APRIMORAMENTO DO Processo de Certificação

National Measurement Office

National Measurement Office Certification

New Legal Framework – a Route to Improving Consistency and Confidence in Certification in Europe

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Introduction to NMO: a brief history

1866	Standards Department of the Board of Trade was set up
1905	First Type Approval Certificate was issued
1978	Standards Department was renamed the National Weights and Measures Laboratory (NWML)
1987	NWML relocated to purpose built laboratory in Teddington
1989	NWML became an Executive Agency of the former Department of Trade & Industry (DTI)
2009	NWML renamed the National Measurement Office (NMO)

Introduction to NMO: what we do

Four main “lines of business”:

- Management of UK National Measurement System
- Weights & Measures and Hallmarking policy
- Enforcement Authority - Environmental Legislation
- Certification Services

Introduction to NMO: Certification Services

- **Certification Body** - operate as a Notified Body (NB), undertaking conformity assessment activities under two European Metrology Directives:
  - Non-Automatic Weighing Instruments (NAWI) Directive 2009/23/EC (formerly 90/384/EEC)
  - Measuring Instruments Directive (MID) 2004/22/EC
- **Calibration and Testing Laboratory**
- **Training**

Europe: the Single Market

- 31 countries in European Economic Area - (27 EU Member States + 4 ETFA countries)
- Range of European Directives covering different products
- Choice of conformity assessment procedures
- Where applicable, Notified Bodies undertake conformity assessment activities
- CE-marking of products

CE

CE-marking: the Basics

- CE-mark indicates a product's compliance with EU legislation - enables free movement of products within the EEA
- By affixing the CE-mark to a product, a manufacturer declares, on his sole responsibility, that the product meets all the legal requirements for the CE-marking. This also applies to products made in other countries which are sold in the EEA
- Not all products must bear the CE-mark. Only products mentioned in specific EU directives on CE-marking

CE-marking: the Basics

- CE-marking states that the product has been assessed before being placed on the market. It means that the manufacturer has:
  - verified that the product complies with all relevant essential requirements laid down in the applicable directive(s), and
  - if stipulated in the directive(s), had it examined by an independent conformity assessment (notified) body.
- It is the manufacturer's responsibility to carry out the conformity assessment, to set up the technical file, to issue the declaration of conformity and to affix the CE-mark to a product.

