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BSI Unannounced Audits

Frequently Asked Questions (FAQs)

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Contents

1 Where can I read the original Commission Recommendation regarding unannounced audits?

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://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:253:0027:0035:EN:PDF

2 Does this recommendation only cover unannounced audits?

No, only Annex III of the Commission Recommendation headed, "Unannounced audits" focusses on these, whereas the full document details the requirements both for the notified body and the legal manufacturer.

Annex I of the Commission Recommendation deals with Product Assessment and Annex II Quality System Assessment. Clause 10 of the recitals (first section of the document ahead of the Annexes) states, "*though regarded as two independent exercises, it is necessary to strengthen the link between the quality system review and the review of the technical documentation on a sampling basis*".

3 Does this recommendation apply to all European Notified Bodies or just BSI?

This recommendation applies to ALL European Notified Bodies and not just solely to BSI. There is only one member state of 28 that will not be enforcing this recommendation.

4 When will unannounced audits start?

BSI will start unannounced audits in April 2014 (and ahead of that in a trial phase) as agreed with both the UK and German Competent Authorities.

The current proposed changes to the European Medical Devices Directives, to be published as Regulations, also incorporates text requiring unannounced audits. However the decision was taken via the publication of the Commission Recommendation (see questions 1 – 2 above), not to wait for the Publication of the Medical Devices Regulation and to commence unannounced audits in 2014.

5 Will I receive prior notice for an Unannounced Audit?

No, according to the criteria in the *Recommendation – General Guidelines for Audits & Assessments Clause 2 (c) "….. without prior notice … in accordance with Annex III*, we will give you no notice; our auditors will arrive at your premises, your critical sub-contractors premises, or your crucial suppliers premises completely without warning. This may happen at any moment during the day or even during the night shift if that is in practice at the facility being visited. You must provide free and unimpeded access to the auditors, you should ensure you have processes and procedures in place as part of your Quality Management System for receipt and hosting of unannounced audits and ensure all staff have been trained and are aware of the requirements and responsibilities.

6 My company manufactures IVD's, will unannounced audits apply to my company?

Yes, 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. Many IVDs are self-declared under Annex III and the manufacturer chooses to use BSI to certify their quality management system according to ISO 13485, although these products bear a CE mark they do not have a Notified Body number associated with it and as such will not receive an unannounced visit. Only Annex II List A and B IVDs plus self-tests using the Annex IV conformity route will receive an unannounced visit.

7 How often will we receive of unannounced audits?

Annex III, Paragraph 1 specifies that it should be undertaken "at least once every third year. Notified bodies should increase the frequency of unannounced audits if the devices bear a high risk."

- For High Risk devices, once every two years (in-line with requirements in the Notified Body Code of Conduct), this category includes all MDD Class III's, AIMD's and List A IVD's.
- For Medium/Low Risk devices, once every three years, this includes Class I manufacturers where Notified Body involvement is required for Measurement or Sterilization purposes.

The visit frequency will be higher for frequently non-compliant devices or where specific reasons for suspecting non-conformities exist.

8 Has an expected audit duration and audit team resource been specified?

Annex III, Paragraph 1 of the Commission Recommendation specifies as a minimum one day and two auditors. For the majority of the unannounced audits conducted by BSI there will be one Quality Management System Assessor and one Product Technical Expert. Normally we will not use your regular Assessors / Experts: however, in some circumstances this may not be possible due to the specialisms required.

You should be aware there may be occasions for larger manufacturing facilities, (for example where there are several hundred employees), as well as for complex products, where it is necessary to increase duration or resource level or possibly both.

9 Will I be charged for the unannounced audits, and can I refuse?

You will be charged for unannounced audits, further communication will be provided detailing the fee structure. Refusal to receive or pay for an audit would potentially render you in breach of the contract between BSI and your company, where BSI will then be required to consider suspension and ultimately withdrawal of the certificate. BSI has been considering various payment options taking into

consideration customer concerns and is now finalising the fee structure which will be communicated shortly.

