



NBOG meeting

On 3 February 2011, NBOG have met for their first meeting in 2011. 26 Representatives from 21 Member States, EFTA and accession countries as well as the European Commission were present.

Key aspects of the meeting were

- 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 different views in NBOG a questionnaire outlining items for discussion with respect to the current legislation as well as in respect to “wishes for the future legislation”, i.e. proposals for specifying requirements for the content of certificates (with pros and cons) should be developed. Member States and NB-MED will be asked for their views.
- a discussion on a subset of questions from COEN – the Compliance and Enforcement Working Group – with regard to Competent Authorities’ views on certificates. Consensus could be reached on answers to 6 questions, 5 other questions need further discussion.
- starting the discussion on the new work items „Handling of Changes“ and „Renewal of Certificates“, guidance documents which are already being referenced as “separate guidance” in [NBOG BPG 2009-1](#) “Guidance on Design-Dossier Examination and Report Content”. Leading Member States have been identified and scope and content of these planned NBOG documents have been briefly discussed. Draft documents for discussion with NB-MED should be developed until end of 2011.
- starting the discussion on the other new work item “Revision of checklists and forms for Designating Authorities currently being part of the NBOG [Designating Authorities Handbook](#)”.
- the first revision of the scope expressions in [NBOG BPG 2009-3](#) “Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment”. In previous meetings it was agreed that amendments to the scope expressions would be made beginning of 2011. The discussion revealed that a new code for medical gas supply systems and a new horizontal code for medical devices utilising or being controlled by software should be added. Due to the [interpretation of the Commission’s Services](#), MDS 7005 “Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)” will be deleted.
- starting the discussions on the three areas in the Notified Body sector needing improvement¹, i.e. more specific mandatory criteria for Notified Bodies, specific criteria for the designation process, and a mandatory peer review system. With respect to mandatory designation criteria, aspects of independence, in-house competence and the Notified Body relationship to subsidiaries and external auditors/experts have been discussed. In this respect, also the presumption of conformity of the ISO/IEC 17000 series of standards was briefly considered. A new report on “[Accreditation of conformity assessment bodies](#)” of the German Commission for Occupational Health and Safety and Standardization ([KAN](#)) analysed if the standards are sufficiently complete and meaningful to satisfy the requirements of Community law. The report outlines the current deficits of the

¹ See [NBOG Progress Report 30 Nov 2010](#)

system and gives recommendations, which should be taken into account in the revision of the medical device directives.

- with respect to the NBOG peer review programme, a separate workshop is planned for detailed discussions on the experience gathered so far. Currently, 15 Designating Authorities out of 25 have been assessed. Based on this experience a set of criteria and a harmonized reporting structure should be developed.

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