Agenda

08:00-08:30: Registration
08:30-08:40: Introduction and Overview
08:40-09:00: Products, Construction and Green Procurement
    Fergal O'Byrne, NSAI
09:00-09:20: Personal Protective Equipment
    Simon Courtney, SATRA
09:20-09:40: Medical Devices
    Colm O'Rourke, NSAI
09:40-10:00: Electromagnetic Compatibility and Radio Equipment
    John McAuley, Compliance Engineering
10:00-10:20: Food Industry
    Anne-Marie Crowley, NSAI
10:20-10:50: Question and Answer Session
10:50-11:00: Wrap up
Getting Ireland Ready for Brexit

- International Standards – ISO
- Certification
- ‘CE’ Mark
- Other marks
- Importers
- Exporters
Current Irish Notified Bodies

• NSAI
• Compliance Engineering Ireland
• SATRA Technology Europe
• Industrial Pressure Testing Ltd.

• Additional Irish Notified Bodies are currently being accredited for Machinery, Personal Protective Equipment, Construction Products, Transportable Pressure Equipment, Pressure Equipment, Radio Equipment, Electromagnetic Capability and Marine Equipment.
‘CE marking’ within the EU
Economic Operators’ Duties
- **European Single Market**
  - Single Market
  - Labour
  - Capital
  - Goods and Services
  - Customs Union
European Single Market

- Single Market
- Labour
- Capital
- Goods and Services
- Customs Union
Purpose of the European Single Market

European standards used to level the playing field

Free trade
Third party certification
Fair trade
Impact of Brexit on Standards

• International Standards – ISO
  • Example: I.S. EN ISO 9001:2015 Quality

• European Standards - ENs
  • Examples: I.S. EN 3 Fire Extinguishers, EN 14081-1 Structural Timber
Impact of Brexit on Motor Vehicles

• EU type approval- draft regulations
• UK’s automotive industry operates complex supply chains
  - highly integrated with EU MS manufacturers inc. Ireland
• Role of manufacturers' representatives post Brexit
• Supply chain implications
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 British 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, it is likely that the UK market will still require evidence of conformity of products
Impact of Brexit on importers

• If the UK is designated a “third country”, importers of UK products may be required to fulfil the legal role of “authorised representatives”

• If you’re importing products via the UK, the UK supplier can no longer act as an “authorised representative” and you will need to put into place an alternative arrangement

• The ‘Blue Guide’ on the implementation of EU products rules 2016 provides further information on the implementation of the "New Legislative Framework" for the marketing of products
Impact of Brexit on exporters

• If you or one of your product suppliers rely on a British Notified Body for certification of conformity, you will need to obtain alternatives before you can export to any EU Member State.

• For further information, please consult The ‘Blue Guide’ on the implementation of EU products rules 2016

• Post-Brexit, you may be required to provide evidence of conformity to UK national standards for products exported to the UK market
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 90010 Quality
- ISO 14001 Environment
- ISO 45001 Occupational Health and Safety
- ISO 23485 Medical Devices
- ISO 22000 Food Safety
Industrial Pressure Testing Limited of Cork was established in 1986

Ireland’s only accredited inspection body operating a quality system for the inspection and testing of a wide range of pressure receptacles including gas cartridges, their valves and other accessories

Currently certifies for EU Directive 2010/35/EU Transportable pressure equipment

Further information available- www.indpt.ie
Thank you

WWW.NSAI.IE
SATRA’s Brexit Solution
Brexit

• UK voted for withdrawal from EU following referendum on 23 June 2016
• UK government evoked Art. 50 of EU treaty on 29 March 2017 to initiate withdrawal
• 29 March 2019 end negotiation period between UK and EU
• Latest news is that EU and UK have agreed a deal
• UK MPs to vote on deal
• EU MPs will then vote on deal
Current PPE industry situation

- EU published PPE regulation (EU) 2016/425 on 31 March 2016
- Replaced PPE directive 89/686/EEC on 21 April 2018
- 21 April 2019 ends the transition period
- European Notified Bodies accredited against PPE Regulation
- PPE suppliers currently recertifying products
Potential outcomes of Brexit

- A Hard-Brexit or a No-deal-Brexit
- UK Notified Bodies with lose status and notified body number
- Worst-case-scenario existing UK Notified Body certificates become invalid
- Misunderstanding by border agencies
SATRA’s Brexit solution

- SATRA opened SATRA Technology Europe Ltd in Bracetown, Dublin
- Manager Geoff Graham
- Certification scope all PPE including; footwear, gloves, fall arrest products, acoustic etc.
- On 21st May 2018 appointed by the government of the Republic of Ireland as a Notified Body for Personal Protective Equipment (PPE) Regulation (EU) 2016/425
- Issued Notified Body Number 2777
- Holders of existing certificates can now choose to transfer them to the Irish Notified Body
- New applications are processed through SATRA Technology Europe Limited.
SATRA’s PPE Testing Services

