Regulatory Requirements for Product / Quality System Assessments and Audits

How to Prepare?

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Unannounced Audits

• What is the *focus* of an Unannounced Audit?

• Document 2013/473/EU makes it clear. There are two main parts:
  ➢ Quality System Part
  ➢ Product Part

• Overall: an UAA is certainly more product focused than the regular audits in the past

• Product focus means: the notified body will select a product from the product portfolio, and most actions will be linked to this selected product
What Actions?

• ... the notified bodies should
  – check a recently produced adequate sample, preferably a device taken from the ongoing manufacturing process, for its conformity with the technical documentation and with legal requirements.

• The check of the conformity of the device should
  – include the verification of the traceability of all critical components and materials and of the manufacturer’s traceability system.
  – include a file review and, if necessary in order to establish the conformity, a test of the device
• Notified bodies in charge of verifying the quality system of the manufacturer should,
  
  – verify whether the manufacturing activity ongoing at the time of the unannounced audit is in line with the manufacturer’s documentation relevant for the manufacturing activity and that both are in conformity with legal requirements.
  
  – in addition, these notified bodies should check in more detail at least two critical processes such as design control, establishment of material specifications, purchasing and control of incoming material or components, assembling, sterilisation, batch-release, packaging, or product quality control.
    
     Amongst the suitable critical processes, notified bodies should select one which has a high likelihood of non-conformity and one which is particularly safety relevant.
• Notified bodies in charge of **product assessment** should:

  – sample devices belonging to at least three different **device types** and, where the manufacturer produces more than 99 device types, devices belonging to at least every hundredth type at the end of the production chain or in the manufacturer’s warehouse with a view of testing the conformity of the device types

  – These samples should be tested by the notified bodies or by qualified personnel under their observation on their own premises, or on the manufacturer’s premises, or on the premises of the manufacturer’s critical subcontractor or crucial supplier or in external laboratories. Sampling criteria and testing procedures should be defined in advance.

  – … if a sampling in the manufacturer’s premises is **not possible**, notified bodies should take samples from the market…or perform testing on a device installed at a customer location
Now: what to expect?

- Visit is not announced

- Challenges are but not limited to:
  - no adjustment with audit team, no audit plan in advance
  - important, critical employees may not be around
  - access to documentation may not be easy
  - people are engaged in normal work
  - scheduled work needs to be postponed, rescheduled
  - you may be in the middle of important preparation for the next exhibition
How to prepare?

- What can be done prior to such an unannounced audit?
  - protocols must be available
    - Who needs to be informed?
    - What supporters must be called in?
    - Who is the first person to be in contact with the audit team?
    - Any specific escalation process? Upper management?
  - Access to production and warehouse must be granted (safety issue?)
  - Auditors need to be accompanied, expect two or more auditors
  - Be prepared to show test plans, test protocols
  - Be prepared to show some physical testing (incoming, in-process, final; type testing)
  - Test equipment may need to be freed from routine work
How to prepare?

• What can be done prior to such an unannounced audit?
  – Have the contracts with suppliers and subcontractors updated
  – Have the qualification protocols of suppliers and subcontractors ready and up-to-date
  – Perform internal product audits in addition to process audits
  – Perform internal Technical File audits in addition to process audits
  – Keep traceability records up-to-date
  – Have the costs of the UAA in the budget
  – Raise awareness in your company
  – Conduct mock audit as unannounced audit
Effort and Stress in Relation to Audits
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• Do you know this?
Effort and Stress in Relation to Audits

Battery

Half-wave rectification

Full-wave rectification
Effort and Stress in Relation to Audits
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Could this be real?
Be prepared – at all times

• Maintain compliance of your quality system with regulatory requirements …
• … and maintain compliance with your quality system
• Keep your products and their documentation up-to-date
• Continously monitor the performance of your device
• Continously monitor the performance of your subcontractors
• Make sure that you know what changes are significant for you, your quality system or your products – have they under your control
Good Luck