

**WRITTEN REPORT TO MDEG  
1 December 2009**

**PROGRESS REPORT FROM THE NOTIFIED BODY OPERATIONS GROUP**

**Agenda Point:** 7.2 NBOG

**Contact Person:** Rainer Edelhaeuser

**MAIN ACTIVITIES/PRIORITIES SINCE THE LAST MDEG REPORT (JUNE 2009):**

Since the last MDEG meeting NBOG met twice at 24 June and 12 November 2009.

**Main achievements** were

- The finalisation of the guidance document relating **Notified Body's Tasks of Technical Documentation Assessment on a Representative Basis**. Here a consensus between the differing expectations of Member States, Notified Bodies and industry could be reached. The document was endorsed by the Competent Authorities during their Meeting in Uppsala in July 2009 and is published as [NBOG BPG 2009-4](#) on [www.nbog.eu](http://www.nbog.eu).
- The development of **forms** to facilitate the renewal of notifications aiming for a uniform description of Notified Body scopes of designation in the NANDO database according to [NBOG BPG 2009-3](#) "Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment". The forms were endorsed by the Competent Authorities during their Meeting in Uppsala July 2009 and are published on [www.nbog.eu](http://www.nbog.eu).
- A **two-day training course** for Designating Authority Assessors held by NBOG in Brussels with 26 participants from 17 Member States and 3 EFTA, accession and MRA countries.
- Comments on NB-MED recommendations on "Machinery Directive's Essential Health and Safety Requirements (EHSR) relevant for Medical Devices" and "Procedure packs per the Medical Device Directive 93/42/EEC" were forwarded to the Chair of NB-MED.
- Comments on the Notified Body section of the proposed revision of MEDDEV 2.7/1 Evaluation of Clinical Data drafted by the Clinical Investigation and Evaluation WG (CIE) were given.
- NBOG contributed to the Member States' discussions on the future regulation in the area of designation and monitoring of Notified Bodies.

**Peer review programme**

- In 2009 already 7 observed assessments were performed and one further assessment is planned.
- Review of existing scopes of Notified Bodies designated according to [NBOG BPG 2009-3](#) "Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment". The implementation of the new scope expressions is aimed for 21 March 2010. It was agreed that necessary amendments to the defined scope expressions would be made once a year.

**Current work items** are amongst others<sup>1</sup>

- A guidance document on Notified Body's Tasks in Auditing Quality Systems with Respect to Subcontractors of Medical Device Manufacturers.
- A guidance document on Audit Report Content, aiming to implement GHTF SGR/N33R16 : 2007 Regulatory Audit Reports in Europe.
- The revision of [NBOG BPG 2006-2](#) "Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC" in order to align the document with the amendments of Directives 90/385/EEC and 93/42/EEC due to Directive 2007/47/EC.
- The development of a template for notifications between Member States on certificates suspended or withdrawn defining the information required and aiming to improve the quality of data circulated. This will be done in line with EUDAMED.
- Commenting on proposed documents of GHTF, especially on SG 4's document on Multiple Site Auditing.

**THE WORK PROGRAMME FOR 2010<sup>2</sup>:**

- Finalization of work items described above.
- Review of 2009 peer assessment activities and adjustment of annual plan 2010 in the first NBOG meeting 2010; additional activities to be defined at CA Meeting in Spain.
- Activities towards future regulation in the area of designation and monitoring of Notified Bodies depending on work assignments by Member State's Competent Authorities and European Commission.

For **further information** please see [www.nbog.eu](http://www.nbog.eu).

14.11.2009

Dr. Rainer Edelhaeuser  
Current Chair of NBOG

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<sup>1</sup> See [http://www.nbog.eu/resources/NBOG\\_report\\_2005\\_2008.pdf](http://www.nbog.eu/resources/NBOG_report_2005_2008.pdf) (Annex A) for further information

<sup>2</sup> The work programme will finally be defined at the CA Meeting in Spain