European Regulatory Update:

*CE Marking (Proposed EU Regulations)*

*13485:20XX*

*Own Brand Labeling*

Paul Brooks
Senior Vice President
BSI Healthcare Solutions
Disclaimer

• The new regulations are not finalized and subject to change

European Commission Proposal September 2012

- After public consultation
- Build on strengths
  - Balance between pre- and post-market control
  - Flexible – Supportive of innovation
  - High safety levels
  - Raid access to market – Cost-effective and SME friendly
- ...but adapt and improve
European Commission Expectation

- Towards increased patient safety:
  - Scope of legislation
  - Governance of system and transparency
  - Criteria for designation, monitoring and obligations of notified bodies
  - Risk classification of devices and the safety and performance requirements
  - Obligations of economic operators, including reprocessing of single use devices
  - Clinical evaluation, traceability and reprocessing of single-use devices
European Commission – Response to PIP

• Lesson learned from PIP scandal
• Amendments from ‘stress test’
  • Reinforced control of high-risk devices through a scrutiny mechanism
  • Obligation for manufacturers to provide an implant card
  • Qualified person responsible for regulatory compliance
  • Notified bodies to conduct unannounced visits, carry-out physical or laboratory tests and rotate auditors
• Member States to encourage incident reporting by healthcare professionals and patients
Three Directives become Two Regulations

- Direct entry into force
  - Three year transition period for MDD/AIMD
  - Three or five year transition period for IVD*
- Regulation should result in more consistent application

*Parliament proposed three year transition for IVDR / industry lobbying for five year
Changes to the System
Already Implemented
Triggers for Short Term Changes to the System

- Discovery of a 16 year fraud in PIP breast implants using low quality “industrial grade” silicon oil
- Stress test performed by EU Commission
- Determined that changes were needed to improve early detection and prevent this type of incident
- Other high profile vigilance cases with hips, pelvic floor meshes, pacemaker leads, etc.
- Outcome: short term changes to the system
  - **Immediate Actions**
  - **Commission Regulation: How Competent Authorities control Notified Bodies**
  - **Commission Recommendation: How Notified Bodies audit Manufacturers**
## Impact of Immediate Actions

<table>
<thead>
<tr>
<th>Action</th>
<th>Impact</th>
</tr>
</thead>
</table>
| Re-assessment of qualifications and scope of activities of NBs         | • NBs submitted to CAs the CVs of all technical experts for high risk devices  
• Reduced scope for some NBs?                                         |
| "Voluntary" Joint Audits of NBs by Designating Authority, Commission (FVO) plus two other CAs | • NBs and Designating Authorities under increasing scrutiny  
• Put the spotlight on the differing approaches within the Member States  
• Some Pain and Some Gain                                                |
| Monthly Vigilance Teleconferences                                      | • Increasing number of COEN requests  
• More open COEN requests requiring detailed follow up }
24 September 2013


Directs Competent Authorities how to control Notified Bodies

COMMISSION RECOMMENDATION (2013/473/EU) of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices

Directs Notified Bodies how to audit Manufacturers

Effective from Jan 2014
**Impact of Commission Implementing Regulation 920/2013 on the designation and the supervision of notified bodies: Criteria to be met for the designation of NB**

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint Audits of NBs by Designating Authority, Commission (FVO) plus two other CAs</td>
<td>• NBs and Designating Authorities under scrutiny&lt;br&gt;• Highlights different approaches in Member States&lt;br&gt;• More scrutiny of competency requirements, in-house clinicians, qualifications&lt;br&gt;• Processes and procedures clarified&lt;br&gt;• NBs withdrawing – check NANDO, ask your CA</td>
</tr>
<tr>
<td>NB Designation valid for a maximum of five years</td>
<td>• No impact yet; will need CA resource&lt;br&gt;• Consistent with CE certification cycle</td>
</tr>
<tr>
<td>Extensions and Renewals follow the same procedure as Designations</td>
<td>• Helps consistency; will need CA resource</td>
</tr>
<tr>
<td>NBs subject to renewal by 14 October 2016</td>
<td>• Helps consistency; requires CA resource</td>
</tr>
<tr>
<td>Designating Authorities shall have sufficient number of competent personnel</td>
<td>• Have they the qualified resource to deliver?</td>
</tr>
</tbody>
</table>
Impact of Com. Recommendation (2013/473/EU) on audits and assessments performed by NBs – Items to be verified by NB during an audit