10 My existing contract with BSI has the provision for unannounced audits, why has it never been used?

To date unannounced audits have not been conducted by BSI or other Notified Bodies across all CE certified manufacturers on a routine basis. The need for routine unannounced audits by all Notified Bodies was stipulated as part of EU Commission recommendation 2013/473/EU dated 24th September 2013 and is part of the Commission's response to strengthen the regulatory system following the PIP scandal.

11 Will BSI be changing their Terms & Conditions to accommodate unannounced audits and how will this impact on my company's critical sub-contractors and crucial suppliers?

Following review by our Legal Department we will not be changing our current Terms & Conditions as the necessary provisions for unannounced audits already exist. In some cases manufacturers will need to be moved from historic Terms and Conditions to the current ones; in such case BSI will notify you directly.

Your company should define your critical sub-contractors and crucial suppliers and then review the contractual arrangements with them in order to ensure the Notified Body has necessary access to perform an Unannounced Audit at their locations. If this is part of an unannounced visit this may be without your prior knowledge. BSI recognises that there are some logistical challenges which need resolution, e.g. common sub-contractors, suppliers used by different manufacturers, potential travel requirements and visa's etc. BSI is actively discussing these issues with the Competent Authorities and TEAM-NB (the European Notified Body association) in order to get a working practical solution.

12 I just became aware of these proposed changes, what should I do to prepare and how will BSI communicate in the future?

We will start the unannounced visits programme on the 1st April 2014; prior to this there will be a limited number of trial assessments to validate the process. Visits will be undertaken for unannounced audits at the frequency described in the Commission Recommendation and will be in addition to your normal routine surveillance programme.

If you have not seen the Recommendation BSI very strongly recommend you read and understand your role and responsibility for compliance, and use your quality system to implement quality plans and processes as appropriate. Please be aware your Unannounced Audit could occur anytime between 1st April 2014 and April 2016 for high risk devices or April 2017 for medium to low risk devices and you should be prepared to ensure continued compliance.

13 Does this Recommendation only apply to legal manufacturers located in Europe?

No, this Recommendation applies to **ALL legal manufacturers** who are placing product on the market within the European Economic Area regardless of where their facilities are located in the world.

14 If on the day of the unannounced visit our key staff is not available, what should we do?

Our auditors will arrive at your site expecting to be able complete their audit, under Annex III of the Recommendation you are required to advise BSI of periods where there is absolutely no manufacturing (for example site shutdown),BSI will take this into account when scheduling visits. Unannounced visits have to be conducted on the basis that the necessary actions have been taken and that processes are in place to ensure you will be able to respond and allow the audit to continue and that all appropriate staff will have been trained to expect such a visit. Where extenuating circumstances do occur during an unannounced visit, BSI will implement a process to review the circumstances and determine the best path to return to compliance. This will be judged on a case- by- case basis.

Any form of obstruction or prevention to permitting the audit to be undertaken will result in a review to determine whether the process to suspend and ultimately withdrawal a certificate should be applied, if the certificate is not brought back into compliance.

15 What should we expect on the day of the audit?

The auditors will arrive and present themselves at your reception asking to speak with the most Senior Executive / Manager on site. They will identify themselves and present identification credentials, explaining the objective of the visit.

In-line with the Commission Recommendation you would be expected to comply with their requests. One of the requirements is to inspect current production, it is therefore important that auditors are given access to information and have the ability to witness such inspection/testing.

In order to meet the requirements our auditors will work to prepared plans taking into account they types of products and compliance history, these plans may need to be adjusted on the day and our auditors would discuss the most appropriate way to achieve this with an attempt to minimise any potential disruption to your operations whilst still completing the necessary activities.

At the close of the audit, you will be given a brief summary of the audit, no report will be available before the auditors leave your site, this will be compiled off-site and sent to you within approximately one week of the audit.

Should any findings be identified you will be advised the process to present your corrective action plan.

16 How does the Unannounced Audit fit into the routine audit reporting cycle, will you be closing outstanding Non-Conformance Report's (NCR's) from previous audits, and will you be issuing Non-Conformities should the need arise from the Unannounced Audit?

