

## Central Management Committee Decision



*PROTECTING PUBLIC HEALTH TOGETHER*

### CMC Decision on Harmonised Implementation of Notified Body Best Practice Guides

#### Decision

The CMC decided:

- i. Member States agree to fully implement Notified Body Operations Group Best Practice Guidance Documents listed below at national level.
- ii. Member States agree to write to inform Notified Bodies for medical devices based in their territory of the requirement to follow the available Best Practice Guidance applicable to Notified Bodies or demonstrate implementation of equally effective practices within 12 months.
- iii. Member States agree to begin auditing Notified Bodies against the criteria outlined in the applicable Best Practice Guidance and raise non-conformities where applicable.

The objective of this decision is to help achieve harmonisation in the performance of NB for medical devices and in the assessments/audits being conducted by MS authorities.

#### **Background**

The NBOG currently have 8 Best Practice Guidance (BPG) documents listed on their website ([www.nbog.eu](http://www.nbog.eu)). These BPG documents have been compiled by colleagues from the competent and designating authorities represented on NBOG. These BPG are finalised following agreement at NBOG and are tabled at the Competent Authority for Medical Device (CAMD) meeting for formal endorsement.

The current guidance documents are:

1. NBOG BPG 2006-1 Change of Notified Body
2. NBOG BPG 2009-1 Guidance on Design-Dossier Examination and Report Content
3. NBOG BPG 2009-2 Role of Notified Bodies in the Medical Device Vigilance System
4. NBOG BPG 2009-3 Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment

5. NBOG BPG 2009-4 Guidance on Notified Body's Task of Technical Documentation Assessment on a Representative Basis
6. NBOG BPG 2010-1 Guidance for Notified Bodies auditing suppliers to medical device manufacturers
7. NBOG BPG 2010-2 Guidance on Audit Report Content
8. NBOG BPG 2010-3 Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC.

Date of the decision: 23rd February 2011