WRITTEN REPORT TO MDEG 16 January 2014 PROGRESS REPORT FROM THE NOTIFIED BODY OPERATIONS GROUP	
Agenda Point:	**II. 6.3**
Contact Person:	**Rainer Edelhäuser**

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

NBOG met in November 2013 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 status report of 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. In November, 16 joint assessments have been conducted. For more information please see NBOG Coordination Group Summary Joint Assessment Programme and NBOG Coordination Group Joint Assessment Programme Interim Overview Report.
- Discussion of questions arising from the new **Commission implementing regulation (EU) No 920/2013** on the designation and the supervision of notified bodies. As agreed at the last Competent Authority Meeting end of September 2013, a "Best practice" document to avoid or minimise "diverging opinions" and to substantiate Annex II of the implementing regulation, a **checklist** in order to avoid creating "chaos" for joint assessors when each DA would use different one's and aspects relating to the "pool of assessors" will be developed.
- Discussion of questions arising from the new Commission recommendation 2013/473/EU on the audits and assessments performed by notified bodies in the field of medical devices.
- Discussion on a first draft "Guidance on **Design Changes and Changes of the Quality System**", which is circulated to NBOG and NB-MED for further comments
- The revision of parts of NBOG BPG 2006-1 "Change of Notified Body"; case 2 will be revised taking into account recent experience made in this area
- Starting again with the work item "Guidance on **Renewal of Certificates**" – a draft is awaited for the next meeting in February 2014
- The ongoing revision of **checklists and forms** for Designating Authorities currently being part of the NBOG Designating Authorities Handbook". Comments on the draft "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 have been discussed and the next have been agreed.