NBOG meeting

On 24 June 2009, NBOG have met for their second meeting in 2009. 29 Representatives from Member States, EFTA, accession countries and the European Commission were present. The agenda covered some new work items of the NBOG work programme, which was amended during the last Competent Authorities Meeting in Prague in February 2009.

Key aspects of the meeting 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 different 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 the NBOG website 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. The forms were endorsed by the Competent Authorities during their Meeting in Uppsala in July 2009 and are published on www.nbog.eu.
- the discussion of first draft guidance documents on Notified Body’s Tasks in Auditing Quality Systems with Respect to Subcontractors of Medical Device Manufacturers and on Audit Report Content. The documents will be further discussed in the next meeting and send out for comments by the Notified Bodies Group NB-MED / NBRG afterwards.
- the work assignment for two new work items given at the CA Meeting in Prague. These are 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” due to the changes by Directive 2007/47/EC and the development of a form for notifications between Member States on certificates suspended or withdrawn to improve the quality of data circulated.
- an update on the peer review programme 2009 (already two observed assessments performed and nine assessments planned).

Other work items having been discussed were i.a.

- the implementation of directive 2007/47/EC and the respective Interpretative Document published by the European Commission,
- activities of EA project groups related to the revised New Approach regulation,
- 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), and
- the 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”, where comments for improvement were provided to NB-MED.

Following the meeting, a **two-day training course** for Designating Authority Assessors was held by NBOG in Brussels with 26 participants from 17 Member States and 3 EFTA, accession and MRA countries.

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