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EU Enforcement: Update on Unannounced Audit Program Progress and Results.

Paul Brooks
Senior Vice President
BSI Healthcare Solutions

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

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Changes to the EU 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**

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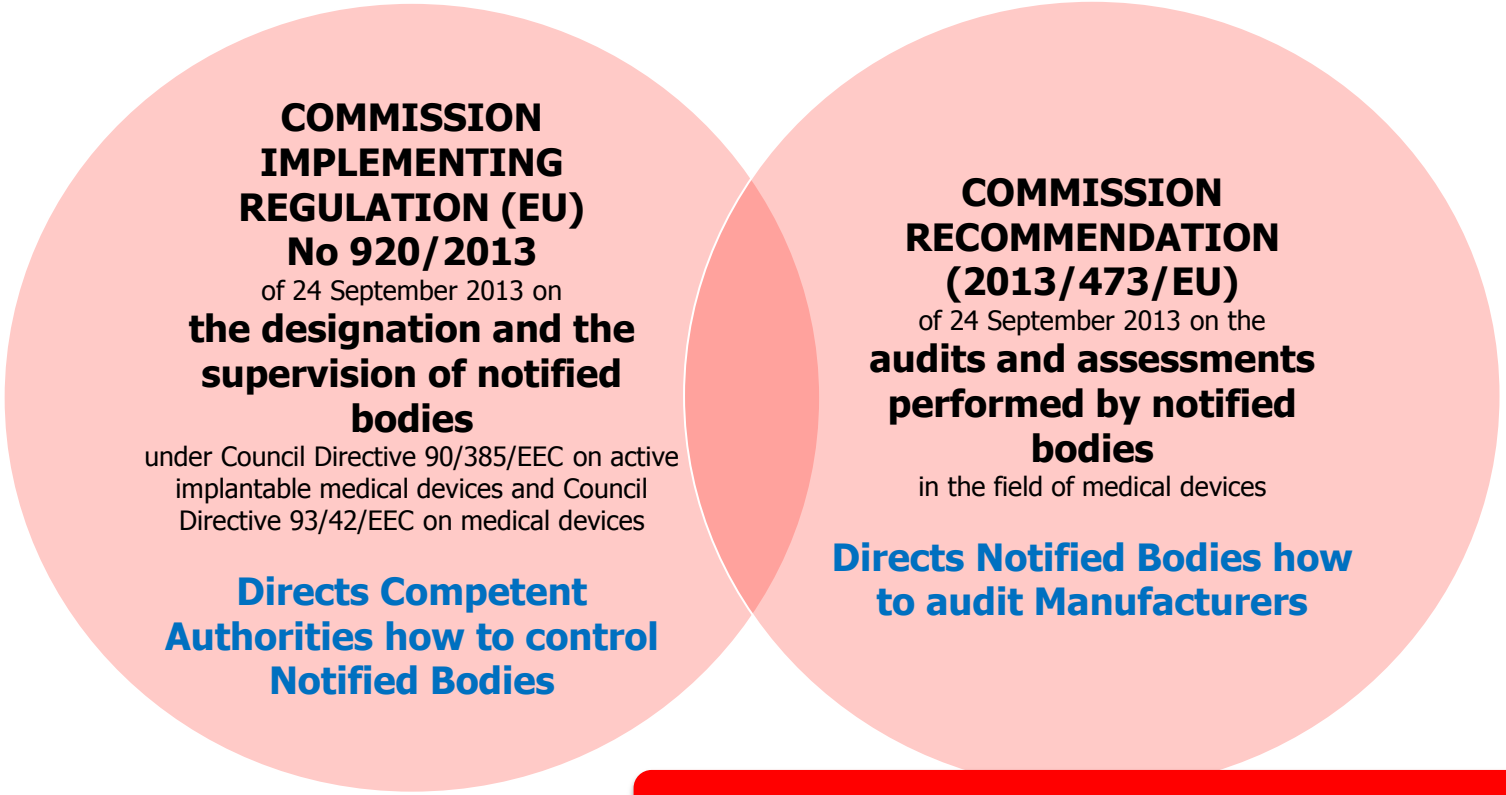
24 September 2013



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	Impact
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 CA 
NB Designation valid for a maximum of five years	• No impact yet; will need CA resource • Consistent with CE certification cycle 
Extensions and Renewals follow the same procedure as Designations	• Helps consistency; will need CA resource
NBs subject to renewal by 14 October 2016	• Helps consistency; requires CA resource
Designating Authorities shall have sufficient number of competent personnel	• Have they the qualified resource to deliver? 