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annex I: Criteria for NBs performing design dossier and type examinations</td>
<td>• Mainly reinforcement of current good practice</td>
</tr>
<tr>
<td></td>
<td>• Increased need for clinical studies, less reliance on equivalence argument</td>
</tr>
<tr>
<td></td>
<td>• Will clarify time needed for reviews</td>
</tr>
<tr>
<td>Annex II: Criteria for NBs performing QMS assessments</td>
<td>• Mainly reinforcement of current good practice</td>
</tr>
<tr>
<td>Annex III: Unannounced visits to manufacturers, &quot;critical subcontractors&quot; or</td>
<td>• Completely new requirement needing extra product and QMS assessors</td>
</tr>
<tr>
<td>“crucial suppliers”, in addition to planned audits</td>
<td>• Significant increase in NB workload and resources</td>
</tr>
<tr>
<td></td>
<td>• IAF rules require planned audit schedules so no scope for substitution</td>
</tr>
<tr>
<td></td>
<td>• Gone well in general</td>
</tr>
<tr>
<td></td>
<td>• Some SMEs feeling burden is disproportionate</td>
</tr>
</tbody>
</table>

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The proposed Medical Device Regulation: Key Issues
The Timeline
MDR Proposals – Key Issues 1

**Notified Bodies**
- Strengthened Designation Criteria
- Joint Audits: Three Member States and Commission (FVO)
- Unannounced Inspections

**Clinical Evidence**
- Less Equivalence, More Data for High Risk Devices
- Publish Safety and Performance Data
- Post Market Clinical Follow-up

**Pre-market**
- Scrutiny for High Risk Devices
- Common Technical Specifications
- Qualified Person for Manufacturers and Authorised Representatives
MDR Proposals – Key Issues 2

Post-Market Surveillance and Vigilance
- Central Database and Co-ordination
- Trend Reporting
- Enforcement Activities

Transparency and Traceability
- Devices and Economic Operators Registered Centrally
- Unique Device Identification (UDI)
- Implant Cards

Governance and Oversight
- Central Committees: Scientific Advice, Harmonised Implementation
- Expert Panels
- JRC, Reference Laboratories
MDR Proposal: Other Issues and Member State Divergence

• Other Issues
  • Invasive devices without a medical purpose
  • Classification rules – implants, surgical instruments

• Member State Divergence
  • Reprocessing or recycling of single-use devices
  • Ingested and absorbed devices
  • The scrutiny mechanism
  • The coordination group
  • The role of the experts panel
  • Reference laboratories

Great political will to find solutions

The Political Timetable: Optimistic?

- Greek Presidency
- Italian Presidency
- Latvian Presidency
- Luxembourg Presidency
- Dutch Presidency

Jan 2014
- Parliament elections

July 2014
- Rapporteurs appointed

Jan 2015
- New Commissioners in place

July 2015
- Begin trilogues?

Jan 2016
- Entry into force?
- Council reaches general approach?
- Conclude trilogues?
The Political Timetable: Realistic?

Greek Presidency

Jan 2014

Parliament elections

July 2014

Rapporteurs appointed

Jan 2015

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Jan 2016

Entry into force?

Council reaches general approach?

Latvian Presidency

Jan 2015

Luxembourg Presidency

July 2015

Conclude trilogues?

Dutch Presidency
The Political Timetable: Best Guess

Greek Presidency

Jan 2014 → Parliament elections
July 2014

Italian Presidency

Jan 2014 → Rapporteurs appointed
July 2014

Latvian Presidency

Jan 2015 → New Commissioners in place

Luxembourg Presidency

July 2015 → Council reaches general approach?

