastructure and transport - General management of road transport

**In June 2011 a MoU was signed between
Accredia and the Ministry of infrastructure
and transport - General management of road
transport to perform the accreditation of
bodies regarding Decision 2009/750/EC
European Electronic Toll Service.**

Agreement: Ministry of infrastructure and transport - Accredia

In November 2011 an agreement was signed between the Ministry of infrastructure and transport and Accredia to perform accreditation of Type A Inspection bodies for directive 2010/35/EU T-PED (Transportable pressure equipment).

**Agreement:
Accredia - Ministry of Economic development -
general planning management of the radio-
electrical spectrum**

**Agreement signed in November 2011 between
the Ministry of Economic development -
general planning management of the radio-
electrical spectrum and Accredia to perform
the accreditation of bodies for Directive
1999/05/EC – R&TTE - Radio and
Telecommunications Terminal Equipment
Directive.**

Agreement between the Ministry of the environment, land and maritime affairs and ACCREDIA

In November 2011 an agreement was signed between the min. of the environment, land and maritime affairs and ACCREDIA to perform the accreditation of bodies for the Directive 2000/14/EC – noise.

HOW ACCREDIA OPERATES

Accredia's audit activities are as follows:

- **Presentation of the application for accreditation or extension of accreditation by the body;**
- **Verificaton of the application and (if ok) issue of a quote (calculated on the basis of the directives, the modules and the product grouping requested as the scope of accreditation);**

HOW ACCREDIA OPERATES

- **Acceptance of the quote by the body giving formal start-up to conformity assessment activities;**
- **Document examination of accreditation or extension;**
- **Initial or extension accreditation audit at the body's location.**

If the body is already authorized and notified the Accredia audit team conducts the full audit (on the basis of documents of receipt of the application to the issue of the certificate) of the files of certain certification files to enable carrying the CE mark; such files are managed by the body;

HOW ACCREDIA OPERATES

After successful outcome of both audit phases (document analysis and on-site audit), the file is presented to the Sector Accreditation Committee for notified bodies for deliberation;

Performance of witness audits (if required by the Directive covering the accreditation) with the auditors of the accredited and notified bodies, chosen according to the criticality of the modules/articles/annexes for each product grouping.

HOW ACCREDIA OPERATES

Accredia has decided that, in agreement with the interested parties, the 2 most suitable standards for accreditation activities for the purposes of qualification/authorization and notification are:

- **UNI CEI EN 45011**

If the modules involve laboratory tests for conformity assessment regarding the product's safety characteristics as set out in the directives or standards, further requirements will have to be evaluated concerning the testing activities in accordance with ISO/IEC 17025;

HOW ACCREDIA OPERATES

- **UNI CEI EN ISO/IEC 17020**

If the conformity is assessed exclusively by means of inspection activities (dimensional, visual, functional, hydraulic, resistance etc examinations) without using testing labs or if so indicated in the Directive.

Granted the above, Accredia, in its assessment activities, applies the "Approach 1 +" whereby, very briefly:

- **1 means the standard against which accreditation is issued;**
- **+ means the additional requirements of other standards to guarantee the completeness of the conformity to the requirements of the Directive.**

Directive 1989/686/EEC – Personal protective equipment

Main reference standard for conformity assessment: UNI CEI EN 45011

Other standards with applicable requirements: ISO/IEC 17021 - ISO/IEC 17025

Number of applications for accreditation or extension received: 16

Number of accreditations or extensions undertaken following acceptance of quote: 16

Number of accreditations deliberated at the date 24/05/2013: 8

Directive 1994/09/EC - ATEX - Apparatus and protection systems for use in potentially explosible

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

Other standards with applicable requirements: ISO/IEC 17021 - ISO/IEC 17025

Number of applications for accreditation or extension received: 8

Number of accreditations or extensions undertaken following acceptance of quote: 8

Number of accreditations deliberated at the date 24/05/2013: 5

Directive 95/16/EC - Lifts

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17020 - ISO/IEC 17021 - ISO/IEC 17025**

**Number of applications for accreditation or extension
received: 103**

**Number of accreditations or extensions undertaken
following acceptance of quote: 83**

**Number of accreditations deliberated at the date
24/05/2013: 40**

Directive 1997/23/EC - PED - High pressure equipment

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17020 - ISO/IEC 17021 - ISO/IEC 17025**

Number of applications for accreditation or extension received: 44

Number of accreditations or extensions undertaken following acceptance of quote: 37

Number of accreditations deliberated at the date 24/05/2013: 23

Directive 1999/5/EC - R&TTE - Radio and Telecommunications Terminal Equipment

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17021 - ISO/IEC 17025**

Number of applications for accreditation or extension received: 5

Number of accreditations or extensions undertaken following acceptance of quote: 2

