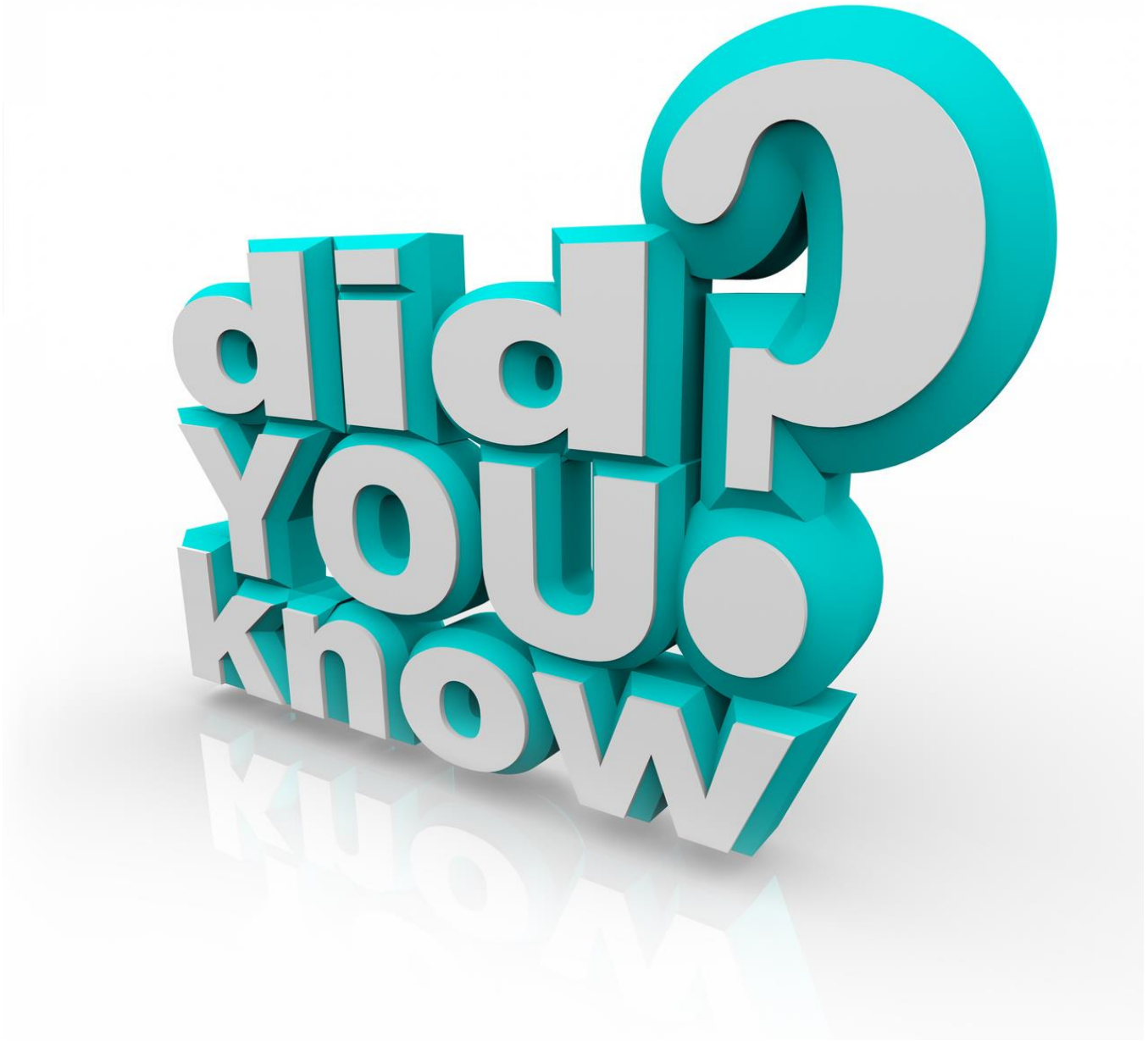
Unraveling the Mystery of EU Unannounced Audits



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What Motivated the Recommendation?

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Commission Recommendation

- EU Commission recommendation 2013/473/EU dated 24th September 2013, was published in The Official Journal ref L253/27 on 25th September 2013.
- The EU Commission web link is: http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0027:0035:EN:PDF

Annex III: Unannounced visits to manufacturers, "critical subcontractors" or "crucial suppliers," in addition to planned audits.

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Commission Recommendation

- Manufacturer and/or
  - Critical Subcontractor
  - Supplier of Crucial Component(s)
- In addition to regular audit
- One day, two auditors at minimum
- One Unannounced Audit (UA) per 3 years at minimum
- Increased frequency

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Frequency of Unannounced Audits

Minimum frequency in # yrs. for an unannounced audit	Classification			
	IVD self test	lla	llb	III / AIMD IVD List A
Normal conditions	3 yr	3 yr	3 yr	2 yr
If the device is 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 concern	2 yr	2 yr	1 yr	1 yr

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What is a Critical Subcontractor (CS)?

