Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (Text with EEA relevance)

Article 5

Surveillance and monitoring

1 For the purpose of surveillance, the designating authority of the Member State where the notified body is established shall assess an appropriate number of notified body's reviews of the manufacturer's clinical evaluations and shall carry out an appropriate number of file reviews, surveillance on-site assessments and observed audits at the following intervals:

a at least every 12 months for notified bodies with more than 100 clients;

b at least every 18 months for all other notified bodies.

That designating authority shall, in particular, examine changes which have occurred since the last assessment and the work the notified body has performed since that assessment.

2 Surveillance and monitoring conducted by the designating authorities shall appropriately address subsidiaries.

3 The designating authority of the Member State where the notified body is established shall continuously monitor that body to ensure ongoing compliance with the applicable requirements. That authority shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from other Member States, which might indicate the non-fulfilment of the obligations by a notified body or its deviation from common or best practice.

In addition to surveillance or renewal on-site assessments, the designating authority of the Member State where the notified body is established shall initiate unannounced or short-notice on-site assessments if those on-site assessments are needed to verify compliance.