Number of accreditations deliberated at the date 24/05/2013: 0

Directive 2000/14/EC - Noise

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17021 - ISO/IEC 17025**

**Number of applications for accreditation or extension
received: 8**

**Number of accreditations or extensions undertaken
following acceptance of quote: 6**

**Number of accreditations deliberated at the date
24/05/2013: 2**

Directive 2004/22/EC - Measurement instruments

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17021 - ISO/IEC 17025**

Number of applications for accreditation or extension received: 2

Number of accreditations or extensions undertaken following acceptance of quote: 2

**Number of accreditations deliberated at the date
24/05/2013: 1**

Directive 2004/108/EC - EMC – Electro Magnetic Compatibility

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17025**

**Number of applications for accreditation or extension
received: 16**

**Number of accreditations or extensions undertaken
following acceptance of quote: 12**

**Number of accreditations deliberated at the date
24/05/2013: 8**

Directive 2006/42/EC - Machinery

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17021 - ISO/IEC 17025**

**Number of applications for accreditation or extension
received: 51**

**Number of accreditations or extensions undertaken
following acceptance of quote: 40**

**Number of accreditations deliberated at the date
24/05/2013: 22**

Directive 2006/95/EC - Low voltage

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17025**

**Number of applications for accreditation or extension
received: 6**

**Number of accreditations or extensions undertaken
following acceptance of quote: 5**

**Number of accreditations deliberated at the date
24/05/2013: 4**

Directive 2009/48/EC - Safety toys

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

**Other standards with applicable requirements:
ISO/IEC 17025**

**Number of applications for accreditation or extension
received: 9**

**Number of accreditations or extensions undertaken
following acceptance of quote: 9**

**Number of accreditations deliberated at the date
24/05/2013: 8**

Directive 2010/35/EU - T-PED - Transportable pressure equipment

Main reference standard for conformity assessment:

ISO/IEC 17020

Other standards with applicable requirements:

ISO/IEC 17021 - ISO/IEC 17025

Number of applications for accreditation or extension received: 17

Number of accreditations or extensions undertaken following acceptance of quote: 15

Number of accreditations deliberated at the date 24/05/2013: 8

Decision 2009/750/EC - Interoperability of Electronic Road Toll Systems

**Main reference standard for conformity assessment:
UNI CEI EN 45011**

Number of applications for accreditation or extension received: 1

Number of accreditations or extensions undertaken following acceptance of quote: 1

Number of accreditations deliberated at the date 24/05/2013: 1

123 bodies for 236 Directives/files

| % | Directive | Number of applications per directive | Application accepted by ACCREDIA | Quotes accepted accettate | SAC notified bodies | % of quotes accepted per directive |
|------|------------------------|--------------------------------------|----------------------------------|---------------------------|---------------------|------------------------------------|
| 3% | 1994/9/CE ATEX | 8 | 8 | 8 | 5 | 63% |
| 2% | 1999/5/CE radios | 5 | 5 | 2 | | 0% |
| 3% | 2000/14/CE noise | 8 | 8 | 6 | 2 | 33% |
| 6% | 2004/108/CE EMC | 16 | 15 | 12 | 8 | 67% |
| 1% | 2004/22/CE MID | 2 | 2 | 2 | 1 | 50% |
| 18% | 2006/42/CE machines | 51 | 44 | 40 | 22 | 55% |
| 2% | 2006/95/CE low tension | 6 | 6 | 5 | 4 | 80% |
| 3% | 2009/48/CE toys | 9 | 9 | 9 | 8 | 89% |
| 6% | 2010/35/UE T-PED | 17 | 15 | 15 | 8 | 53% |
| 36% | 95/16/CE lifts | 103 | 91 | 83 | 40 | 48% |
| 15% | 97/23/CE PED | 44 | 41 | 37 | 23 | 62% |
| 0% | Decisione 2009/750/CE | 1 | 1 | 1 | 1 | 100% |
| 6% | 89/686/CEE DPI | 16 | 16 | 16 | 8 | 50% |
| 100% | Total | 289 | 263 | 236 | 130 | 55% |

Summary of the main document findings

- **Representative committee of the parties: absence, inadequate composition and inadequate functioning rules.**
- **Decision-taking body: absence of competence regarding all or part of the activities required in the accreditation scope.**
- **Subcontract: absence of procedures for the qualification of laboratories.**
- **General regulations and contracts: absence or inadequacy of documents.**
- **Quality manual and audit support documents: incomplete.**
- **Inspectors: incomplete or not updated CVs. Qualification procedures lacking requirements of applicable directives.**
- **Insurance policies: inadequate.**

Summary of the main findings of the audit

- **Contracts with the clients: incomplete or absent.**
- **Technical : incomplete.**
- **Records in audits and deliberations: incomplete for deciding with regard to certification.**
- **Deliberating body: not competent.**
- **Subcontracts: not properly managed.**
- **Communication: not correct with regard to the websites and/or the ministries.**

ACCREDIA L'ente italiano di accreditamento

Thanks for your attention

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