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BSI Implementation of Unannounced Audits - Response Required - UK & APAC

1 message

Richard Tully <Richard.Tully@bsigroup.com> 8 July 2014 08:08

THIS LETTER WITH ATTACHMENTS CONTAINS IMPORTANT INFORMATION – PLEASE READ

BSI Implementation of EU Commission Recommendation – 2013/473/EU – Unannounced Audits

Background

As you are likely aware, the requirement for conduct of Unannounced Audits by Notified Bodies was introduced by the publication of the above Commission Recommendation in September 2013. All legal manufacturers placing CE marked devices on the EU Market are obliged to adhere to the provisions of the Commission Recommendation.

The EU Commission, through the Member States Designating Authorities, required the Commission Recommendation to be adopted and implemented by Notified Bodies, with the main new requirement being the conduct of routine Unannounced Audits in addition to the regular announced assessment visits.

The first BSI implementation, as agreed with the UK and German Designating authorities (MHRA and ZLG respectively), started on 1st April 2014.

For further information, and to listen to previous webinars or review FAQ's, please use the following link to our BSI Unannounced Audit webpage:

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

BSI Implementation of Unannounced Audits

BSI are now moving into the main phase of our roll out of Unannounced Audits and this letter and

the attachments are particularly important and require your action.

In the following sections we have included details of:

1. BSI Fees for Unannounced Audits
2. Revised BSI Terms of Contract
3. Manufacturer, Critical Subcontractor & Crucial Supplier Details Form

1) Fees for Unannounced Audits

The following table details our fees by Region which will be charged for an unannounced audit. The fees are fully inclusive of planning and reporting, travel and expenses (but excluding applicable local taxes).

As the Commission Recommendation mandates two auditors, fees are based on one Medical Device QMS Assessor and one Technical Specialist for one day onsite, and incorporate the additional offsite time required for planning, scheduling, audit preparation, travel and reporting.

Unannounced audits will be conducted once every third year, however for devices with a higher risk, i.e. Class III medical device, AIMD or Annex II List A IVD, it shall be every two years; this is based on the Commission Recommendation requirement and the Notified Body – Code of Conduct.

Region	Pricing Local Currency		Notes
EMEA	**5510**	**EUROs**	All inclusive of travel time, expenses and including the additional offsite time required for scheduling, planning, audit preparation, and reporting.
UK	**4680**	**GBP**	
US	**8000**	**USD**	
APAC	**4680**	**GBP**	

Note: Fees are subject to annual review, and for larger more complex organisations or audits requiring additional time additional fees will be charged.

The provisions of the Recommendation also include for the audit to be undertaken at the critical subcontractor or crucial supplier location. Should this occur the fees detailed above are applicable and are the responsibility of the legal manufacturer.

In addition, if any of the following situations should arise:

- Notified Body refused access to facility;
- Notified Body aborts audit due to the inability of the audit team to carry out the audit as a result of manufacturer constraints or obstacles; or
- Notified Body partially aborts the audit as a result of manufacturer constraints or lack of cooperation;

the full invoice value will be charged.

Note on Commission Recommendation Compliance

You should be aware that Notified Bodies are being directed by National Competent Authorities to ensure that all legal manufacturers are in compliance with this EU Recommendation; it is not optional and failure to comply will result in enforcement action that if not resolved without undue delay, could result in escalation actions to suspension or cancellation of EC certificates.

2) BSI Terms of Contract

Attached for your information is a copy of our revised Terms of Contract ref (UK)(version 05/2014).

In respect of Unannounced Audits these are referenced in Part 5, clause 3. We draw your particular attention to these as they have been revised, and recommend you give consideration to the whole of this document.

For our clients who have existing contracts we will not be issuing an updated proposal (quotation) document as existing contracts will continue. However, these revised Terms of Contract are effective immediately.

3) Manufacturer, Critical Subcontractor & Crucial Supplier Details Form

The Commission Recommendation requires the legal manufacturer to provide the Notified Body with some specific details and information e.g. dates of non-manufacturing activity etc.

To assist with the collection of the information and to have all necessary details on all sites that may be subject to Unannounced Audits, and in order to make the process as smooth as possible, we have compiled a form, (Manufacturer, Critical Subcontractor & Crucial Supplier Details Form) in Excel spread-sheet format, which we request you to complete and return to your BSI Scheme Manager.

IMPORTANT NOTE: If you participated in the trials of this form – please read

For those Manufacturers who have already completed this form in its "trial" version, and have provided it to their Scheme Manger, you do not have to resubmit the form again.)

Please review, complete and return completed form by 30 July 2014

To assist with the completion of this form we have compiled some instructions and these are included on the form. Please refer to these or should you have any a particular questions please contact your BSI Scheme Manager.

For the future, it is our intention to develop a customer web-based portal which can be used to update the information on a continuing basis; we will provide more details at a later date.

Over the next few months we will be sending out updates on email regarding important changes in the Medical Device regulatory world, to ensure you receive these please confirm which email you would like these sending to and add the email address medical.devices@bsigroup.com to your safe sender list.

Thank you for your continuing support and participation with unannounced audits. We hope you are well prepared to receive an unannounced audit or have well-developed implementation plans.

Should you have any further questions please do not hesitate to contact me.

Yours sincerely

Richard Tully

Product Specialist, Technical Manager & Client Manager

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Attachments:

- Terms and Conditions – (UK)(version 05/2014)
- Manufacturer, Critical Subcontractor & Crucial Supplier Details Form

http://medicaldevices.bsigroup.com

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By Royal Charter

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3 attachments

image001.png
6K

Medical Device Terms (2014) UK May 14.doc
279K

MDF 695 Final - Information on Manufacturer Locations and Subcontractors....xlsx
30K