EU Update - Proposed Regulations, Own Brand Labelling, Unannounced Audits

Neil Adams, Medical Devices Director Operations and Delivery
September 2015
Great, we’ll get the upgrade started

First, here’s some important stuff:

MICROSOFT SOFTWARE LICENSE TERMS

WINDOWS OPERATING SYSTEM

IF YOU LIVE IN (OR IF YOUR PRINCIPAL PLACE OF BUSINESS IS IN) THE UNITED STATES, PLEASE READ THE BINDING ARBITRATION CLAUSE AND CLASS ACTION WAIVER IN SECTION 10. IT AFFECTS HOW DISPUTES ARE RESOLVED.

Thank you for choosing Microsoft!

INSTALLATION INFORMATION: Some Windows 10 features require advanced hardware; some existing features have been modified or removed; Windows 10 is automatically updated during the support period; support may vary by device.

More information
Overview

• Commission Regulation: How Competent Authorities control Notified Bodies
• Commission Recommendation: How Notified Bodies audit Manufacturers
• State of Play Now
  • Own Brand Labels
  • Unannounced Audits
• Proposed Medical Device Regulation
  • Key Provisions
  • Timetable for Implementation

Health Warning
Negotiations are on-going
There will be changes
24 September 2013


Directs Competent Authorities how to control Notified Bodies

COMMISION 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

## Requirements

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| Joint Audits of NBs by Designating Authority, Commission (FVO) plus two other CAs | • NBs and Designating Authorities under scrutiny  
• Highlights different approaches in Member States  
• More scrutiny of competency requirements, in-house clinicians, qualifications  
• Processes and procedures clarified  
• **NBs withdrawing - check NANDO, ask your Competent Authority** |
| NBs subject to renewal by 14 October 2016                                     | • Helps consistency; requires CA resource                                                                          |

BSI 0086 has been redesignated
Recitals - explain the intention of legislation

8) To facilitate the verification by the notified bodies of the technical documentation, the manufacturer’s device identification system and the declaration of conformity, it is important to provide specific advice with regard to the control of those requirements. Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC do not provide any exceptions for outsourced production compared to in-house production. Accordingly, it is necessary to include in duly substantiated cases the most important subcontractors and suppliers in the conformity assessment procedures.

9) Subcontractors or suppliers cannot fulfil in the manufacturers’ place crucial obligations of manufacturers, such as keeping available the full technical documentation, as this would void the concept of the manufacturer as responsible in accordance with Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC. Therefore, the notified bodies should be advised on what they need to verify in case of outsourcing.
Impact of Com. Recommendation (2013/473/EU) on audits and assessments performed by NBs - Items to be verified by NB during an audit

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| Annex I: Criteria for NBs performing design dossier and type examinations  | • Mainly reinforcement of current good practice  
• Increased need for clinical studies, less reliance on equivalence argument  
• Will clarify time needed for reviews |
| Annex II: Criteria for NBs performing QMS assessments, including “General advice in case of outsourcing of the production via subcontractors or suppliers” | • Mainly reinforcement of current good practice  
• Re-writes the rules for “Own Brand Labels” and the oversight of the supply chain |
| Annex III: Unannounced visits to manufacturers, "critical subcontractors" or “crucial suppliers”, in addition to planned audits | • Completely new requirement needing extra product and QMS assessors  
• Significant increase in NB workload and resources  
• IAF rules require planned audit schedules so no scope for substitution |
Changes to Own Brand Label (OBL) Process
Basis for the Changes in Process

- Recommendation 2013/473/EU requires Notified Body on-site Audits of Legal Manufacturers
- MHRA Bulletin 19 on OBL Guidance Withdrawn
- New MHRA Draft Guidance to meet requirements of 2013/473/EU
  - Circulated to UK Notified Bodies and Trade Associations April / May 2014
  - Revised October 2014
  - Draft shared but not published
New 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
New 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:
  - a direct link between the OBL and OEM products
  - a clause allowing access to the OEM’s full technical documentation to Regulatory Authorities and Notified Bodies
  - arrangements for post market surveillance and vigilance activities
- They register Class I devices and In Vitro Diagnostics with a relevant Competent Authority
- 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.
- **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
- Allows an OBL chain
- Needs an agreement been all OBL and the first OEM
- In most instances, just to get hold of the technical documentation, if required
- Deleted:
  - 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.
New MHRA Guidance: The ‘own brand labeller’ must ensure that:

- 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

- Direct link to STED, now prescribing the content of the summary technical documentation
- Guidance also includes a link to the IVD STED document
New MHRA Guidance related to the Quality System and Product

