

**WRITTEN REPORT TO MDEG
9 July 2013**

PROGRESS REPORT FROM THE NOTIFIED BODY OPERATIONS GROUP

Agenda Point: II. 7.3

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MAIN ACTIVITIES/PRIORITIES SINCE THE LAST MDEG REPORT (JANUARY 2013):

NBOG held two meetings on 5 February and 26 June 2013 with representatives from around 20 Member States, EFTA countries, MRA partners and the Commission, now also including representatives from the Food and Veterinary Office (FVO).

Key aspects of the meetings were

- The former Commissioner Dalli's **Joint Plan for Immediate Action**, especially the **pilot programme** concerning the performance and designation of Notified Bodies in the medical devices sector. This pilot programme is operated by a **co-ordination group** composed of representatives from the Commission and NBOG and consists of voluntary **joint assessments** across Europe involving the national Designating Authorities responsible for designation of Notified Bodies, national experts from Designating Authorities in other countries and Commission experts from FVO.

The joint assessments started in January 2013 and the co-ordination group detailed the process and developed some policies, e.g. taking, where appropriate, one more and one less experienced expert from different Designating Authorities to foster co-operation and harmonisation between assessors from Designating Authorities.

NBOG is also used as a **forum** to discuss and clarify questions arising from the joint assessments aiming to identify examples of "best practice" and to further align the practice in the conduct of Notified Body assessments and designation activities.

In addition, a first specific **training** of national Designating Authority assessors has been conducted.

- The revision of [NBOG BPG 2006-1](#) "Change of Notified Body" in order to include experience made in this area; a first draft was discussed and circulated for further comments.
- The re-opening of discussions on and development of a draft "Guidance on **Design Changes and Changes of the Quality System**"; the document will be revised and circulated for further comments.
- Re-opening the discussions on the postponed work item "Guidance on **Renewal of Certificates**".
- The revision of **checklists and forms** for Designating Authorities currently being part of the NBOG [Designating Authorities Handbook](#)". The group discussed a "guidance document on the information required for Notified Body medical device personnel involved in conformity assessment activities", which is linked to the template "qualification of personnel" used by Notified Bodies.
- Revisions of the scope expressions in [NBOG BPG 2009-3](#) "Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment". Changes have been implemented in the revised and published forms [NBOG F 2012-1](#) to [NBOG F 2012-3](#), which will be used for future (re-)designations.

- Discussions on procedural aspects, e.g. information obligations of Notified Bodies and information flow between Notified Bodies and competent authorities being responsible for market surveillance, vigilance or designation.
- Discussions on standards in respect to the partially insufficient contents of informative Annexes Z and their respective **presumption of conformity**.
- Discussions on activities of NB-MED, IAF and IMDRF, e.g. on the IMDRF Regulated product submission (RPS) and on the Medical Device Single Audit Program (MDSAP).

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Current Chair of NBOG

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