Any non-conformities arising from Unannounced Visits will be issued in the normal way. Since unannounced visits are conducted outside the normal surveillance programme it is not appropriate to conduct routine audit activities such as following up on non-conformities from previous assessments, these will be followed up in the normal way through the routine surveillance cycle. Your compliance history including recent non-conformities will be taken into account when preparing for and performing

the Unannounced Assessments. The non-conformities raised as part of any Unannounced Visit will then be followed up through the routine assessments.

17 Can my company's critical sub-contractors or crucial suppliers refuse entry to the Notified Body Unannounced Audit team and if so, would my company be subject to any sanctions?

If your company's critical subcontractors or crucial suppliers choose to deny access to our audit team it will risk your compliance status. It is therefore very important that as part of your preparation for compliance with the 2013/473/EU Commission Recommendation that you review and revise as applicable, the contracts/agreements to ensure your critical sub-contractors and critical suppliers understand their obligations under your contract and that contractual arrangement are updated appropriately.

18 If BSI visits a critical subcontractors or crucial supplier who will receive the audit report and any non-conformities?

The audit report will be issued to the manufacturer who holds the CE certificate and all non-conformities will also be issued to the manufacturer. BSI will not provide a copy of the audit report or non-conformities to the critical subcontractors or crucial supplier.

19 If this is a recommendation why do we need to meet the requirements given the fact that not all member states enforce the recommendation to their notified bodies?

Although this is a recommendation it describes the requirements already required in the existing regulations and clarifies the Competent Authority expectations and is therefore not optional. MHRA and ZLG (UK and German Competent Authorities) have instructed BSI clearly to follow up in detail on the recommendation as part of the requirements for continued designation as notified body.

20 During a recent webinar it was stated that the provision for Unannounced Audits already exists. Can you please show me where I can find that provision in the current European Medical Devices Directives?

In the MDD, 93/42/EEC, it is in Annexes II, V and VI; under the section entitled 'Surveillance' it refers to Unannounced Audits by the Notified Body.

In the AIMD, 90/385/EEC, it is in Annexes II and V; under the section entitled 'Surveillance' it refers to Unannounced Audits by the Notified Body.

In the IVDD, 98/79/EC, it is in Annex IV; under the section entitled, 'Surveillance' it refers to Unannounced Audits by the Notified Body. Annex VII Production QA section 4 Surveillance states "The provision of Annex IV, section 5, shall apply"

21 Where can I find an announcement relating to the EU Commission Recommendation 2013/473/EU? Is this recommendation applicable in any

other global regulatory jurisdiction and does it apply to all European Notified Bodies?

The EU Commission published a Press Release dated 24th September 2013, reference IP/13/854 entitled, "Strengthening Consumer Safety: Improving the Safety of Medical Devices". Although this document does not specifically reference 2013/473/EU the content does reference notified bodies undertaking Unannounced Audits. For example, the fourth bullet states, "*In terms of functioning of notified bodies, they will be able to carry out random and unannounced factory audits and to check samples of materials and final products (for substitutions or adulteration of materials).*"

The following is a link to this Press release:

http://ec.europa.eu/unitedkingdom/press/frontpage/2013/13_104_en.htm

The Commission Recommendation requirements are solely applicable to manufacturers (with Notified Body EC certification) that are placing product on the market the European Economic Area. The Commission Recommendation requirements are not relevant to placing product on the market in any other countries, such as the USA, Canada, Japan, Australia etc. However, it does apply to manufacturers in those countries placing product on the market in Europe.

The Commission Recommendation is applicable to all European Notified Bodies and a full listing of these can be found on the European Commission's NANDO database website.

22 Where in my current contract with BSI can I find the provision for Unannounced Audits?

BSI's existing Terms and Conditions have the provision for the Notified Body to undertake Unannounced Audits; see clause 3. In some older contracts the provision is elsewhere; please contact your BSI Scheme Manager if you cannot find the reference.

23 How will BSI deal with companies requiring prior authorisation/approval for visitors, or those requiring additional security checks or clearance?