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.
OBL Conclusions

• What do Notified Bodies need to deliver?
  • Onsite Audits
  • Unannounced Audits, likely to be at the OEM
  • Technical file audits (initial product certification)
  • Technical file sampling in line with a sampling plan
  • Design Dossier reviews
• The same requirements for all legal manufacturers
• No recognition that OBLs are “different” from other legal manufacturers
Unannounced Audits Update
Unannounced Audit Requirements: see Webinars & BSI Website for Full Details


- Commission Recommendation
- E-Updates
- Webinar Details & Recordings
- Frequently Asked Questions
• Notified Bodies should perform unannounced audits in addition to product assessments and quality system assessments
Articles explain the requirements of instrument

• The Unannounced Audit can be at the manufacturer or critical subcontractor or crucial supplier (or both)
• Notified Bodies risk de-designation if they do not implement the requirements of the Commission Recommendation
Annex III Unannounced Audits

• Unpredictable additional visit - at least once per 3rd year
• At least one day by two assessors
• Increased frequency for ‘high risk’ or for non-compliant or specific reasons to suspect non-conformities
• Focus of Visit:
  • On-going manufacture
  • Legal requirements
  • Manufacturing link to technical file
  • Product identification & traceability
  • Verification of components
  • Witness testing of product
Annex III Unannounced Audits – section 5

• + At least two of the following critical processes:
  • Design control
  • Establishment of material specifications
  • Purchasing and control of incoming material
  • Assembling
  • Sterilisation
  • Batch-release
  • Packaging
  • Product quality control
Annex III Unannounced Audits - section 4

• For Devices subject to ‘Product Assessment’ (e.g. MDD Class III or IIb via Design or Type Examination), Notified Body should:
  • Sample and perform or witness testing of device
  • Prepare for the test in advance including final batch testing reports, previous test protocols and results
Implementation of Unannounced Audits
Who will Undertake the Audit?

- Commission Recommendation specifies at least two assessors
- BSI Assessment Team
  - One QMS Assessor (Client Manager)
  - One Product Technical Specialist
- In advance briefing preparation by the Scheme Manager
- Often not the regular assessor(s)
Legal Manufacturer?
YES if all or some manufacturing, design or test activities performed onsite for all or some products

Critical Subcontractor or Crucial Supplier?
YES, for virtual manufacturers
“...if this is likely to ensure more efficient control... in particular if the main part of the design development, manufacturing, testing or another crucial process is located with the subcontractor or supplier.”

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<tr>
<th>Critical Subcontractor</th>
<th>Crucial Supplier</th>
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<tr>
<td>E.g. Manufacturer of finished devices, key sub-assembly or significant components. Regulatory responsibility and / or activities essential for ensuring compliance with legal requirements. Design or software development, sterilisation, sterile packaging.</td>
<td>E.g. Critical raw materials such as silicone gel component for an implant, animal tissue for use in heart valve. Proprietary items.</td>
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BSI Experience to Date
Timelines and Experience

• Timelines
  • Unannounced Audit trials started March 2014
  • Full global roll out July 2014 onwards
  • Review of progress and issues with MHRA planned 30th September 2015
  • Finish first cycle by end of 2016

• Experience so Far
  • Vast majority of audits extremely good and well handled by manufacturers
Experience on the Day

• Assessment Agenda
  • BSI Assessors have detailed briefing but no fixed assessment agenda
  • Following arrival and overview meeting generally swift progress to manufacturing and / or final product areas

• Typical Timings
  • Morning spent in product areas, then working lunch
  • Afternoon finish production etc, then more office-based, documentation audit trails link to Technical Files & Dossiers
  • End of day wrap-up / brief closing meeting
Key Lessons to Learn

• A very few manufacturers are still to return requested critical information to BSI to enable effective planning
• Audits have been conducted to locations which would not have been visited had the information been available (e.g. move ongoing, a planned site closure)
• Lack of returned information does not mean no Unannounced Audit
  • Lack of response could trigger EC certificate suspension or cancellation
• Unusual situations encountered
  • Manufacture site moving or moved
  • Re-modellers in facility
  • Audit from a national regulator ongoing
  • CE Certificate about to be cancelled
• Procedures and training emphasise the importance of “speedy” access to manufacturing
  • Please help… no long factory tours or routing, cups of coffee (can be later), network passwords, navigation / access issues
On the day

1. Ensure guide(s) assigned
2. Be aware of requirement and assist the auditors, e.g. get to manufacturing as soon as possible
3. Let the assessment team know of any concerns or issues (e.g. no CE devices in production that day, fire alarm planned)
4. Think ahead – remember likely need access to Technical Files / Design Dossiers for devices
5. Feel free to ask questions (will they break for lunch, approximate time to wrap-up etc)
6. Conduct (and share?) internal post audit review on any learnings – ready for next time . .
OBL and Unannounced Audit Conclusions