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Impact of Com. Recommendation (2013/473/EU) on audits and assessments performed by NBs – Items to be verified by NB during an audit

Requirements	Impact
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	• Mainly reinforcement of current good practice
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  • Gone well in general • Some SMEs feeling burden is disproportionate

EU Unannounced Visits: The Requirements

Articles

2) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States r... implantable medical devices... /EEC of 14 June 1... Directive 98/79/EC of... of the Council of 27 October 1998 on... diagnostic medical devices (3), contain certain provisions with regard to the audits, assessments and unannounced audits performed by notified bodies in the field of medical devices.

The legal provision exists in the current medical directives (MDD, AIMD & IVDD)

Articles

5) Subject to the respective conformity assessment procedure, notified bodies perform product assessme[illegible]quality system assessments. Accordin[illegible]differentiate between these tw[illegible] continuous co[illegible] notified bodies should perfo[illegible] audits in addition to product assessments a[illegible] quality system assessments.

Unannounced Visits IN ADDITION TO product & QMS Assessments

Articles

11) In the absence of established practice for unannounced audits it is important to determine the practicalities for such audits, as well as to provide advice on the arrangements needed for facilitating these audits.

Make Unannounced Audits an established practice

1. PURPOSE

To facilitate the consistent application of the conformity assessment provisions contained in Directive 90/385/EEC, Directive 93/42/EEC and Directive [illegible], the notified bodies should apply the [illegible] Recommendation when they per[illegible] system assessm[illegible]. By providing general gui[illegible] assessments and unannounced audits, t[illegible] Recommendation should facilitate the work of the notified bodies as well as the Member States' evaluation thereof.

Consistency of Notified Bodies application and Competent Authority evaluation

2. GENERAL GUIDELINES FOR AUDITS AND ASSESSMENTS

c) To verify the day-to-day compliance with legal obligation[illegible] bodies should, in addition to the initial[illegible] audits, visit the manufac[illegible] efficient[illegible] charge[illegible] ensurin[illegible] ('critical subcont[illegible] components or of the entire de[illegible] supplier') without prior notice ('unannounced audits') in accordance with Annex III.

In addition to… regular visits
Unannounced Visit can be at the manufacturer or critical subcontractor or crucial supplier (or both – more later)

3. FOLLOW-UP

Member States should draw this Recommendation to the attention of the notified bodies in the field of medical devices and should supervise the practice of [illegible] bodies with respect to this Recomm[illegible]aluate the notified [illegible] Recomm[illegible] unannounced audi[illegible] designations of bodies and on re[illegible] withdrawal of designations.

Notified Bodies will be assessed to ensure we are implementing the requirements of the Commission Recommendation

Annex III - Unannounced Audits

1. Notified bodies should carry out unannounced audits at leas ry
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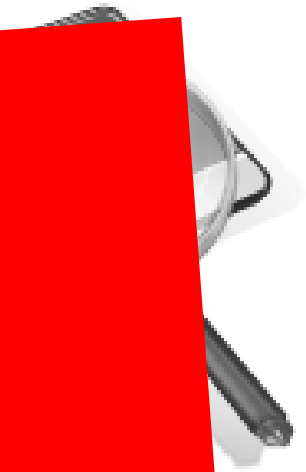
- Unpredictable additional visit - at least once per 3rd year
- At least one day by two assessors
- Increased frequency for 'high risk' or for non-compliant or specific reasons to suspect non-conformities

Annex III - Unannounced Audits

2. Notified bodies may, instead of or in addition to visiting the manufacturer, visit one of the premises of the subcontractor or supplier that is likely to ensure more efficient control if this applies to the manufacturer's design or production or another subcontractor or supplier.



- Visits not only to the manufacturer
- Also to critical subcontractors or crucial suppliers *if this is likely to ensure more efficient control.*

Note: "instead of or in addition to"

Annex III - Unannounced Audits

3. Within the context of such unannounced audits, the notified bodies should check a recently produced adequate sample, preferably a device taken from the ongoing manufacturing process, for its conf

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Focus of Visit =

- Ongoing manufacture
- Legal requirements
- Manufacturing link to technical file
- Product identification & traceability
- Verification of components
- Witness testing of product

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by the notified body. The test may also be performed by the manufacturer, its critical subcontractor or crucial supplier under observation of the notified body.

Annex III - Unannounced Audits

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+ 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

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Annex III - Unannounced Audits

- *4)* Notified bodies in charge of product assessment (...) should ... on to the steps foreseen in Sect... least three ... than 99 dev... e end of the ... f testing ... differen... be counte... e regarde... n. These s... onnel under th... premise... r crucial s...