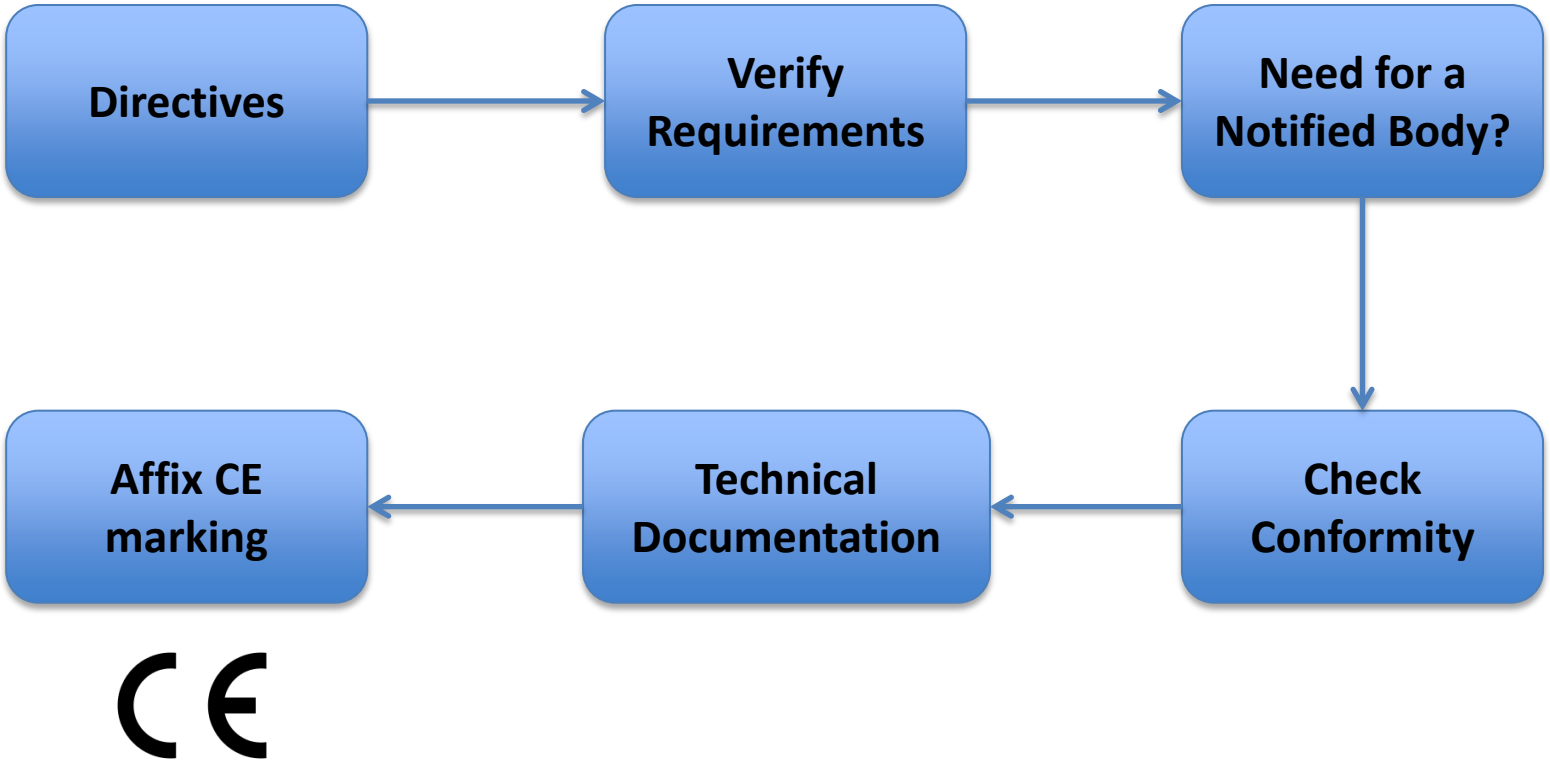
CE-marking: the Process

Directives

CE-marking: Directives

Active implantable medical devices
Appliances burning gaseous fuels
Cableway installations designed to carry persons
Eco-design of energy related products
Electromagnetic compatibility
Equipment and protective systems intended for use potentially explosive atmospheres
Explosives for civil uses
Hot-water boilers
In vitro diagnostic medical devices
Lifts
Low Voltage Devices
Machinery
Measuring Instruments
Medical devices (93/42/EEC)
Noise emission in the environment
Non-automatic weighing instruments
Personal protective equipment
Pressure equipment
Pyrotechnics
Radio and telecommunications terminal equipment
Recreational craft
Safety of toys
Simple pressure vessels

CE-marking: the Process



When Certification Goes Wrong!

Breast Implant Scandal

Breast Implant Scandal: what happened?

- Thousands of faulty breast implants supplied
- 300,000 women in 65 countries affected
- Implants filled with **non-medical grade silicon**
- Implants more likely to rupture (4000 cases reported)
- Company quality system covering **manufacturing process** certified by a Notified Body
- Failing of inspection/market surveillance

Confidence in Certification and the CE-mark

- Issues such as the breast implant scandal, and other less publicised ‘concerns’ in other sectors, has resulted in a lack of trust
- Doubts raised about the credibility of certification and use of the CE-mark
- Competence and consistency of Notified Bodies questioned
- Failings relating to market surveillance
- No harmonisation in product directives

HOW TO ADDRESS THESE ISSUES?

New Legislative Framework: Background

- **EU Decision 768/2008/EC** on a common framework for the marketing of products – harmonisation of product directives
- **Regulation 765/2008/EC** setting out requirements for accreditation and market surveillance of products
- Together they constitute **"New Legislative Framework"** - shortened to **"New Legal Framework"** or **"NLF"** for this presentation

Purpose - Alignment not Revision!

