



NBOG meeting

On 14 January 2009, NBOG have met for their first meeting in 2009.

28 Representatives from Member States, EFTA, accession countries and the European Commission were present.

Key aspects of the meeting were

- the finalization of the guidance documents on Notified Bodies and the vigilance system and on the scope of designation. Both documents will be forwarded to the Competent Authorities Meeting in Prague for approval.
- the discussion on the draft guidance document relating Notified Body's Tasks of Technical File Assessment on a Representative Basis. A first agreement on timing, documents to be assessed, and sampling was achieved. The document will be forwarded to the Notified Bodies Group NB-MED / NBRG for comments.
- the presentation of a first draft guidance document on Audit Report Content, aiming to implement GHTF SGR/N33R16 : 2007 Regulatory Audit Reports in Europe.
- the presentation of a first draft guidance document on Notified Body's Tasks in Auditing Quality Systems with Respect to Subcontractors of Medical Device Manufacturers. The document will be discussed in the next meeting and send out for comments by the Notified Bodies Group NB-MED / NBRG afterwards.
- the peer review programme (observed assessments performed and planning for 2009)
- the outline of the NBOG report 2005 – 2008 with descriptions of each Member State's assessment, designation and monitoring system established and an overview of its operation and assessments undertaken. The report will be published after the Competent Authorities meeting in Prague.
- the plan to provide training for Designating Authority assessors in summer 2009.

Other work items having been discussed were

- the public consultation on the Recast of the Medical Device Directives and the summary of responses published by the European Commission
- the Co-operation with the Notified Bodies Group NB-MED / NBRG,
- and activities of EA project groups related to the revised New Approach regulation.

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