Dutch Presidency

Jan 2016 → Begin trilogues?

Entry into force?

Conclude trilogues?
Don’t Lose the Legacy Benefits of MDD 93/42/EEC and 2007/47/EC

EU CE Approach

• Evidence suggests EU regime has protected patients equally as well as the most robust Central government Schemes
• Third party provision of manufacturing audit ensure effective coverage of global manufacturers
• Patients access new technology in Europe on average far earlier than other developed markets bringing real health benefits. e.g. minimally invasive surgical products leading to reduced recovery time, reduced hospital stay, return to work economic benefits.  http://goo.gl/UMJ2NJ
• Enables EU Industry to Develop and Market New Technology Faster

Governmental Central Approaches

• No evidence to suggest more effective
• Government agencies struggle to resource to meet demand leading to poor coverage and infrequent audit.  Examples FDA audit coverage outside US is very low. Backlog Anvisa Brazil and MHLW Japan.
• Patients in the US on average waited three years to access equivalent technology (between 2000 and 2011).  For devices approved via PMA circa 43 months delay.
• USA, Japan and Canada moving towards more third party provision
• Other countries would love this advantage
The new ISO 13485 and ISO 9001 – Where are we?
2 – ISO 9001:2015 Update
3 – Future - ISO 13485:201X
4 – Key additions for ISO 13485:201X
5 – Potential Timings
EN ISO 13485:2012

• European harmonised standard for Medical Device Quality Management Systems
• Allows the presumption of conformity to Medical Directives - MDD, AIMD and IVD
• Published February 2012 and harmonised as of 30 August 2012

EN ISO 13485:2012 only applies to manufacturers placing devices on the market in Europe
What is the difference?

**ISO 13485:2003**
- The current International Standard

**EN ISO 13485:2003**
- The previous version of the European Harmonised Standard
- Obsolete as of 30 August 2012

**EN ISO 13485:2012**
- Changes within Foreword & Annex Zs only
- **No change** to requirements (Normative Text)
- Annex Z’s to provide greater clarity on applicability & alignment with AIMDD, MDD & IVDD
### Relationship between Annex II of 93/42/EEC and clauses of ISO 13485

<table>
<thead>
<tr>
<th>Paragraph of Directive 93/42/EEC, Annex II</th>
<th>Clause(s) of EN ISO 13485</th>
<th>Comments-Qualifying remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 first sentence</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>1st indent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 second sentence 2nd indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 3rd indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.1 second sentence 4th indent</td>
<td>4.1, 4.2</td>
<td>Partial coverage: The documentation required in 4.2 of the standard does not cover entirely the quality system documentation detailed in 3.2 of Annex II unless the explicit legal requirements are incorporated into the quality system documentation. See also coverage of 3.2 below.</td>
</tr>
<tr>
<td>3.1 second sentence 5th indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 6th indent</td>
<td>4.1, 5.1, 5.4, 5.5, 5.6</td>
<td>Covered</td>
</tr>
<tr>
<td>3.1 second sentence 7th indent</td>
<td></td>
<td>Not covered</td>
</tr>
<tr>
<td>3.2 first paragraph first sentence</td>
<td></td>
<td>Not covered. The application of EN ISO 13485 does not by itself assure the fulfilment of all regulatory requirements of Directive 93/42/EEC. The legal requirements must be examined,</td>
</tr>
</tbody>
</table>
ISO 9001:2015
New ISO Management Systems High Level Structure

• New and revised ISO MS Standards now using ISO Annex SL

• A standard for standard writers

• Provides a 10 clause high-level structure and common text

• Standardises terminology for fundamental Management System requirements

• Follows the Plan → Do → Check → Act (PDCA) principle
ISO 9001: 2015 – Key Envisaged Changes