- "Alignment" means bringing an existing Directive into line with provisions of Decision 768/2008/EC, but doing nothing else
- Basic principle of Alignment – align unless there are powerful sector-specific arguments for making the sector an exception
- "Revision" means bringing it into line AND making significant sector-specific changes as well, e.g. to its scope or essential requirements
- Purpose of the NLF is **alignment** – scope of directives and the essential requirements remain the same (existing certificates still valid)

Legislative provision

Regulation 765/2008/EC

- mainly addresses the duties and responsibilities of EU member States
- **directly applicable**; with effect from 1 January 2010, i.e. no national implementation required by member States
- member States required to revoke any national legislation and provide legal clarification
- member States required to designate a single National Accreditation Body, e.g. in the UK this is UKAS
- market surveillance provisions considered alongside individual Directive provisions

Legislative change/purpose

EU Decision 768/2008/EC

- a politically but not legally binding obligation for EU institutions to legislate to bring individual Directives into line with its provisions
- means to update, align and clarify framework provisions of existing 'single market' legislation:
  - non-compliance
  - competence of Notified Bodies
  - consistency between Directives

Nine Alignment Measures

- Measuring Instruments Directive: 2004/22/EC;
- Non-Automatic Weighing Instruments Directive: 2009/23/EC ;
- Simple Pressure Vessels Directive: 2009/105/EC;
- "ATEX" Directive: 94/9/EEC;
- Pyrotechnic Articles Directive: 2007/23/EC ;
- Civil Explosives Directive: 93/15/EEC;
- Electromagnetic Compatibility Directive: 2004/108/EC;
- Low Voltage Electrical Equipment Directive: 2006/95/EC, and
- Lifts Directive: 1995/16/EC

Other Directives not listed above have either already incorporated the latest alignment requirements or are in the process of a full revision (which will incorporate alignment requirements)

Reasons for Decision & Alignment

Non-compliance

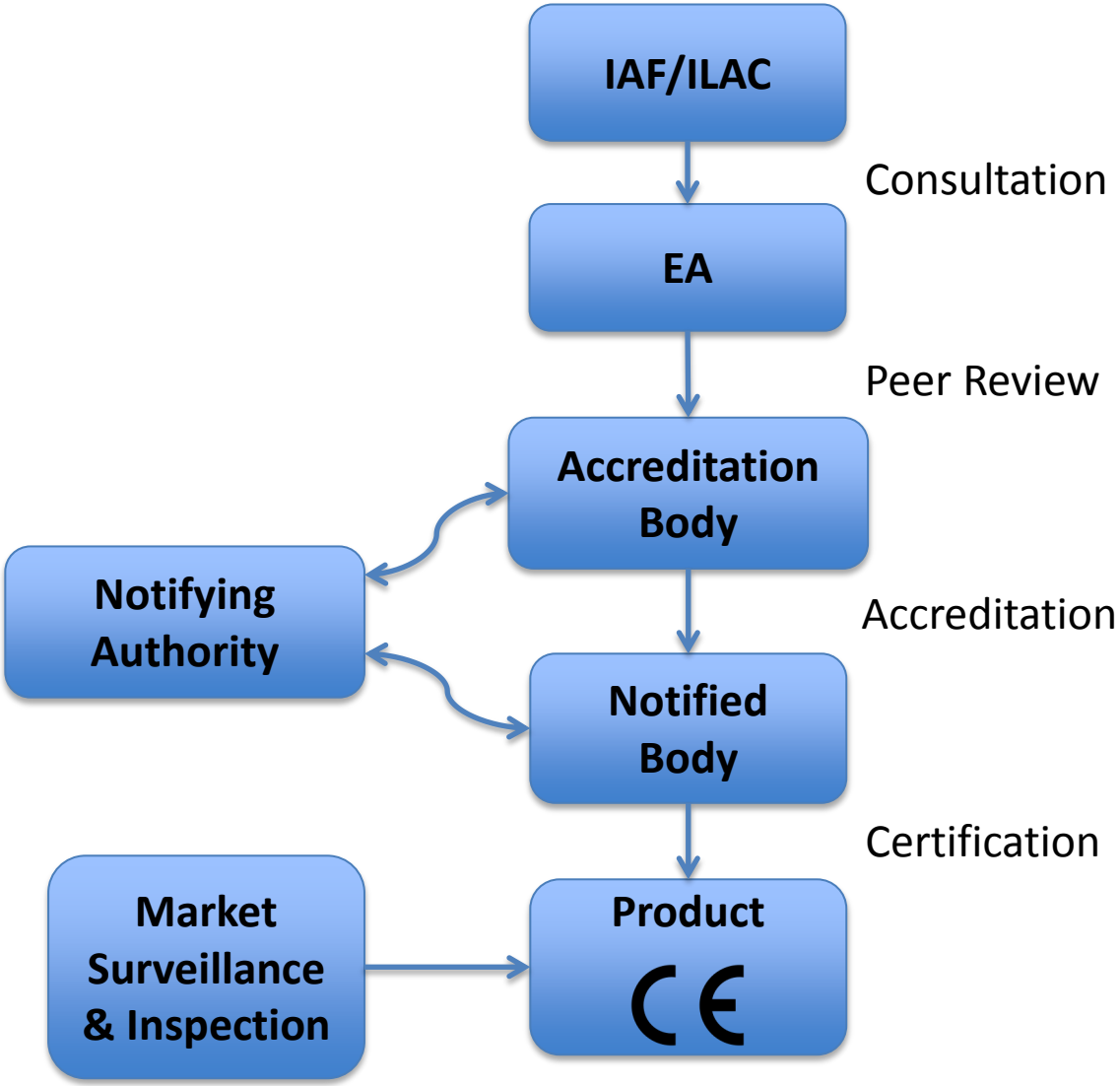
- provide improved traceability with clearer requirements on manufacturers, importers and distributors and greater co-operation with enforcement authorities

