

MDEG Agenda Item 6.2.2 Operational Conclusions from Working Groups Notified Body Operations Group (NBOG)

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Contents

- **Work programme – Main achievements
2008 and projects 2009**
- Guidance on NB assessment of technical
documentation for class IIa/IIb devices

Achievements 2008

- Website www.nbog.eu launched for **better visibility / transparency** and **publication of already endorsed documents**
 - Change of Notified Body
 - Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC
- **Review of NB Recommendations** finalized
- **Guidance on Design-Dossier Examination and Report Content** finalized for CA endorsement
- ...

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Achievements 2008 / Projects 2009

Peer Review activities e.g.

- **NBOG questionnaire** (current practices of assessment, designation and notification in the MD sector) leading to **Brdo Resolution**
- new structure for **scope of designations** (NANDO) necessary prior to revision of scopes
- **peer assessments** (operating phase, tracking tool established, use of (pilot) report document)
- decision to re-introduce **NBOG annual reports**

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... Achievements 2008 / Projects 2009

Progress made / Projects started

- Guidance on NB assessment of technical documentation for class IIa/IIb devices
- Notified Bodies and the vigilance system
- NB Guidance on Manufacturers acting as “Own Brand Labellers”
- “**mirror group**“ for GHTF documents related to NB activities, e.g. comments on GHTF SG 4 N 28 R 4

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■ ...



... Projects 2009

- Guidance on **NB assessment of technical documentation** for class IIa/IIb devices
- Revision of MEDDEV 2.10/2 (taking into account 2007/47/EC and GHTF SG 4 N 28 R 4)
- Content of audit reports (European implementation of respective GHTF document)
- Guidance on NB's tasks in auditing quality systems with respect to subcontractors of medical device manufacturers
- Revision of clinical data checklist (with CIE)
- **Training for DA assessors** (decision by CAs req.)

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Technical Documentations – Sampling

Guidance on NB's tasks of **technical documentation assessment on a representative basis**

Questions related to

- Timing
- Kind/depth of assessment
- Reporting requirements for NBs
- Sampling: number of samples for initial/surveillance assessment
- Changes ...

presented at CA Meetings (Brdo, Paris) for decision.
Linked to this is guidance on NB's scope description:

Grouping of collective terms

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Direction to be taken by NBOG

as decided by CAs (Paris)

Timing: to be applied beginning 21 March 2010;
certificates issued before keep valid

Kind/depth of assessment: less than a design dossier examination; risk based approach; minimum assessment of essential requirements checklist, risk analysis, clinical data/evaluation and Declaration of Conformity

Reporting: according to design dossier examination for those parts to be assessed

Sampling: different approach for initial / surveillance audits; "logarithmic approach" for high numbers of generic device groups / subcategories covered ...

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Thank you for your attention!



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