• Clause 4 – **Context of the organization** - NEW
• Clause 5 – **Leadership** – ENHANCED
• Clause 6 – **Risks & opportunities** – SIGNIFICANT **Change Management** – ENHANCED
• Clause 7 – **Resource management** – ENHANCED, **Knowledge management** – NEW
• Clause 8 – **Contingency planning** – NEW **Outsourcing** – ENHANCED **Design & development** – SIMPLIFIED **Post delivery activities** – ENHANCED
• Clause 9 – **Performance indicators** – NEW
• Clause 10 – **Continual improvement** – MORE STRUCTURED

• Numbering system changed as noted above
• Risk Management verses Preventive Action
• Greater flexibility with multiple management systems –
  • Eg 14000, 18000, 27000, etc
QMS Structure

4 Context of organization
- Understanding of the organization and its context
- Expectations of interested parties
- Scope of management system
- QMS

5 Leadership
- Leadership and commitment
- Quality policy
- Roles, responsibilities and authorities

6 Planning
- Actions to address risk and opportunity
- Quality objectives
- Planning of changes

7 Support
- Resources
- Competence
- Awareness
- Communication
- Documented information

8 Operation
- Operations of planning and control
- Determination of requirements for products and services
- Design and development of products and services
- Control of external provided products and services
- Production and service provision
- Release of products and services
- Control of nonconforming process outputs, products and services

9 Performance and Evaluation
- Monitoring, measurement, analysis and evaluation
- Internal audit
- Management review

10 Improvement
- Nonconformity and corrective action
- Continual improvement

PLAN → DO → CHECK → ACT

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Current ISO 9001:2015 Timeline

- **2013**
  - May 2013 CD
    (Committee Draft)

- **2014**
  - May 2014 DIS
    (Draft International Standard)

- **2015**
  - February 2015 FDIS
    (Final Draft International Standard)
  - September 2015
    Published International Standard
ISO 9001:2015 -

- 3 year transition period – if published September 2015, transition will end September 2018
  - Relevant interested parties:
    - Organisations certified and/or using ISO 9001:2008
    - Accreditation bodies (AB’s)
    - Certification bodies (CB’s)
    - Training bodies and consultants
- Questions include:
  - When will current certificates expire
  - For how long will CB’s continue to audit and grant certificates to the 2008 version
  - If we are certified to 2008 version when should start to align
  - If a medical device company with dual certification ie 13485 & 9001 what do we do?
The Future?

ISO 9001  ISO 13485
ISO 13485:201X

3rd Edition – Based on Draft International Standard (DIS2) of February 2015
ISO 13485:201X – What’s New?

- Many additions
- Some new requirements
- Some expansion and clarification
- Increased clarity of interrelationship between clauses and requirements

NOTE: 13485 Presentation comments based on DIS2, requirements may be subject to change
4 – Quality Management System

4.1 General Requirements
- + Document role(s) undertaken by organization under regulatory requirements
- + Risk based approach for developing QMS processes

4.1.3 - 5 General requirements
- Records to meet regulatory requirements
- + For outsourced processes control based on risk and ability

4.1.6 General Requirements
- + Requirement to validate the computer software used for QMS prior to initial use & after changes

4.2 Documentation Requirements
- Requirements similar - Detailed list of items (a-z) {in DIS} removed that can be included in a product or technical file to meet regulatory requirements
5 – Management Responsibility

<table>
<thead>
<tr>
<th>5</th>
<th>General requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Regulatory requirements (throughout)</td>
<td></td>
</tr>
<tr>
<td>+ Responsibilities &amp; authorities documented (5.5.1)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.4.2</th>
<th>QMS planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ NOTE Quality objectives consistent with quality policy, action items to accomplish objectives, monitoring progress, and revision</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.5.2</th>
<th>Management representative</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ NOTE on management rep to include liaison with external parties, including regulatory authorities</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.6</th>
<th>Management review</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Recorded rationale for frequency for management review</td>
<td></td>
</tr>
<tr>
<td>+ documented</td>
<td></td>
</tr>
</tbody>
</table>

| + Improvement needed for new or revised regulatory requirements |
6 – Resource Management

6.2.1 Human resources – General
+ Personnel at all levels across product, process, regulatory requirements and QMS

6.2.2 Competence, awareness & training
+ Maintain competency
+ NOTE effectiveness methodology link to risk of work for which training provided