Performance of Notified Bodies

- provide greater accountability in designation and consistency of performance between NBs - reinforced designation process

Inconsistencies between Directives

- to provide an alignment of conformity procedures and commonly used definitions, e.g. notifying authority, accreditation body
- repeal of 1993 decision – basis on which all Directives were drafted (updated by 'Blue Guide')


IAF/ILAC
Consultation
EA
Peer Review
Accreditation Body
Notifying Authority
Accreditation
Notified Body
Certification
Market Surveillance & Inspection
Product
CE

Non-compliance

Obligations of Economic Operators

- Manufacturers – extended/made more explicit
  - design and manufacture to essential requirements, technical documentation, consistent production, legal markings, non-conforming instruments, **risk policy**, cooperation with competent authorities
- Authorised Representatives – extended/made more explicit
  - as above where acting on behalf on the manufacturer, excluding technical documentation and ensuring design and manufacture is in compliance with essential requirements
- Importers – explicit obligations for the first time
  - as above in relation to certain market issues
- Distributors – explicit obligations for the first time
  - as above in relation to more limited market issues

Manufacturer, Importer, Distributor

- **Manufacturers** – obligation to ensure products are in compliance with essential requirements
- **Importers** – place only compliant products on the market by ensuring certain things have been done
- **Distributors** – take due care by verifying certain things have been done
- Increasing levels of responsibility
- Where instruments are purchased from a manufacturer outside the EEA the economic operator within the EEA will either be an “importer” or an “authorised representative”
- Purchasing instruments from within the EEA may mean an “importer” takes on the obligations of a “distributor”
- One economic operator may have multiple roles across their range of instruments

Role of Notified Bodies

Conformity Assessment modules

- Eight conformity assessment procedures or "modules" which cover the design and production phases