This is an issue that we have already identified as we recognise the need to be aware of manufacturer's procedures for site access during both our routine surveillance audits and Unannounced Visits.

All information on this type of site-specific requirement will be collated via a facility / site profile using a designated form, currently being designed, to collect all the appropriate information. We will be liaising with all clients to collate all information related to access of each of their facilities using this form. If there are particular requirements on access control we will liaise further as needed in order for us to achieve a mutually acceptable solution.

24 We were told BSI will be setting up a portal to allow input of information in regard to contractors and suppliers which will be used to determine which are critical and/or crucial. When do you anticipate this portal to be available?

BSI does need to collect and collate more information relating to manufacturers, their significant subcontractors and crucial suppliers; initially this will be achieved using a designated form (starting April 2014). In the longer term, (timescale to be confirmed) we intend to have a web-based Customer Portal

where a manufacturer can update or amend all relevant facility information directly. This information will need to include a listing of all critical subcontractors and crucial suppliers and details of those facilities. Guidance on the definitions of critical subcontractors and crucial suppliers will be provided.

25 I'm aware that BSI will be preparing an Unannounced Audit Plan for each manufacturer. When do you anticipate the Scheme Manager will begin this process? Will the final plan be shared with the manufacturer?

BSI Scheme Managers will develop a "brief" for the Unannounced Audit based on their knowledge and expertise of a particular manufacturer, including devices manufactured, manufacturing and other processes on site and other relevant factors. The selected audit team will use this brief to determine an approximate plan for their visit. This plan will not be shared with manufacturers. There will be no communication of any kind prior to an Unannounced Audit; the first knowledge will be our arrival on site. All BSI internal planning processes for determination of conduct of Unannounced Visits will remain confidential, including how and when audits will be scheduled.

26 What do you expect to be in place at our facility in regard to Unannounced Audits when BSI comes in April 2014 (or beyond that) for our regular surveillance audit ?

The EU Commission Recommendation (2013/473/EU) was published in September 2013 and it details the responsibilities not only for the Notified Body but also for the manufacturer. BSI's start date for routine conduct of Unannounced Visits, as agreed with our Designating Authorities, (MHRA and ZLG for the UK and German Notified Bodies respectively), is April 2014.

As of April 2014 we will start to check via our routine audits for evidence of awareness of this EU Commission Recommendation, and the evidence of progress towards readiness including draft processes and procedures, staff awareness and training, general preparedness etc.

How your company chooses to manage Unannounced Audits is clearly your decision. The important point to be aware of is that each manufacturer has a responsibility under the Commission Recommendation to be able to receive an Unannounced Audit from a Notified Body.

27 When do you expect to have the costs for Unannounced Audits available?

BSI plans to release the fee structure for Unannounced Audits by April 2014. We realise there is a cost/budget burden and we have been having discussions as to how to most equitably manage costs and to support our clients with making fees predictable and affordable.

28 When BSI performs an Unannounced Audit of one of our Crucial Suppliers or Critical Subcontractors, will they call us and let us know they are there?

The whole area of critical sub-contractors and crucial suppliers is a complex topic. We can confirm that you, (as the legal manufacturer), will not be notified by BSI in advance of our attendance to audit one of your critical sub-contractors or crucial suppliers, although they may notify you on the day. You have a responsibility as per the Commission Recommendation to review and revise any agreements (if needed)

with these critical sub-contractors and crucial suppliers, in order to allow Unannounced Audits by the Notified Body.

29 The Commission Recommendation states the manufacturer must notify the Notified Body of their manufacturing schedule on a continuous basis. We don't have a manufacturing forecast much past two weeks, how does BSI see the notification of our manufacturing schedule working?

The Commission Recommendation states that manufacturers must inform the Notified Body, '*on the periods when the devices falling under the notified bodies' certificates will not be manufactured*'.