• Lots of planning and preparation for Unannounced Audits, for Notified Bodies and Manufacturers

• Commission Recommendations are “Soft Law” not guidance
  • If Notified Bodies do not apply them Competent Authorities will restrict scope or de-designate
  • If Competent Authorities do not implement them the European Commission will start proceedings against the Member State
Proposed Medical Device Regulation

Key Provisions
Timetable for Implementation
19 June 2015: Council “Agreement”
29 September 2015: Council Agreement

- Partial General Approach
  - Political agreement of all substantive points in Articles and Annexes

- General Approach
  - includes Recitals, and all technical/drafting issues with texts

- The recitals, as well as a range of non-substantive, technical issues with the Articles and Annexes still being reviewed in Working Group

- Once agreed at Coreper, between the Permanent Representatives of Member States, this would constitute agreement of a full ‘General Approach’
  - expected in late September
The political timetable

- **Jan 2014**: Parliament elections
- **July 2014**: Rapporteurs appointed
- **Jan 2015**: New Commissioners in place
- **July 2015**: Conclude trilogues?
- **Jan 2016**: Entry into force?

**Greek Presidency**
- Council agrees (partial) general approach!

**Italian Presidency**
- New Commissioners in place

**Latvian Presidency**
- Begin trilogues?

**Luxembourg Presidency**
- Council agrees full general approach

**Dutch Presidency**
What are Trilogues?

- Negotiations between European Parliament, Council and Commission
- Four ‘blocks’ of negotiations (to be confirmed)
- October-December 2015?
- Luxembourg Health Minister promise
Key Issues in Council text: Pre-market scrutiny

- Expert Panels
- Class III, implantable devices only
- Notified Body retains final decision
- Clinical Evaluation guidance & Common Specifications
- Exemptions if NB judges conformity with the above, and for non-substantial modifications
Key Issues in Council text: Reprocessing of single-use devices

- Member State discretion
- EU minimum standard
  - No less than in-house manufacturing, and reflect Common Specifications
- Much member state debate still to be had
Key Issues in Council text: Eudamed & unique device identification (UDI)

- Single Registration Number (SRN) for Manufacturers and Importers
- Manufacturers and Importers required to store UDI
- Healthcare institutions not required but some system needed
- Lots still to resolve on UDI
Key Issues in Council text: Software

• Not an active device
• Classification concerns
• CE marking Laboratory Information Management Systems (LIMS)
Key Issue with Council text: Non-medical medical devices

- Will be covered
- Common specifications as a trigger
More Key Issues Council text

Clinical investigations
  • Coherence with Clinical Trials Regulation
  • Clinical evidence & equivalence

Post-market surveillance
  • Clearer requirements
  • Regular reporting for higher risk devices

Classification rules
  • Further clarification during implementation
Yet More Key Issues with the Council text

**Medicine/ Device combination products**
- Device if principal mode of action is physical, e.g. antacids
- Consultation with medicines authority

**Non-viable tissues & cells**
- Device if tissues/cells perform action ancillary to main purpose of product, e.g. tissue-coated pacemakers
- Consultation with tissues authority
MDR Transition Provisions: Article 97: Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day after its publication in the Official Journal of the European Union.
2. It shall apply from [three years after entry into force]
   - Look at seven years:

   ![Diagram showing timeline for entry into force and date of application]

   **Best Guess:** Q2 2016?
**Article 94 Transitional provisions Point 1**

- From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void

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Article 94 Transitional provisions Point 2 - 1

- Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

Certificates under 90/385/EEC and 93/42/EEC before MDR Adoption: 5yrs

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Article 94 Transitional provisions Point 2 - 2

• Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation.

* Batch verification certificates have no expiry date
Article 94 Transitional provisions Point 2 - 3

- Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

MDD/AIMD Certificates after MDR Adoption: 2yrs after Application

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Year -1  Year 1  Year 2  Year 3  Year 4  Year 5  Year 6

OJ
Entry into Force
Adoption

Date of Application

Directives 90/385/EEC and 93/42/EEC become void
Article 94 Transitional provisions Points 3 and 4

• By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.

• By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

MDR Certificates after Adoption before Application: 5yrs

Year -1  Year 1  Year 2  Year 3  Year 4  Year 5  Year 6

OJ Entry into Force Adoption

Date of Application
Conclusions

• A lot still to negotiate and agree
• Even when agreed Implementing and Delegated Acts will work on the details and could still change the scope
• You will have to accept the terms and conditions – you better try and understand them . . .
...making excellence a habit™