For Devices subject to 'Product Assessment', e.g. MDD Class III or IIb via Design or Type Examination. Notified Body to

- Sample and perform or witness testing of device
- Prepare for the test in advance including final batch testing reports, previous test protocols and results

Annex III – General advice…

- *Unannounced audits in premises of the manufa*
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- Contractual arrangements
- Travel & Visas
- Manufacturers to continuously inform the notified bodies when devices will not be manufactured
- Financial compensation for the audits including device acquisition, testing and security arrangements

BSI Implementation

Who?

- 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)

Where?

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

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Where?

"…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."

Critical Subcontractor

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.

Crucial Supplier

E.g. Critical raw materials such as silicone gel component for an implant, animal tissue for use in heart valve. Proprietary items.

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What information should we have on file?

- Facility Details

Access details: Hours of operation, contact names & phone numbers, PPE / Health & Safety requirements, language skills on site, shutdown periods etc.

- Critical Subcontractors & Crucial Suppliers (CS/CS)

Details of device types, activities performed & frequency + all above

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How often?

Per Commission Recommendation & NB Code of Conduct

Minimum frequency in number of years for an unannounced visit	Classification			
	Is / Im IVD self test	IIa	IIb	III / AIMD IVD List A
Normal conditions	3 yr	3 yr	3 yr	2 yr
If the device bears high risk	2 yr	2 yr	1 yr	1 yr
Devices that are often non-compliant	2 yr	2 yr	1 yr	1 yr
Specific reasons for suspicion	2 yr	2 yr	1 yr	1 yr

As frequently as needed

Version 3.2 – 22 July 2014

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For how long?

- Most Manufacturers

- Including small & medium sized facilities
- One day by two auditors

- Very Large Manufacturers

- Several hundred employees +
- Four man-days (or more in extreme cases). Likely two assessors for two days
- Or an increase in frequency of visits

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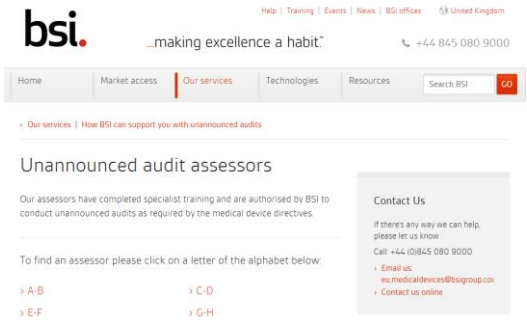
What happens on the day?

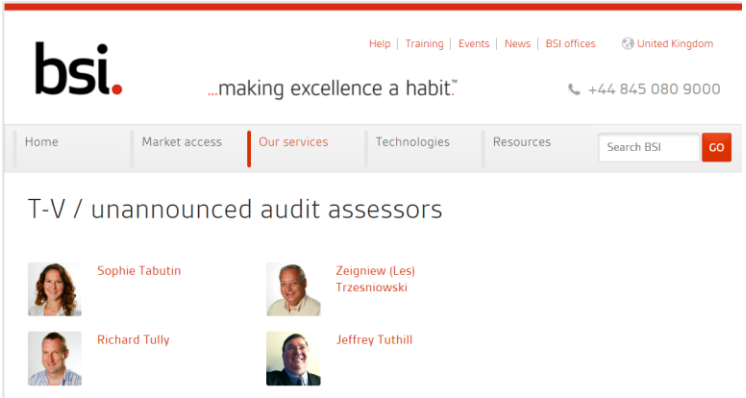
- Arrival

BSI Assessors present an introduction / overview letter referencing the objective, EC Certificate(s), location to be assessed, date and assessment team



- Identification

The letter contains a link to the BSI website which contains names and photos of all assessors authorized to conduct Unannounced Audits for BSI



What happens on the day?

BSI Assessors arrive onsite and present identification (letter and weblink)

Request to speak to allocated contact or the most senior person on site

Explanation of visit within brief opening meeting

Audit team progress swiftly to manufacturing area

Assessment team work together to audit all elements specified in the Commission Recommendation and identify areas / processes for further audit as part of the visit

Brief closing meeting, with details of findings where possible

Report will be provided within approximately one week

Follow up of any non-conformities through normal audit processes

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What happens on the day for a CS/CS?

Advise the CS/CS to contact their customer (the legal manufacturer)

Assessment of agreement / procedures / specifications between legal manufacturer & CS/CS

Brief closing meeting, with permission / phone attendance of Legal Manufacturer & details of findings where possible
Report provided to Legal Manufacturer within approx one week
Follow up of non-conformities via normal audit processes (at any location)

What happens on the day if…?