Annex		Description
-	A / A1	Declaration of Conformity based on internal production control (plus product testing by a Notified Body)
-	B	Type Examination
B	C / C1	Declaration of Conformity to type based on internal production control (plus product testing by a Notified Body)
(B)	D / D1	Declaration of Conformity (to type) based on Quality Assurance of the production process
(B)	E / E1	Declaration of Conformity (to type) based on Quality Assurance of final product Inspection and testing
(B)	F / F1	Declaration of Conformity (to type) based on Product Verification
-	G	Declaration of Conformity based on Unit Verification
-	H / H1	Declaration of Conformity based on full Quality Assurance (plus Design Examination)

Role of Notified Bodies

Selection of procedures

- Choice of Conformity Assessment Procedures
  - modules A to H1; not all directives call up all modules
  - greater degree of harmonisation across directives
  - adapted to take into account unique characteristics and scope
- Notified Bodies appointed for specific Conformity Assessment procedures and product types

Performance of Notified Bodies

Designation process

- Appointment on the basis of accreditation (accepted route)
- Alternative methods of appointment (and maintenance) based on 'in house' criteria permitted – competence, equivalence must be evidenced
- Notification to the Commission
- Potential to object to designation by Commission or other member States
- Open to greater scrutiny
  - 2 weeks where basis is accreditation
  - 6 weeks where alternative method is used
- Re-designation of existing Notified Bodies

Surveillance, Safeguard Procedures…

- Each Directive incorporates an obligation to apply the Regulation 765/2008 Market Surveillance & Border Control duties of Member States
- Requirement that economic operators resolve any non-compliance issues
- Where non-compliance issues are outside national territories Commission and other member States to be informed
- Establish whether non-compliance is a failure to meet the requirements or shortcomings in harmonised standards
- Safeguard procedures available for products presenting a risk at national level

Transitional & Final Provisions

- Member States' duty to apply penalties in relation to non-compliant products, i.e. proportionate & dissuasive
- Transitional provisions – continued free movement of products complying with legislation
- Anticipate new directives by end of this year
- Transposition – proposed for two years after adoption
  - discussions in Council; due to the nature of the changes whether this could be extended to three years (particular support to SMEs)

Will NLF be enough to provide consistency and confidence in certification?

- NLF intended to provide consistency between product directives and to address issues regarding non-compliant product and the competence of NBs (to provide a consistent level of performance)
- However, a number of questions/issues still remain regarding NLF:
  - Accreditation for NBs is still not mandatory – 'equivalent' methods permitted
  - Who assesses the competence of the notifying authority?
  - Which standards (e.g. ISO 17020, 17021, 17025, 17065) to apply for different conformity assessment modules?
  - Timescales for implementing changes and re-designation of NBs
  - Funding/resources for market surveillance and inspection – who will provide?
  - Availability of information for market surveillance and inspection activities, e.g. how to determine instrument is in conformity with approved type – currently being discussed by the Legal Metrology community

Will NLF be enough to provide consistency and confidence in certification?

- Further proposals for a product safety and market surveillance package – **More Product Safety and better Market Surveillance!**
- Medical devices sector proposing more stringent requirements:
  - Strengthen role of NBs – independent control and surveillance
  - Development of product verification
  - More intensive market surveillance
  - Type examination mandatory for high-risk products
  - Obligation to perform unannounced visits for inspections and tests
  - Closer cooperation between NBs, competent authorities and market surveillance authorities
  - NBs to be involved in a new Medical Device Coordination Group
- Other sectors may follow lead of medical devices sector?

Can we ever be sure that a product affixed with the CE-mark is safe?

Due to counterfeiting or misuse, there is never a 100% guarantee that a product bearing the CE-mark is safe.

However, with the adoption of Regulation 765/2008 and Decision 768/2008, the obligations of the manufacturer are spelled out and it is clear that by affixing the CE-mark to a product, the manufacturer assumes full responsibility for its compliance with all applicable requirements in EU legislation.

It is the system behind the CE-marking that ensures its proper functioning. The entire system, consisting of manufacturers, importers, distributors, notified bodies and market surveillance authorities, has been strengthened through the NLF.

However, NLF does not appear to provide a complete solution and further work may be required, e.g. the proposed Product Safety and Market Surveillance Package, to ensure consistency and confidence in certification in Europe.

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Thank you for your attention

Any Questions?