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## Preparing for Unannounced Inspections from Notified Bodies

*Europe has introduced further measures for unannounced audits of manufacturers by notified bodies. With this in mind, James Pink, VP Europe-Health Sciences Medical Devices at [NSF International](#), provides a little help to prepare for them.*

### Background

There are two important documents that are concerned with unannounced inspections:

- [European Commission \(EC\) recommendation](#) of September 24, 2013 concerning unannounced audits by notified bodies in the field of medical devices
- [Team NB's Code of Conduct for Notified Bodies](#) version 3.0 October 2012, Pages 21-23

Unannounced inspections are already being undertaken by notified bodies and competent authorities are preparing for them to become mainstream by early 2014.

Consider the following steps to ensure that you are prepared for EU notified body unannounced inspections.

### Step 1: Be prepared

Establish and review the sources of information for unannounced inspections; in particular, ensure you create links with other companies in the area with the same notified body and products. Review your contract with your notified body and ensure you identify when you are manufacturing product. Communicate this through your organization and to your notified body.

### Step 2: Plan for unannounced audits

Undertake formal business continuity planning activities to ensure you consider worst-case scenarios and develop procedures that can be used later for drills, exercises and simulations. These procedures can then serve as the basis of your business continuity strategy.

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### **Step 3: Undertake your own mock unannounced audits**

There is nothing better than actually undertaking mock audits. Utilize NSF Health Sciences' expert audit team to help kick off unannounced inspections so you can learn lessons from the best in the business and refine your contingency procedures.

### **Step 4: Implement procedures for unannounced inspections**

It is imperative that you have procedures that inform and train all personnel involved in unannounced inspections so that they can implement them as soon as an unannounced inspection occurs. Do not forget that this also needs to extend to your supply chain!

### **Step 5: Raise awareness and train your people and suppliers for managing inspections**

Practice makes perfect. Simulation, exercises, drills, scenarios – whatever you call them, there is nothing better than training your people and suppliers so that you can use assessment methods to understand whether they are able to contingency plan, apply unannounced audit procedures and, more importantly, effectively respond to notified body requests during the audit. Do not underestimate the importance of having competent and confident people on hand during the audit.

### **Step 6: Maintain compliance to the EU medical device directives**

Are your devices classified correctly? Do your declarations of conformity actually cover every medical device? Is your technical file updated with the appropriate information so that it shows you are on top of things? If not, you need to ensure that you have a technical file review, a risk management review and post-market surveillance summaries that are current and responding to your data.

Consider the scenario of a notified body suspecting that your device is not in accordance with the medical device directive's essential requirements – How do you prove it is, do you have the evidence and do you have access to the relevant tests and information?

### **Step 7: Use the NSF Health Sciences Medical Devices team for support**

Whether regulatory strategy, regulatory science, quality assurance, training, auditing or testing, we can help you. We are only a phone call away.

Each of these steps is addressed in more detail below.

## ***Step 1: Be Prepared! It's going to happen – Get used to it!***

### ***Predicting when the inspection will occur***

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The minimum frequency for an unannounced inspection is once in a three-year cycle and potentially more frequently for Class III products. If your company or supplier has introduced “cause for concern” with a European competent authority or your notified body, you will receive an unannounced inspection regardless of the recommended frequencies.

Competent authorities are expecting a relatively quick implementation of this requirement. For example, the Medicines and Healthcare Products Regulatory Agency (MHRA) has agreed to a six-month implementation period (by March 2014) and the Netherlands prefers a timeframe yet in 2013.

In order to execute unannounced inspections within a framework of limited financial resources, the notified body will probably look to “group” audits based on the audit team competence and the location where the unannounced audit is going to take place. Hence, striking up a relationship with a competitor in the area with the same notified body may enable you to share information and get a head’s up when the inspectors come knocking.

### ***Predicting the focus of the inspection***

An assortment of intelligence will begin to be generated reasonably early in the process, including the “case studies” of where unannounced inspection has worked (with respect to safeguarding public health) and the “counter intelligence” surrounding what the notified body auditors are actually looking for and at.

In order to stay ahead of the game, we suggest you look at various communication forums, professional groups and your own notified body communications to keep abreast of what is happening.

Important communities to be involved in include:

- LinkedIn group on notified body unannounced inspections
  - <http://www.linkedin.com/groups?viewMembers=&gid=6546505&sik=1383578005051>
- Eucomed newsletters
  - <http://www.eucomed.com/media-centre/newsletters>
- Team NB website
  - <http://www.team-nb.org/>
- Competent authority websites
  - [http://ec.europa.eu/health/medical-devices/files/list-of-contact-points-within-the-national\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/list-of-contact-points-within-the-national_en.pdf)

Keep checking in at [www.nsf.org](http://www.nsf.org) (Medical Devices) too as we are committed to gathering and maintaining intelligence with respect to unannounced inspections.