- No manufacturing or other processes ongoing?
  - Review applicable evidence? E.g. Recent activity, warehouse stock, physical areas used, i.e. manufacturing, design, records etc and associated documentation
  - If CS/CS (& within limits of confidentiality) review similar activities/processes/areas
  - Assessment team judgement to a recommendation on audit validity

- Audit team is refused or denied access
  - Assessors complete report providing full details of situation encountered
  - Directly inform BSI Scheme Manager (& BSI notify Legal Manufacturer if CS/CS)
  - Note – any refusal or non co-operation will lead to review & follow-up action
  - Potential escalation to certificate scope reduction, suspension or cancellation

BSI Experience to Date

Timelines

March 2014	BSI trial period Several Unannounced Audits conducted as trials across a range of companies and devices
April 2014	BSI live with routine Unannounced Audits (per European Competent Authorities expectations) Small volume conducted
May – June 2014	Global roll-out of internal training (5 events and 140 people) Finalized practises, polices and procedures
July 2014 –>	Full global roll out and ramp up, with significant volume of routine Unannounced Audits across remainder of 2014 + Continuous internal review, policy finalization and refinement

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What did we learn?

- So far all were ready, including small manufacturers

- Some surprise (from auditees) at:-
  - The assessment team working together
  - No detailed assessment agenda
  - Different focus to normal visits. i.e. more on product, less on supporting QMS processes (No routine coverage of Management Review, Internal Audit, CAPA etc)
  - Having a visit so soon!

- Feedback indicated a more positive experience than expected!

What did we learn? Key Points

- Unusual situations encountered
  - Manufacture site moving or moved
  - Re-modellers in facility
  - Audit from a national regulator ongoing
  - CE Certificate about to be cancelled

- Our procedures & 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

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What happened 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

Are you ready? Have you?

1. Studied the requirement?
2. Factored additional costs into budgets?
3. Implemented processes and procedures for receiving visits?
4. Responded to requests from your NB?
5. Reviewed (or are reviewing) critical subcontractors & crucial suppliers contracts?
6. Communicated awareness across all staff and trained appropriate staff?
7. Practised?
8. Had one?! Did you conduct a post-audit review to learn from the experience?

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On the day

1. Ensure guide(s) assigned
2. Be aware of requirement & 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 (& share?) internal post audit review on any learnings – ready for next time?!

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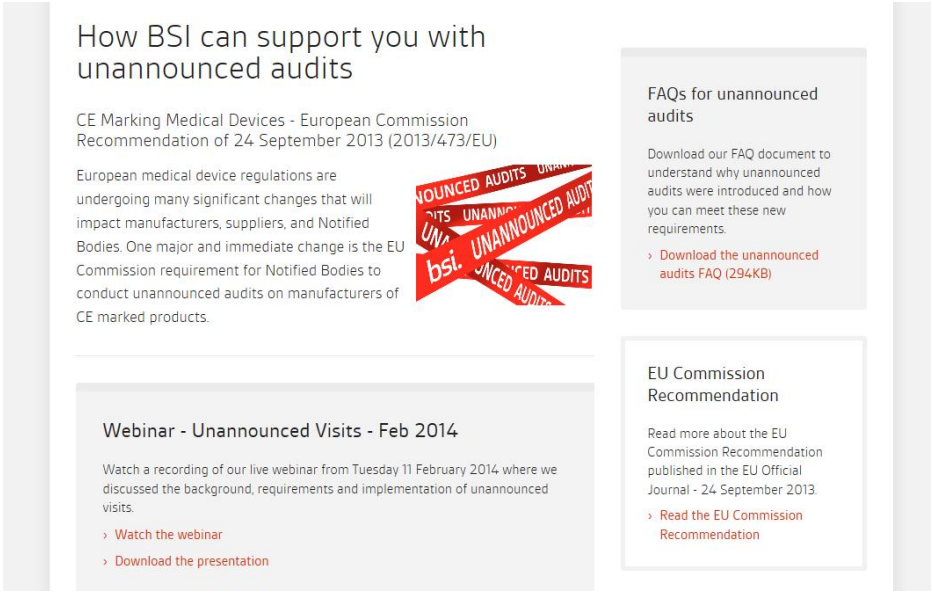
BSI Resources

http://medicaldevices.bsigroup.com/en-GB/our-services/Unannounced-audits-from-BSI/

- Commission Recommendation
- e-Updates
- Webinar Details & Recordings
- Frequently Asked Questions



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Any Questions

Paul Brooks
paul.brooks@bsigroup.com
+1-703-464-1923

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