POST-BREXIT

Standards, Certification and the CE Mark

“What Must I Do?”

Mary White
Head of NSAI Brexit Unit
What I will cover

• Introduction to NSAI
• EU Legislation and NANDO
• What CE Does and Notified Bodies (NBs)
• Impact of Brexit for UK Certification
• Responsibility of Manufacturer/Importer
• Transit of Goods (wood packaging material)
About NSAI

Four main divisions

Standards
Certification
Legal Metrology
National Metrology Laboratory
About NSAI

Four main divisions

1. Standards
2. Certification
3. Legal Metrology
4. National Metrology Laboratory
Where do Standards come from

162 members worldwide

28 EU countries 33 members

Member of International and European committees

Process relationships between the Standards Organizations
New version close to publication
Systematic Innovation Management
ISO 56000 Series + 8 Principles

1. Realization of value
2. Future-focused leaders
3. Strategic direction
4. Culture
5. Exploiting insights
6. Managing uncertainty
7. Adaptability
8. Systems approach
Future and Emerging Technologies

- Nanotechnologies
  - Graphene
  - Additive Manufacturing
  - Robotics & Cobots
  - Blockchain
  - Biotechnology
  - Medical & Neuro Technologies
  - Internet of Things
  - Artificial Intelligence
NSAI ICT Standards committees are engaged in developing international standards for these key enablers.
ISO/TC 299 - Robotics
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Purpose of the European Single Market

• European Standards used to level the playing field

Free trade

• Third Party Certification

Fair trade
Non Harmonised Standards

Reinforcing Steel I.S. EN 10080
Concrete I.S. EN 206

Compression Fittings I.S. EN 1254-2
Product Certification Scheme for ready mixed concrete

- Tightly Regulated
- Industry Led Certification Scheme
- In response to client demand, NSAI has put in place a product certification scheme covering ready-mix concrete.

No CE Marking Required

What CE does

- Enables free movement of goods throughout EU member states and beyond. Removes technical barriers to trade.

- Places responsibility with the **manufacturer** or **importer** of goods; whoever places the product on the market.

- Relates to EU Directives/Regulations **Primarily self certification**.

- Allows manufacturer to declare performance and place product on the market.
<table>
<thead>
<tr>
<th>Regulation</th>
<th>Description</th>
<th>EU Notified Bodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU 305/2011</td>
<td>Construction Products Regulation</td>
<td>699</td>
</tr>
<tr>
<td>2006/42/EC</td>
<td>Machinery</td>
<td>180</td>
</tr>
<tr>
<td>2014/33/EU</td>
<td>Lifts and safety components for lifts</td>
<td>230</td>
</tr>
<tr>
<td>2014/68/EU</td>
<td>Pressure Equipment</td>
<td>309</td>
</tr>
<tr>
<td>2001/95/EC</td>
<td>General product Safety Directive</td>
<td>None</td>
</tr>
<tr>
<td>2011/65/EU</td>
<td>Restriction of Hazardous Substance Directive</td>
<td>None</td>
</tr>
<tr>
<td><strong>LVD(2014/35/EU)</strong></td>
<td><strong>Low Voltage Directive</strong></td>
<td>None</td>
</tr>
<tr>
<td>2014/30/EU</td>
<td>Electromagnetic Capability</td>
<td>116</td>
</tr>
<tr>
<td>2014/53/EU</td>
<td>Radio Equipment</td>
<td>78</td>
</tr>
<tr>
<td>2016/425</td>
<td>Personal Protective Equipment Regulation</td>
<td>108</td>
</tr>
</tbody>
</table>
6 Steps to CE Marking (hEN Route).

1. Identify Directives and hEN applicable to your product.
2. Verify Essential Characteristics.
3. Determine if a NB is required.
4. Test the product.
6. Affix CE mark.
Notified Bodies

• The primary task of a notified body is to provide conformity assessment services on the conditions set out in the applicable EU harmonisation legislation.

• Notified Bodies must be accredited by the National Accreditation Body in the Member State (MS) in which they are established.

• Following accreditation they are notified to the EU and are listed on the EU NANDO website.

• The may provide conformity assessment to a manufacturer based in any MS or in third countries.

• After Brexit all UK Notified Bodies will cease to be recognised as EU NBs and will be removed from the NANDO website.
## NANDO = New Approach Notified and Designated Organisations

### 2018 Notified Bodies
- EU: 1508
- UK: 174
- Construction: 78
- Medical Devices: 4
- Ireland: 8
- Construction: 2
- Medical Devices: 1

### 2019 Notified Bodies
- EU: 1508
- UK: (-2) 172
- Construction: (-19) 59
- Medical Devices: (-2) 2
- Ireland: (+3) 11
- Construction: (+3) 5
- Medical Devices: 1
**EU Notified Bodies based in Ireland**