### ***Ensuring the correct agreements are in place***

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You should establish that your supplier agreements and internal quality agreements will allow for unannounced audits.

## **Step 2: Plan for the unannounced inspection**

### ***Murphy's law – If it can go wrong, it will!***

In the context of unannounced inspections, you need to prepare for the most inconvenient situations and timing as they will be a disruption to your normal business operations.

Consider **business continuity planning** so that you can prepare for the likely situations that you may encounter during an unannounced inspection and then create **formal procedures** that consider appropriate contingencies such as:

- Who will manage the inspection from the manufacturer's side (even at a subcontractor location)?
- Who will access critical IT and information systems if people who usually have access are not available?
- How will we know if a critical supplier is having an unannounced inspection, but on behalf of another customer?
- What if the inspection occurs during the only week that every manager is out?

It may be helpful to take a look at business continuity principles to help you formulate your plan so that you consider all of the things that are not at the forefront of your mind when trying to deal with these situations.

### **Use business continuity principles (Take a look at ISO22301:2012)**

The most basic principles around business continuity include:

- Undertaking a business impact analysis
- Establishing a risk analysis considering people, infrastructure, technology, resources and of course the items required to be reviewed by the notified bodies in question. (See pages 21-23 of the [Team NB Code of Conduct](#))
- Preparing business continuity strategies (for you, your manufacturing locations and your subcontractors/suppliers)
- Preparing an emergency response (What happens after the knock on the door at head office, an authorized representative or remote facility or critical supplier location?)
- Implementing business continuity plans (lining up the interim management team) and assigning responsibilities
- Conducting awareness and training programs
- Simulating and auditing plans and actions so the organization knows how to execute them

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### ***Preparation with your NB including updating your contract***

The EC recommendation calls upon your notified body to contact you to update your contract if necessary to allow for unannounced audits, including your critical subcontractors. This includes the provision that the manufacturer should “continuously inform” the NB of periods when manufacturing will not be taking place. The above contact is an excellent opportunity to find out more about your NB’s intentions for implementing this Commission recommendation.

There has been much discussion about the practicalities of the NB obtaining visas to visit countries where a sponsor invitation is necessary, but this problem is nowhere near resolved.

### ***Step 3: Prepare through mock audits***

#### ***Understanding the basic vulnerabilities in staging unannounced visits***

A suggested way to prepare for unannounced inspection is to begin your own series of unannounced inspections in-company and at your critical suppliers with a minimum of two people.

A useful audit checklist has been developed in [Team NB's Code of Conduct for Notified Bodies](#) on pages 21-23. It is important that you create your own internal audit strategies to “mock audit” the suggested focus in the code of conduct and ensure you update your annual audit agenda to make provisions for internal “unannounced” audits.

The Commission recommendation says that the NB should “check a recently produced adequate sample, preferably taken from the ongoing manufacturing process” for conformity. This will involve scrutiny of “...all the relevant technical documentation including previous test protocols and results.” (One wonders how the NB will manage to complete all this, together with all the items below, during a two or four person-day audit!)

It is also clear that the audit should include the following:

- **Product assessment (Annex I)**
  - Appropriate qualification as a medical device, in particular whether a proper medical purpose has been assigned
  - Appropriate classification and consultation with relevant bodies (for instance, the European Medicines Agency)
  - Appropriate product coverage on the CE certificates linking to unequivocal identification of all devices and variants including linkage to the declarations of conformity
  - Evidence of compliance with the essential requirements
  - Appropriate Design, Manufacturing and Packaging specification

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- Appropriate Risk Management file (up to date and in line with all post-market surveillance, post-market clinical follow-up and complaints data)
- Risk controls/safety principles compatible with the state of the art as defined in current product standards and/or by other similar products currently on the market
- Up-to-date clinical evaluation responding to post-market surveillance data and post-market clinical follow-up or in the case of IVDs, a corresponding up-to-date performance evaluation report
- **Quality system assessment**
  - Risk-based approach to each device's critical subcontractors and crucial suppliers
  - Outline of the tests that may be required to demonstrate that the product conforms to its specification (as this is likely to be requested by the notified body if it suspects any deficiency in the quality system)
  - Quality manual and procedures that are relevant and applicable to the device under consideration
  - An organizational structure that can sustain a safe medical device
  - A management team and personnel qualified to conduct their activities
  - An internal audit program capable of monitoring the effectiveness of the QMS
  - A critical subcontractor and crucial supplier monitoring program capable of controlling product safety
  - Appropriate metrological traceability, particularly associated with reference standards or other measurement confirmation systems where accuracy and precision are essential to device performance
  - Sound change control procedures, consistent with the design and development procedure
  - Material specification development, purchasing and goods inwards verification as well as the controls applied to consolidate materials received with manufactured product
  - Control of the environment to produce a safe medical device
  - Application of suitable methods for validation, batch identification, sterilization, product quality control and batch release
  - Systematic review of complaints and post-market surveillance data and effective corrective action and change control
  - Proper implementation of the procedures for clinical evaluation and its update via post-market surveillance; for IVDs, correct execution of working procedures for performance evaluation including traceability to appropriate reference materials

