Sustainable anaesthetic practice: joint stakeholder meeting – Regulations v “The Market”
21 Portland Place – 16th November 2016

Paul Sim – Barema Council & Barema/AAGBI Environmental WG
BSI – Standards & Publishing Medical Devices Knowledge Manager
Medical Device Regulations v “The Market”

Agenda - topics include

- Introduction
- Regulations impacting on medical device manufacturers relating to Environment
- Impact of these regulations on the design, manufacture & distribution including some factors to be considered for sustainability and environmental
- The Market, global access
- For the future, what next
- **Question:** What role does the user have?
Introduction

Barema & AAGBI Environmental Working Group

• Barema founded 1971, UK Medical Device companies – anaesthesia & respiratory
  • East, M&I E, Penlon, Blease, Gardner, & BOC Medical/Medishield
• Currently a membership of 50+
• Independent, not for profit, relationships with MHRA, ABHI, EUROM VI, BI VDA, etc
• VISION: providing patients with the best possible anaesthetic and respiratory equipment
• Relationship with AAGBI
  • Association Officers & Barema Council
  • AAGBI Safety Committee
  • Environmental WG
  • Standards
“Our healthcare system is unsustainable.” When politicians say this, they’re usually speaking in terms of cost. But it’s just as true in terms of medical device design.

Seth GaleWrick May 2014 (Bresslergroup)

Design for environment
Most of our environmental footprint occurs in our supply chain and when customers use of products and solutions. Together, these phases account for 94% of HP’s carbon footprint and 93% of our water footprint. Product use impacts come mostly from energy consumption, associated water use, and paper manufacturing. Reducing these impacts though how we design our products is the single greatest lever we can use to improve our overall environmental performance.

Environmentally, where are you? & what does it mean for you?, and your work?
Environmental Management Systems - Requirements with guidance for use - ISO 14001:2015

- **Definition:**
- **3.2.1 - environment**
  - surroundings in which an organization (3.1.4) operates, including air, water, land, natural resources, flora, fauna, humans and their interrelationships
  - Note 1 to entry: Surroundings can extend from within an organization to the local, regional and global system.
  - Note 2 to entry: Surroundings can be described in terms of biodiversity, ecosystems, climate or other characteristics.

- **3.1.4 - organisation**
  - person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.2.5)
  - Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.
LIFE CYCLE PERSPECTIVE – ISO 14001:2015

6.1.2 Determine the environmental aspects of its activities, products and services considering a life cycle perspective

8.1 Consistent with a life cycle perspective, the organisation shall:

   a) establish controls, as appropriate, to ensure that its environmental requirement(s) is (are) addressed in the design and development process for the product or service, considering each life cycle stage
   b) determine its environmental requirement(s) for the procurement of products and services, as appropriate
   c) communicate its relevant environmental requirement(s) to external providers, including contractors
   d) consider the need to provide information about potential significant environmental impacts associated with the transportation or delivery, use, end-of-life treatment and final disposal of its products and services
We all have an alternative opinion/starting point

- Some more questions:
  - Is it an issue/should we be concerned?
  - What motivates you?
  - What are we missing?
  - What frustrates you with this subject?
  - What could we action as a Profession & Industry?
Some example medical devices

- Material selection: titanium
- Overall packaging
- Manufacturing process
1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they........

2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In........

3. The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that ....

4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, others ............

5. The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage.

6. Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

7. 6a Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.

NOTE: this is not an exhaustive list, and to an extent it is dependent upon the device type as to the applicability of the additional regulations.
9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:
— the risk of injury, in connection…… and where appropriate ergonomic features,
— risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
— the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
— risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

9.3 Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

This ER is very specific and describes the operational environment

Global Regulations

Country/Region Specific

California Proposition 65

others
Part of the Product life cycle

**Design & Material Selection**
- Functional performance
- Toxicology
- Biocompatibility
- Single Use
- If sterile, method of sterilisation
- Anaesthetic gas compatibility
- Physical strength
- Cost
- User, healthcare professional or patients
- CAD design for minimal parts/assembly
- Non phthalate grade of PVC
- Hazardous substances
- Mould graphics to avoid label
- Transparency/colour

**Packaging & Transport**
- Optimise packaging, nos/box
- Locally sourced material
- Ship parts & assemble locally

**Manufacture and Assembly**
- Use of modern electric moulding machines, hot runners eliminate need for “sprues”
- Tooling cavitation and tools with changeable inserts
- Design for auto assembly
- Some material bulk delivered
- Material from stock or special material

**Use & Disposal**
- Minimal gas leakage
- Recycling
- Emissions form burning plastics
- Re-use
- Re-processing single use devices
- Re-manufacture

**Business Strategy/ Opportunity Costs Market access**

**Medical Device**

as a result of risk management the medical benefit outweighs the associated adverse environmental aspects.
Barema Member Company, images for illustration purposes only.