<table>
<thead>
<tr>
<th>2018</th>
<th>New in 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAI</td>
<td>Irish Engineering Services</td>
</tr>
<tr>
<td>NSAI Legal Metrology Service</td>
<td>(Vertigo Inspections)</td>
</tr>
<tr>
<td>Industrial Pressure Testing</td>
<td>OMNI</td>
</tr>
<tr>
<td>Compliance Engineering</td>
<td>BRE</td>
</tr>
<tr>
<td>FM Approvals</td>
<td></td>
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<tr>
<td>Hpi Verification Systems (Ireland)</td>
<td></td>
</tr>
<tr>
<td>Satra Technology Europe</td>
<td></td>
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<tr>
<td>Safenet</td>
<td></td>
</tr>
<tr>
<td><strong>Total = 8</strong></td>
<td><strong>Total 3</strong></td>
</tr>
</tbody>
</table>

Additional Irish Notified Bodies are currently being accredited or formally notified for Machinery, Personal Protective Equipment, Construction Products, Transportable Pressure Equipment, Pressure Equipment, Radio Equipment, Electromagnetic Capability and Marine Equipment.
CE marking in the EU

Post-Brexit
Economic Operators

EU legislation defines **economic operators**: 

- Manufacturer
- Importer
- Authorised representative
- Distributor
Broad changes for Economic Operators

- **4 Economic Operators:** Distributor, Importer, Manufacturer & Authorised Representative – See the **EU Blue Guide** for more info

- Distributors become **Importers post-Brexit**, for UK products sold to EU

- Authorised reps **mandatory** for **Marine Medical, Pressure & Cosmetic** products

- UK reps recognition ceases post-Brexit, requires an **EU-based rep** instead

- Irish **exports require UK rep** post-Brexit
Impact of Brexit on ‘CE’ marking

• If you currently ‘CE’ mark your product under existing EU rules, you will be required to continue to do so post Brexit

• Post-Brexit, UK Notified Bodies will lose their status as EU Notified Bodies

• If you or one of your product suppliers rely on a UK Notified Body for certification of conformity for ‘CE’ marking purposes, you will need to obtain alternatives

• While ‘CE’ marking for products may no longer be a legal requirement in the UK post Brexit, the UK market will still require evidence of conformity of products
Impact of Brexit on Management Systems Certifications

It is expected that Certification to any of the International Standards Organisations Management Systems Standards below will not be directly impacted by Brexit.

- ISO 9001  Quality
- ISO 14001  Environmental Management System
- ISO 45001  Occupational Health and Safety
- ISO 13485  Medical Devices
- ISO 22000  Food Safety
- ISO 50001  Energy Management
What can I do to minimise disruption?

1. If you import goods from the UK you will:
   a. be required to hold additional information on your products
   b. take on additional responsibilities as an importer

2. If you have businesses based in both the UK and EU-27 consider how to reorganise business processes to minimise disruption

3. If you currently use a UK based Notified Body you will have to move to another EU Notified Body based in the EU-27.

4. Check the EU ‘NANDO’ website and find a NB based in an EU-27 MS

5. Contact the new NB and find out what you need to do to transfer product certification
ISPM 15 Example

• All products either imported from a 3rd country or exported to a 3rd country (UK Post-Brexit,) which are being shipped on a pallet must comply to the following:

  • Any Wood Packaging Materials (WPM) used has been debarked, heat-treated to 51°C / fumigated

• Pallet Stamped in accordance with ISPM 15 standards.
Experience with Turkey

- To imagine a worst case scenario, we could look at Turkey
- Turkey is not in the EU, but is in the customs union.
- Over the past number of years, huge delays have been reported at the main EU/Turkish border post in Bulgaria
- Along with customs documentation it is imperative to have the correct declaration of conformity (DOC) in place
- Experience from one company’s challenges
  - “...... We have until Monday to present an updated CE Declaration of Conformity to the Turkish customs authorities. ”
  - “...... We have a shipment that has been sitting at a Turkish customs authorities warehouse for three months pending the verification.”
  - “...... We are paying warehouse fees”
Incorrectly packed crate at the Bulgarian-Turkish border, which is cited as being the busiest road border in Europe.
What can I do to minimise disruption

• If you import goods from the UK you will:
  • be required to hold additional information on your products
  • take on additional responsibilities as an importer
  • **engage with your suppliers**
• If you have businesses based in both the UK and EU-27 consider how to reorganise business processes to minimise disruption
• If you currently use a UK based Notified Body you will have to move to another Notified Body based in the EU-27.
  • Check the EU ‘NANDO’ website and find a NB based in an EU-27 MS
  • Contact the new NB and find out what you need to do to transfer product certification
NSAI Brexit Unit’s Dedicated Website and Email Address

- **Website:** [https://www.nsai.ie/brexit](https://www.nsai.ie/brexit)
- **Email:** brexitunit@nsai.ie
- **NANDO:** [https://ec.europa.eu/growth/tools-databases/nando](https://ec.europa.eu/growth/tools-databases/nando)
Thank you.

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