## Step 4: Implement procedures for managing aspects of the unannounced inspection

Developing and implementing basic procedures will help companies manage various aspects of unannounced inspections. When developing these procedures, think about the unannounced inspection lifecycle:

- What happens upon announcement and arrival of the NB audit team
- Who will cover the product design aspects
- Who will cover the regulatory/technical documentation
- Who will cover the supplier control aspects
- Who will cover the QMS aspects
- Who will cover the manufacturing and release aspects
- Who will cover the product surveillance and vigilance aspects
- How the auditees will work and communicate
- Who the auditees will work with each other and the auditing body
- How the audit will be documented by the internal organization
- The work instructions for dealing with NB audit scenarios

## Step 5: Raise awareness through in-company training

You will need to ensure that you have appropriate people who can manage the unannounced inspection. They need to be prepared and ready to act across your internal organization and your supply chain. As a result, you will need to provide timely communication in several phases:

- Straight away – right now, as soon as you read this
  - Consider a simple awareness program for all personnel likely to be involved in an unannounced inspection. This way they can begin to discuss their contingencies and draw up a resource plan.
- Upon completion of your continuity strategy
  - Train your core teams and the people who are now responsible for initiating contingency plans. Get them aware of the software, information resources and the sequence and interactions so that they can respond with confidence to a notified body auditor enquiry without unnecessary delay.
  - Work with your supply chain (particularly those identified through product risk management) to implement a robust strategy for unannounced inspections where the supplier is likely to be involved. (This needs to be considered if the subcontractor or supplier is considered critical to other medical device companies too.)

## Step 6: Stay compliant with the EU medical device directives

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***Warning! This step makes a very basic assumption – that you already comply with the European medical devices directives.***

Prior to implementing any of these recommendations, you should ensure that the following processes are working well, continually updating and responding:

- Classification and conformity assessment
- Risk management
- Design control
- Change control
- Clinical evaluation
- Process control
- Supplier control
- Product surveillance
- Post-market surveillance and vigilance
- Organizational structures and personnel competencies

## **Step 7: If you are still concerned, talk to the experts**

NSF Health Sciences is committed to helping you deal with unannounced audits as easily as possible. Through the following services, we can support you:

- White papers
  - We are committed to producing white papers throughout 2014 that deal with all aspects of European notified body unannounced audits.
- Study days
  - We will be holding a regulatory study day that discusses, among other things, the practical aspects for manufacturers dealing with unannounced inspections.
- Regulatory strategy
  - Our people have the necessary expertise to help you ensure that your devices are appropriately classified and subjected to the appropriate regulatory requirements.
- Regulatory science
  - If you require an up-to-date risk management, biological evaluation, product testing strategy, clinical evaluation or other help demonstrating your product fulfils the essential requirements of the medical devices directives, we have a team of European renowned experts on hand to help in any capacity you require.
- Quality systems/remediation
  - Our people understand what it takes to build effective quality management systems and to ensure that those systems operate in the most optimum way and to the varying regulatory inputs that modern medical device regulatory frameworks demand. We are able to help you implement quality system improvements, class-leading processes

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for change control, design control, process control, corrective and preventive action as well as help you manage any remediation activities resulting from EU notified body or competent authority action.

- Auditing
  - Our auditors have worked for over 15 years each in the world's leading European medical device notified bodies. Our mock unannounced inspections accurately test your systems and provide honest and reliable feedback about the capability of your organization and its supply chain to withstand unannounced inspections. We provide:
    - Technical file reviews
    - Product quality and test method reviews
    - Risk management
    - Supply chain management
    - Full unannounced audits undertaken globally
- Training
  - We run a series of courses that can be delivered at your company locations most likely to receive unannounced audits:
    - Developing a business continuity plan for unannounced audits
    - Preparing for unannounced audits
    - Planning and conducting mock unannounced audits
- Qualified Person program
  - NSF Health Sciences has a class-leading program of education for today's quality and regulatory affairs professionals. If you want to prove your competence, enroll in our flexible post-graduate quality and regulatory modules:
    - Module 1 – EU Regulatory Frameworks
    - Module 2 – EU Medical Device Design and Risk Management
    - Module 3 – Clinical Evaluation for Medical Devices
    - Module 4 – Developing and Maintaining Technical Documentation
    - Module 5 – Quality Management Systems for Medical Devices
    - Module 6 – Post-Market Surveillance and Vigilance for Medical Devices
    - Module 7 – Working with EU Regulatory Stakeholders as Part of the EU Conformity Assessment Process
  - Take our Qualified Person viva and prove to a board of experts that you are indeed qualified to undertake your duties and responsibilities in medical device quality assurance and regulatory affairs.

**Learn more about NSF Health Sciences Medical Devices' range of [medical device services](#)**

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