ISO 15223 - 1 Symbols

ISO 15986 Specific labelling requirements for medical devices containing phthalates

Cirrus™2 nebuliser, mouthpiece kit and tubing 2.1m (single patient use)

REF 1455000

Er 13 - Information supplied by the manufacturer

The Association of Anaesthetists of Great Britain & Ireland,

Distribution in the USA by: Intersurgical Incorporated, 6757 Kinne Street, East Syracuse, NY 13067

T: (800) 826 9633, support@intersurgicalinc.com

Intersurgical Ltd, Crono House, Moly Millen Lane, Wokingham, Berkshire, RG41 2RZ, UK

T: +44 (0)118 988 3000 F: +44 (0)118 988 3580 info@intersurgical.com www.intersurgical.com

1455000-3-A 7153 issue 9 IP 12.15
Council of the European Union

Brussels, 8 August 2015
(OE HR)

10217/11/6
REV 1

NOTE

From: General Secretariat of the Council
Delegations

To:

No. prev. doc.: 09452/12 PHARM 30 SAN 211 MI 370 COMPET 318 CODEC 572
No. Conc. doc.: 14434/12 PHARM 71 SAN 215 MI 897 COMPET 800 CODEC 2305 +
COP 1

Subject: Proposal for a Regulation of the European Parliament and of the Council

Delegations will find the consolidated text of the draft Regulations on medical services in the Annex
to this Text. This is a "clean" version without any difference between "new text" and text from the
Commission proposal.

bsi.
In 2014, our single-use medical device reprocessing programs helped our customers save $258 million and divert 10.5 million lbs. of waste from landfills.
ER 9 – Construction and environmental properties

9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.

9.2 Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:

— the risk of injury, in connection with……. and where appropriate ergonomic features,
— risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
— the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
— risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.

9.3 Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

Global Regulations

Country/Region Specific

This ER is very specific and describes the operational environment others

California Proposition 65

Team Consulting Insight 2016/02

“Sustainability” is a buzzword in almost every industry sector – but what about medical device design? What does it really mean in such a specialised and highly regulated context?

Q1. Easy to say but hard to define. What does sustainability mean for medical device design?

Q2. Is it the case, therefore, that sustainability is an issue that is not well understood in the medical devices sector?

Q3. Disposability – an obvious sustainability challenge – is clearly an important issue for the sector. What is the current state of play?

Q4. Looking further ahead, if sustainability drivers are currently weak, what will deliver the critical impetus for change?

But all this is meaningless without the force of regulation. Sustainability is simply enlightened self-interest without legislation, or else considered a constraint making the pursuit of sustainability harder to justify in a highly competitive market

…… design principles such as “zero defects” and streamlined manufacture, strategies which meet sustainability goals of minimal waste energy and so on. Perhaps a greater focus on these strategies as contributors to sustainability could help……..
“The Market”

Global Medical Devices

- **Heavily regulated** in major global markets and growing in emerging markets
- Why? to ensure “**safety and efficacy**” when used in **clinical practise**
- Manufactures produce for global markets – for economy of scale
- “**Environmental**” & “**sustainability topics**” **not mandated** with exceptions
- **Commercial impact**
  - Potential additional costs
  - Market very price sensitive dependent upon device type
- **Motivation for manufacturer** – what is the incentive?
- **Motivation of the Users** – Clinicians, other healthcare professionals, patients
- **Patients** becoming more aware, and express their views about “green” issues
- Where is the NHS? and what might be next?

bsi.
WARNING. THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 15 JANUARY 2017.

BS 8001:201X

Framework for implementing the principles of the circular economy in organizations – Guide

NOTE FOR COMMENTERS

We draw your attention to the fact that BS 8001 is a guide. As a guide, this British Standard takes the form of guidance and recommendations. It is not a specification of a code of practice and it is not intended that claims of compliance are to be made to it.

Please note that this is a draft and not a typeset document. Persons commenting on this draft are advised not to comment on matters of typography and layout.

We would ask that comments, where possible, are accompanied by suggested changes.

We invite comments on all aspects of the standard but have also placed specific questions within the draft that we would particularly welcome feedback on. These are in the
Conclusions

• Summary, and may be more questions?

• Environmental
• Product Development Life cycle – potential impact of MDR
• Sustainability
• Where are you and your organisations
• Is there partnership with Industry, and how could this be optimised
• What next
  – Smart City’s
  – Smart Healthcare
• A question to reflect – where is the patient in this debate, do they have a role? & responsibility, and, is a responsibility owed to them?
Thank you for your time and attention

Questions?
Contact details

Paul Sim – Barema/AAGBI Environmental Working Group
BSI - Knowledge Solutions
Medical Devices Knowledge Manager
Paul.sim@bsigroup.com
Mobile: +44 7786 701022