Therefore we would expect to be informed of periods of non-manufacture. For example, annual shutdown, or if there is no manufacture of a particular device listed on your certificate for an extended period. We will not expect to receive detailed manufacturing schedules as we appreciate these may be complex and will vary on a weekly or daily basis. Information on periods of non-manufacture will assist with our planning and scheduling of an Unannounced Audit, where the focus is on the inspection and testing of devices being manufactured at the time of audit and verification against the specification. We will be flexible in our approach onsite to the Unannounced Visit. For example, we may have originally identified a particular device for inspection which is not currently being manufactured. In these instances the assessment team will assess the situation and may select a suitable alternative.

30 We are a subcontractor manufacturer and supplier and have many customers who have a Notified Body who may each perform Unannounced Audits to our facility. What would BSI do if they show up on a day another Notified Body is already here? If BSI is also the Notified Body for several of our customers, would this reduce the need to perform an Unannounced Audit of our facility or would the audit still need to be performed?

We are aware of this potential conflict and recognise that a degree of pragmatism is needed, and we do not have a full solution yet. Where a particular significant subcontractor / crucial supplier supports several manufacturers holding BSI EC Certification we will attempt as far as possible to conduct the visit to support all of these.

As a Notified Body we are bound by confidentiality agreements and are therefore unable to share data or information dealing with several clients. We plan to raise this and other related topics with our Competent / Designating Authorities.

31 Can you explain where can I find the definition for Critical Sub-Contractor and Crucial Supplier, what is the difference?

The Commission Recommendations specifies a significant subcontractor or crucial supplier should be visited "…*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*." For example:

Critical Subcontractor: a manufacturer of significant components; a site with regulatory responsibility or activities essential for ensuring compliance with legal requirements; design or software development;

sterilisation; sterile packaging. Crucial Supplier: a manufacturer of finished devices or key sub-assembly; supplier of critical raw materials such as silicone gel component for an implant; animal tissue for use in a heart valve.

32 Will Unannounced Audits be performed at sites that use BSI for CE product assessments only, or also for sites using BSI for quality systems assessments?

The Commission Recommendation requirements for Unannounced Visits apply to any manufacturer that is placing product on the market in Europe and holds certification from a Notified Body, for example MDD 93/42/EEC Annex II.3 or Annex V Certification, or IVD 98/79/EC Annex IV 5.4 and Annex VII section 4.

The requirement does not relate to manufacturers that place only Class I (non-sterile, non-measuring devices) on the market in Europe. It is also not a requirement for manufactures that hold only ISO 13485 certification (unless they are a class I device manufacturer or a critical subcontractor or crucial supplier to a legal manufacturer). MHRA have indicated that self-test IVD devices under Annex III.6 will not receive unannounced visits as they currently do not receive a site audit; however, self-tests using Annex IV Full Quality Assurance will require an unannounced visit.

33 My company manufactures devices across the whole range of device classifications, i.e. Class I, Class I Sterile, Class I Measuring, Class IIa, IIb &Class III. How will the frequency of Unannounced Audits be determined?

Devices which do not require Notified Body, i.e. Class I under the MDD, or self-declared devices under the IVDD are not subject to the Unannounced Audit requirements of the Commission Recommendation.

Frequency of audit is defined in the Commission Recommendation, as at least once every 3 years, and more frequently for high risk devices (specified in the Notified Body Code of Conduct as MDD Class III, all AIMD and IVD Annex II List A devices), with an Unannounced Visit frequency of once every two years. This means that for a manufacturer of devices of a range of classifications, including high risk devices, the visit cycle will default to the highest frequency.

Through our planning processes we will aim to be as efficient and cost effective as possible in scheduling Unannounced Audits to cover a range of devices manufactured at a particular site. However that may not always be possible if the product range is quite wide, across a range of device classifications and it maybe that additional visits (or duration) are required.

34 During the recent webinar a "trial phase" was mentioned, would it be possible to volunteer my company for that trial, and if so what costs would be associated with participating?

We are conducting a "trial phase" for Unannounced Audits in March 2014, in order to aid our learning, development and verification of our own systems and procedures. All manufacturers are welcome to confirm a willingness to be considered for inclusion in this trial. However we will not disclose whether any application has been included in the trial phase or not. There will be no charges associated with Unannounced Audits in the trial phase and the visit will not count in the normal Unannounced Audit cycle.