• UK’s decision to withdraw from the EU will not affect the validity of existing or future test reports issued from SATRA in the UK
• Test reports will be accepted for certification purposes by SATRA Technology Europe Limited and other PPE Notified Bodies
• Accredited to ISO/IEC 17025:2017 – ‘General requirements for the competence of testing and calibration laboratories’
• SATRA’s continued involvement with CEN standardization committee
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Product Certification Manager
SATRA Technology Europe Limited
(Notified body number 2777)
Geoff.Graham@satra.com
Brexit and Medical Devices
NSAI Brexit Information Briefing

Colm O’Rourke
Business Development, Medical Devices
Areas Covered

• Device certification
• Authorised Representatives
• Import/Distribution
• Rules of Origin
Device Certification

• European system is based on the CE Mark
• Conformity assessment carried out by Notified Bodies – designated by a Member State Competent Authority
• Currently there are 4 UK based Notified Bodies
• Many have made public their process of establishing a “new” NB in a Member State
Device Certification

• In a no-deal scenario, product certificates issued by UK-based NBs will no longer be valid
• MHRA stated UK will recognise the CE Mark for “time-limited period” post-Brexit
• The UK is planning to comply with MDR & IVDR
Authorised Representatives (ARs)

• ARs are required for all legal manufacturers who are not located in a Member State
• Irish based manufacturers do not require an AR – however, they may require a UK-based AR to sell into UK post-Brexit
• UK manufacturers will likely need EU based AR
• Non-EU based manufacturers currently using UK-based AR will need to engage an EU-based AR
Import/Distribution

• Irish entities who bring in devices from UK will assume the role of importer post-Brexit – more information cited in Article 13 of the MDR 2017/745

• If you previously acted as a distributor for a UK-based manufacturer you may now also become the importer of that product
Rules of Origin

- If exporting to a third country where a FTA is in place – preferential tariff rate may be applicable on products which have enough “EU content”
- Post-Brexit – content from UK sources can not be counted as “EU content”
- Potential supply-chain effects in order to source other “EU content”
Thank you.

WWW.NSAI.IE

colm.orourke@nsai.ie

Search "NSAI"
Compliance Engineering

Notified Body
EMC
Radio Equipment Directive

John McAuley
Notified Bodies

Majority of non medical electrical/electronic goods do not need a Notified Body TEC so those UK manufacturers should experience minimum impact of Brexit (from a regulatory point of view)

UK Notified Bodies to be withdrawn

Number of UK NBs applying to INAB

HPiVS - UK Notified Body for PED and RCD now based at Compliance Engineering Ireland
Brexit - Irish Manufacturers

Europe – Business as usual

Exports to UK – business as usual, for the meantime

Future UK national mark similar to CE mark?
EU Declaration of Conformity

Product model / product:

Product Radio Product
Model/type Super 77
Serial nos. 00120 - 01000

This declaration is issued under the sole responsibility of the manufacturer.

Object of the declaration:

Product Short Range Radio

The object of the declaration described above is conformity with the relevant Union harmonisation legislation:

2014/30/EU The Electromagnetic Compatibility Directive
2011/65/EU The Restriction of Hazardous Substances Directive

References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

EN 300 220-2 V3.1.1 2017 Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz
EN 301 489-1 V2.2.0 2017 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

Signed for and on behalf of:
Experience with Turkey

Turkey is in a customs union with the EU. 
Huge delays at Turkish border over the last few years
Experience from one of our client companies

“…… 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”
The customs union means free movement of our goods. It doesn’t mean free movement of our trucks

Erman Ereke (Financial Times)
Thank you for your attention

John McAuley

Dunshaughlin, Co Meath
Tel: 01 8017000
www.cei-compliance.com
Food Industry and Brexit

Anne Marie Crowley
SSO Food/Agriculture Sector
Brexit Proposal Article 185

Contains 30 Pages of Text
Refers to 50+ EU Regs/Directives for food/agri
Primary Regulations

• All food businesses
  EU Reg 178/2002 Traceability
  EU Reg 852/2004 General Hygiene
  EU Reg 853/2004 Animal origin
  EU Reg 1169/2011 FIC
Supply chain

• Assured via EU plant numbers
• Product labelling/information
• Traceability best before/use by
• Product testing – accredited labs
Certification

• ISO 22000 / FSSC
  suitable for all types
  international recognition
  first published 2005 new 2018
  sector specific documents e.g. Transport and storage in 2019
Thank you.
Looking for further information?

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Q&As