6.3 Infrastructure
+ Product performance, documented procedures for production & work env, including intervals
+ Records

6.4 Work environment
+ Significant additional detail to clarify requirements
+ 6.4.2 Particular requirements for sterile medical devices
7 – Product Realization

7.1 Planning of product realization
- Risk management
- Records
- Required planning for verification, validation, revalidation, monitoring, measurement, inspection, test activities, handling, storage, & traceability

7.2 Customer-related processes
- Regulatory requirement
- User training
- Methods for protecting confidential health information

7.2.3.2 Communication with regulatory authorities
- New clause
- Document arrangements, product information, enquiries, complaints, advisory notices
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.3.2</td>
<td>Design &amp; development planning</td>
</tr>
<tr>
<td></td>
<td>+ Emphasis on planning, decision points, transfer activities, resources &amp; suitability</td>
</tr>
<tr>
<td>7.3.6 &amp; 7</td>
<td>Design &amp; development verification &amp; validation</td>
</tr>
<tr>
<td></td>
<td>+ Plan, method, criteria, sample size, &amp; device interfaces</td>
</tr>
<tr>
<td></td>
<td>+ Validation on production units or (documented) equivalents</td>
</tr>
<tr>
<td>7.3.8</td>
<td>Design &amp; development transfer</td>
</tr>
<tr>
<td></td>
<td>New Clause</td>
</tr>
<tr>
<td></td>
<td>+ Transfer plans for supplier, manufacturing, process, personnel, tools, environment, installation, etc</td>
</tr>
<tr>
<td>7.3.10</td>
<td>Design and development records</td>
</tr>
<tr>
<td></td>
<td>New Clause</td>
</tr>
<tr>
<td></td>
<td>+ Records shall be clearly identified and maintained in the design and development file...</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>7.4 Purchasing</td>
<td></td>
</tr>
<tr>
<td>7.4.1.1 Supplier approval</td>
<td></td>
</tr>
<tr>
<td>7.4.1.2 Monitoring of suppliers</td>
<td></td>
</tr>
<tr>
<td>7.4.1.3 Supplier documentation</td>
<td>+ Criteria for selection, evaluation / re-evaluation consistent with risk</td>
</tr>
<tr>
<td>7.4.2 Purchasing information</td>
<td>+ Purchasing information to include, where possible, suppliers agree to notify changes</td>
</tr>
<tr>
<td>7.4.3 Verification of purchased product</td>
<td>+ Extent of verification commensurate with risks and result of evaluation and re-evaluation</td>
</tr>
</tbody>
</table>
## 7 – Product Realization (continued)

<table>
<thead>
<tr>
<th>Section</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.5.2 Validation of processes for production &amp; service provision</td>
<td>+ Validate processes for production &amp; service provision where output cannot be or is not verified&lt;br&gt;+ Documented validation plans &amp; procedures, <strong>including procedures for validation of sterilization &amp; packaging processes</strong></td>
</tr>
<tr>
<td>7.5.3 Identification &amp; traceability</td>
<td>+ UDI where required by national or regional regulations&lt;br&gt;+ Requirement for procedures for separation of returned products</td>
</tr>
<tr>
<td>7.5.5 Preservation of product</td>
<td>+ Detailed requirements on device packaging &amp; shipping&lt;br&gt;+ Validation of packaging&lt;br&gt;+ Particular requirements for sterile devices</td>
</tr>
</tbody>
</table>
### 8 – Measurement, Analysis and Improvement