A manufacturer of significant components; a site with regulatory responsibility or activities essential for ensuring compliance with legal requirements; design or software development; sterilization; sterile packaging.

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What is a Crucial Supplier (CS)?

A manufacturer of finished devices or key sub-assemblies; a supplier of critical raw materials such as silicone gel component for an implant or animal tissue for use in a heart valve.

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Are All Products Included in the Unannounced Audit Requirement?

- *Unannounced audits will apply to all devices under Clause 6 of the Commission Recommendation including:*
  - *Active Implantable Medical Device Directive, 90/385/EEC*
  - *Medical Device Directive, 93/42/EEC*
  - *In Vitro Diagnostic Directive, 98/79/EC*
- *Unannounced audits only apply to CE marked products which require a Notified Body to perform a conformity assessment (not self-declared IVDs under Annex III)*

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Fees

- Legal Manufacturers will be charged for unannounced audits of their own facilities
- Legal Manufacturers will be charged for unannounced audits of their critical subcontractors / crucial suppliers facilities
- Costs include
  - Audit
  - Devices acquired
  - Testing
  - Security
- Refusal to pay
  - Breach of contract
  - Suspension of certificate(s)
  - Withdrawal of certificate(s)

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Basis for Fees

- Number of days
- Number of auditors
- Travel expenses based on location
- Report fees
- Security for audit team
- Device Tests
  - Cost of devices
  - Lab fees
    - Separate fees from audit
    - Paid and approved up front
    - Shipping

Logistics of Audit

- Contracts with suppliers
- Travel/Visas (invitation letter)
- Inform Notified Body (NB) when devices are NOT being manufactured
- Facility access
- List of all CS/CS

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Can Suppliers Refuse Entry?

- YES they CAN, but….
  - Assessors complete report providing full details of situation encountered
  - Directly inform NB
    - If supplier, NB will notify LM
  - Any refusal or non co-operation will lead to review & follow-up action
  - Potential escalation to certificate scope reduction, suspension or cancellation

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What to Expect on the Day of the Audit

- Overview Letter
- URL Identification
  - If supplier, contact Legal Manufacturer (LM)
- Senior representative
- Opening meeting (no fixed agenda)
- Rapid progress to manufacturing area
  - If supplier, assess contracts, procedures and specifications
- Closing meeting
  - If supplier, LM phone attendance

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What to Expect on the Day of the Audit

- Typical Timing:
  - Morning:
    - Opening Meeting
    - Production Area
  - Lunch:
    - Typically working lunch
  - Afternoon:
    - Finish Production Area
    - Document Review (TF/DD)
    - Closing Meeting

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Audit Focal Points

- Manufacturing
- Testing
- Technical File
- Device Specifications
- ID and Traceability
- Reconciliation of Materials
- Witness Testing

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Focal Points, cont'd.

At least two of the following critical processes will be included in the unannounced audit:

- Design control
- Establishment of material specifications
- Purchasing and control of incoming material
- Assembling
- Sterilization
- Batch release
- Packaging
- Product quality control

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Product Assessment

- MDD Class III or IIb
- Design or Type Examination
- NB
  - Review previous protocols / results
  - Witness or perform device testing

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After the Audit

- Who Will Receive the Audit Report?
  - If supplier was audited, the audit report will be sent to the legal manufacturer in one week.
- Follow up of UA non-conformities via normal audit processes at any location (CS or LM) as part of routine surveillance
- No follow up of routine audit activities such as non-conformities during UA

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Roll-Out

- April 2014
  - Routine UAs begin
  - Findings fed back into procedures
- June 2014
  - Procedures finalized
- July 2014
  - Ramp-up begins
- High risk by 2016
- Low/Med risk by 2017

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What We're Seeing

- UAs of several Class III cardiovascular device manufacturers
- Battery manufacturers audited Spring 2015
- Implantable material focus
- LMs not preparing CS for UAs
  - Lack of procedures
  - IP concerns
  - Change of address

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How to Get Ready

- Review the Directives and Commission Recommendation
- Budget for supplier audits
- Ensure suppliers have procedures for receiving UAs
- Review all supplier contracts
- Communicate to NB
  - Supplier new address
  - NOT manufacturing dates
- Review TF/DD
- Ensure suppliers have validated test methods for inspection/testing
- Confirm sampling is based on risk and statistically valid techniques
- Mock audits

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References

- http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0027:0035:EN:PDF
- http://www.meddeviceonline.com/doc/are-unannounced-audits-the-new-norm-for-eu-devicemakers-0001
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- http://ec.europa.eu/health/medical-devices/files/list-of-contact-points-within-the-national en.pdf

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