

**WRITTEN REPORT TO MDEG
17 November 2014**

PROGRESS REPORT FROM THE NOTIFIED BODY OPERATIONS GROUP

Agenda Point: II. 7.3

Contact Person: Rainer Edelhäuser

MAIN ACTIVITIES/PRIORITIES SINCE THE LAST MDEG REPORT (JANUARY 2014):

NBOG had two meetings in February and June 2014 with representatives from more than 20 Member States, EFTA countries, MRA partners and the Commission (including representatives from FVO, the Food and Veterinary Office).

Key aspects of the meetings were

- The **voluntary** and the **mandatory joint assessments** concerning the performance and designation of Notified Bodies in the medical devices sector. The joint assessments are operated by a **coordination group** composed of representatives from the Commission and NBOG. Joint assessment teams consist of experts from other national Designating Authorities and Commission experts from FVO. They accompany national Designating Authorities when they perform (re-)designation assessments of their notified bodies. The coordination group also discusses procedural and content aspects arising from the joint assessments.

For information on the voluntary programme see [NBOG Coordination Group Summary Joint Assessment Programme](#) and [NBOG Coordination Group Joint Assessment Programme Interim Overview Report](#). A final report will be published by the Commission soon.

For the mandatory joint assessments an **application form** according to Commission implementing regulation (EU) No 920/2013 has been developed, which has been published as [NBOG F 2014-1](#).

- The work items relating to the discussion on and questions arising from the **Commission implementing regulation (EU) No 920/2013** on the designation and the supervision of notified bodies:
 - to establish a “Best practice” document and a checklist to avoid or minimise “diverging opinions” and to substantiate Annex II of the implementing regulation in order to avoid creating “chaos” for joint assessors when each DA would use different one’s
 - aspects relating to the “pool of assessors”

These work items have been postponed to incorporate more practical experience from the various mandatory joint assessments performed up to now.

- Discussion of questions arising from the Commission recommendation 2013/473/EU on the audits and assessments performed by notified bodies in the field of medical devices.
- Finalising the discussion on the work item “Guidance on **Renewal of Certificates**“. The document has been endorsed by the CAMD Meeting and has been published as [NBOG BPG 2014-1](#) “Renewal of EC Design-Examination and Type-Examination Certificates: Conformity assessment procedures and general rules”.

- Finalising the “Guidance on the **Information Required for Notified Body Medical Device Personnel** Involved in Conformity Assessment Activities”; this document has been endorsed by the CAMD Meeting and published as [NBOG BPG 2014-2](#) together with the respective form [NBOG F 2014-2](#) “**Qualification of personnel**”.
- Finalising the discussion on the work item “Guidance for manufacturers and Notified Bodies on reporting of **Design Changes and Changes of the Quality System**“, taking into account comments received from NB-MED/NBRG. The document has been endorsed by the CAMD Meeting and published as [NBOG BPG 2014-3](#).
- Discussion on the revision of [NBOG BPG 2006-1](#) “Change of Notified Body”, which is still ongoing. Here the current discussions in the Council Working Party on the new medical device regulations should be taken into account.
- Discussion on the various **communication** flows between authorities. Aim is to improve the current situation by aligning existing tools for a better defined and directed information exchange between the various authorities. Starting point is a cooperation of COEN and NBOG representatives analysing necessary steps for improving the currently used tools.
- Discussion on IMDRF issues, especially the medical device single audit programme (MDSAP). In principle advantages of this programme are seen but currently practical reasons made clear that a mix of mandatory joint assessments and assessments according to MDSAP should not be envisaged.

WORK PROGRAMME

NBOG will focus on work items relating to the implementation of

- the Commission Implementing Regulation (EU) No 920/2013 on the designation and the supervision of notified bodies
- the Commission Recommendation on audits and assessments performed by notified bodies in the field of medical devices
- and the preparation of tasks resulting from the revision of the medical device directives, esp. on the scope of NB designation under the future IVD regulation.

Dr. Rainer Edelhäuser
Current Chair of NBOG

ZLG – Zentralstelle der Länder für Gesundheitsschutz
bei Arzneimitteln und Medizinprodukten
Central Authority of the Laender for Health Protection
with regard to Medicinal Products and Medical Devices
Heinrich-Böll-Ring 10
D-53119 Bonn
Fon: +49 228 97794 10
Fax: +49 228 97794 44
E-Mail: rainer.edelhaeuser@zlg.nrw.de
Website: www.zlg.de, www.nbog.eu