<table>
<thead>
<tr>
<th>Section</th>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.2</td>
<td>Monitoring and measurement</td>
<td>+ Feedback procedures, input to risk management, statistical evaluation using statistical tools for input to CAPA</td>
</tr>
<tr>
<td>8.2.4</td>
<td>Monitoring and measurement of product</td>
<td>+ Identify test equipment used to perform measurement (as well as person)</td>
</tr>
<tr>
<td>8.3</td>
<td>Control of nonconforming product</td>
<td>+ Determine need to investigate, escalation to CA</td>
</tr>
<tr>
<td>8.5.2 &amp; 8.5.3</td>
<td>Corrective &amp; Preventive action</td>
<td>+ 8.3.2 - 5 New clauses for nonconforming product after delivery and rework</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+ Link to CAPA, Risk Management &amp; Management Review</td>
</tr>
</tbody>
</table>
Potential Timings
EN ISO 13485:201X – Potential Timings

- **July 2014**: Draft International Standard (DIS) published vote – **Negative**.
- **September 2014**: ISOTC 210 WG1 Meeting – Reviewed DIS comments. Decision to issue 2nd DIS.
  - WG meeting held Dec 2014, all comments reviewed.
- **Dec 2014**: Consolidated comments, reviewed and prepared 2nd DIS.
- **January 2015**: Finalize 2nd DIS text, submit to CEN/CENELEC for translation, required for parallel vote ISO/CEN.
- **February 2015**: Issue 2nd DIS for 2 month vote & parallel vote under the Vienna Agreement.
  - May 2015 Consolidate comments in preparation for meeting.
- **June 2015**: Working Group meeting, to review comments. Review next steps dependent upon voting.
- **June 2015 – forward**: Next options include:
  - an FDIS,
  - proceed to publication depending on voting result.

**Predicted publication date is the End of 2015.**
ISO 13485:201X – summary

• ISO TC 210 WG1 - ISO TMB approval to use ISO 9001:2008 format, not 2015
  • Clause/Structure cross reference tables compiled for 9001:2008 & 2015 version
  • Proposal to develop a similar cross reference for 13485:201x with 9001:2015 expected

• Expected 3 year transition period, therefore full adoption late 2018

• Next steps
  • DIS voting closes 5th May 2015
  • ISOTC 210 WG1 meeting, June 2015 in Denver
  • For information the DIS passed the positive vote, but failed the negative vote, so was disapproved
    • Comments basically fell into 3 categories
      o i) adopt Annex SL format
      o ii) delete the NOTES from the normative section of the Standards, {alignment with proposed EU MDR, revised Annex Z's}
      o iii) Technical comments etc
  • Publication date anticipated late 4th Qtr
Bigger Global Picture

- ISO 9001 and ISO 13485 Revisions
- Medical Device Directive Updates
- IVD Directive Updates
- AIMD Directive Updates
- Japanese Requirement Updates (November 2014)
- MDSAP (US, Canada, Brazil, Australia with the EU and Japan watching carefully)
Own Brand Label Update
Basis for process

• Recommendation 2013/473/EU issued 24th September 2013

• Mandates on-site audits to Legal Manufacturers

• MHRA Bulletin 19 (OBL Guidance) now withdrawn

• Draft guidance circulated to UK Notified Bodies in April 2014 and to ABHI in May 2014. The website is NOT up to date yet.

Basis for process

- Recommendation 2013/473/EU issued 24th September 2013

- Mandates on-site audits to Legal Manufacturers

- MHRA Bulletin 19 (OBL Guidance) now withdrawn

- Draft guidance circulated to UK Notified Bodies in April 2014 and to ABHI in May 2014. The website is NOT up to date yet.

- There was an additional meeting at the MHRA, (10/October) which was attended by the UK NB and industry bodies

- Result: A new draft guidance, which is yet to be published.
Basis for process – MHRA guidance

• An ‘own brander’ is the person who places the product on the market under his own name or trademark and is therefore the manufacturer (as defined) for the purpose of the Regulations.

• This may not be the person who actually designed, manufactured, packaged or labelled the product but nevertheless the regulatory responsibility rests with them alone.