However if any issues (non-conformities) are identified we will need to follow these up in the normal way. For those companies who express a willingness to be considered, BSI is really appreciative of that offer.

35 Does the EU Commission Recommendation provide for joint audits with other regulatory agencies?

The Commission Recommendation has no provision for joint audits with any other regulatory agencies, such as US FDA or Health Canada. The Unannounced Audit will be conducted solely by BSI's Notified Body QMS Assessors and Technical Specialists. Initial indications are that Unannounced Audits are unlikely to be subject to regular witness by a Competent Authority.

36 How will Unannounced Audits work in practice? Will the Notified Body take the risk of non-availability of relevant staff or no manufacturing in progress?

Please see the response to Question 10. The manufacturer has an obligation under the Commission Recommendation to advise the Notified Body of periods of non-manufacture. Based on the information provided we will develop our schedule for Unannounced Audits, and would expect manufacturing to be in progress when we arrive to undertake such audit. It will be expected that the manufacturer will be able to host an audit within any periods not excluded by lack of manufacture.

We recognise that certain key personnel may not be available on a particular day. All staff should aware of the requirement for Unannounced Audits and be trained accordingly. We appreciate that complex or mitigating circumstances may arise on the day. Should a visit not occur we will conduct an internal review and make a determination of what follow-up action, if any, to take. This may include rescheduling to sometime in the future. If the visit has been refused, we will review the certificate status and consider the need for escalation actions to certificate suspension or cancellation.

37 Will Unannounced Audits be based on each certificate or each legal manufacturer and will they take the place of the scheduled audit?

Unannounced Audits will be based on the devices listed on the certificates issued to a particular legal manufacturer. We recognise that some manufacturers may have more than one BSI EC Certificate issued to a particular facility / location, and our audit planning will consider covering as many devices and certificates as possible as part of an individual visit.

Unannounced Audits will not take the place of the scheduled visit; they are required by the Commission Recommendation to be in addition to the regular / scheduled audits.

38 What will happen if another audit is already on-going on that day, such as by FDA?

Should another agency be undertaking an audit at the manufacturer when we arrive to perform an Unannounced Audit, it is hoped a mutually agreeable solution could be reached. This ideally would be to proceed with the assessment, but if this is impossible may result in the Unannounced Audit being re-scheduled. As a result you may be liable for any costs incurred by your Notified Body. However if we

have already started the Unannounced Audit and another agency arrives on site we would expect to complete our audit to continue and be appropriately supported.

39 If BSI is going to run further webinars how will they be promoted?

It is our intent to run further webinars on Unannounced Audits in order to explain the requirements so that manufacturers can gain a wider understanding of these and to share details or our policies, procedures and experiences as the implementation moves forward. If you are an existing BSI client you will receive an e-update notification in advance of these and there will also be notifications via our website. Please note that individuals will have to register in advance for these webinars.

40 What happens if our critical sub-contractor and/or crucial supplier refuse access to the Notified Body audit team when they arrive at the location?

This situation is challenging and the answer not straightforward. There is a provision in the Commission Recommendation (and current Medical Device Directives) outlining the manufacturers responsibility to ensure that the contract which exists between the manufacturer and critical sub-contractor and /or crucial supplier provides for the Notified Body to conduct an Unannounced Audit of that critical subcontractor or crucial supplier.

Commission Recommendation Annex III, Paragraph 2 states, "*Notified Bodies may, instead of or in addition to visiting the manufacturer, visit one of the premises of the manufacturers critical sub-contractors or crucial suppliers if this is likely to ensure more efficient control. This applies in particular if the main part of the design development, manufacturing, testing or another crucial process is located with the sub-contractor or supplier.*"

If the Notified Body is denied access, this could place the manufacturer in breach of the contract which exists between the manufacturer and BSI, which has potential consequences for the manufacturers CE certification. It is important to remember the criteria outlined in the Commission Recommendation Annex III, Paragraph 2 (see above). This will be taken into careful consideration during our planning process to determine where the audit will be undertaken. It is therefore important to ensure the company data is up to date and accurate.