• The OEM (Original Equipment Manufacturer) must have gone through an appropriate conformity assessment process for their products themselves.
Basis for process – MHRA guidance

• The ‘own brand labeller’ must ensure that:
  • the appropriate conformity assessment procedure is correctly followed by them and any subcontractor
  • a formal contract(s) is/are in place between the relevant parties linking the OBL to the OEM and which containing at least the following:
    o a direct link between the OBL and OEM products
    o a clause allowing access to the OEM’s full technical documentation to Regulatory Authorities and Notified Bodies
    o arrangements for post market surveillance and vigilance activities
  • they register Class I devices and In Vitro Diagnostics with a relevant Competent Authority
Basis for process – MHRA guidance

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  • the appropriate conformity assessment procedure is correctly followed by them and any subcontractor
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    o a clause allowing access to the OEM’s full technical documentation to Regulatory Authorities and Notified Bodies
    o arrangements for post market surveillance activities
  • they register Class I devices and In Vitro Diagnostics with a relevant Competent Authority

- This new text allows on OBL-chain, as long as there is an agreement been all OBL and the very first OEM. In most instances, just to get hold of the technical documentation, if required.
Basis for process – MHRA guidance

• The ‘own brand labeller’ must ensure that (continued):

  • if appropriate, an application is lodged with a notified body. In the MHRA’s view any existing notified body approvals to the sub-contractor remain valid and must be recognised by any subsequent notified body. The subsequent notified body may thus only need to review the contract between the ‘own brander’ and the sub-contractor, and the documents confirming existing notified body approval. Replaced by the following:

  It should be noted that an own brander should have notified body certification in their own name and **be subject to an assessment** themselves.

  A notified body should take into account any previous OEM certification.
Basis for process – MHRA guidance

• The ‘own brand labeller’ must ensure that (continued):
  • any notified body which may be involved and the competent authority have access to the appropriate documentation necessary for them to fulfil their respective responsibilities. As a minimum the OBL should maintain an abridged or summary technical file (http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n011r20-essential-principles-safety-performance-medical-devices-sted.pdf) for their products which does not contain any proprietary information of the OEM
  • The OBL makes a declaration of conformity for the products concerned, and retains them for future reference by the competent authority
  • the CE marking of conformity is properly applied
  • post-marketing obligations such as vigilance are satisfied
Basis for process – MHRA guidance

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  • The OBL makes a declaration of conformity and retains them for future reference.
  • the CE marking of conformity is properly applied.
  • post-marketing obligations such as vigilant are satisfied.

- Direct link to STED, now prescribing the content of the summary technical documentation.
Basis for process – MHRA guidance

Quality System:
• The notified body should carry out their usual sampling regimes of the OBL’s technical documentation and perform an appropriate assessment to provide them with sufficient confidence about the device’s safety and performance. An alternative to this would be to obtain copies of the OEM’s Notified Body’s technical documentation reviews. Where further information is required this should be requested.

Product Specific:
• For product, type and design dossier examination conformity routes the OBL’s Notified Body should still review the technical documentation themselves in sufficient depth to confirm safety and performance of the devices. An alternative to this would be for the OBL to obtain for their Notified Body copies of the OEM’s Notified Body’s technical documentation reviews and for this to be reviewed for suitability by the OBL NB.
Basis for process – MHRA guidance

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- It is unclear what sufficient depth is to confirm safety and performance. Therefore, we interpret this as full review of the technical file or design dossier.

- This is not a workable solution. (what about NC? – against the OEM?)

- Ideally we review the technical file audit or design dossier review report of the OEM NB, to ensure that STED has been covered in sufficient depth.

- Can we accept the audit report for a product in the same Generic Device Group or same Subcategory? – possibly
Basis for process – MHRA guidance

Class I:
• For Class Im/s devices, where the NB has no involvement in the review of the technical file, the NB of the OBL needs to ensure that the measuring and/or sterile aspects have been sufficiently covered by the OEM NB. This can be in the form of a review of the suitability of the OEM NB audit report and associated documents. Where further information is required this should be requested by the OBL NB.

• They allow access to their notified body for the purpose of any unannounced audit.
Basis for process – MHRA guidance

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• They allow access to their notified body for the purpose of any unannounced audit.

- The agreement needs to allow BSI to conduct an unannounced audit of the OBL
- In reality BSI want to conduct an unannounced audit of the OEM