NBOG Report for the period 2005 – 2008

1 Introduction

In the past, public NBOG reports were produced each year but stopped doing so in 2005. In 2008, the Competent Authorities for Medical Devices agreed that the practice should begin again to help enhance a better understanding of the work of NBOG and Designating Authorities.

The present report describes the activities and achievements and reviews the function, aims and workload of the Notified Body Operations Group (NBOG) within the period 2005 until 2008.

NBOG hopes the report will be of interest to all stakeholders in the medical devices sector. Further information on the group and its activities can be obtained from NBOG's website www.nbog.eu or from its current Chairman.

2 Background

NBOG was set up following a decision taken at a meeting of Competent Authorities in Paris in July 2000. This was in response to widespread concern that the performance of Notified Bodies in the medical device sector, and that of the Designating Authorities responsible for them, was variable and inconsistent.

Accordingly NBOG's terms of reference were agreed to be:

> **To improve the overall performance of Notified Bodies in the medical devices sector by primarily identifying and promulgating examples of best practice to be adopted by both Notified Bodies and those organisations responsible for their designation and control.**

NBOG first met in November 2000 and produced a suggested work programme, which was endorsed by Member States in December 2000. NBOG is chaired by a representative of a Member State's Competent Authority and hosted by the European Commission.

NBOG reports on its activities to the twice-yearly Competent Authorities meetings, which also review and agree its work programme.

The relation of NBOG to other European working groups is explained in MEDDEV 2.15 Rev 3 Committees/Working Groups contributing to the implementation of the Medical Device Directives.

3 Work Programme, Activities, Achievements

3.1 Overview

The usual working method is that one representative of the group takes the lead in producing a draft of a required guidance paper. This is discussed in NBOG meetings and circulated electronically to the rest of the group for comments. Appropriate documents may be discussed with the Notified Bodies Group (NB-MED) and/or relevant working groups of the Medical Devices Expert Group (MDEG). The process is repeated until the whole of the Group is able to endorse the document for approval at the Competent Authorities meetings.

In between, NBOG's tasks have been extended[1] in that "They review the "recommendations" issued by the NB-MED (group where all the EU Notified Bodies participate) and acts as a "Mirror Group" following GHTF work relating to Notified Bodies."

Within the reporting period NBOG met on

- 11 December 2006
- 12 June 2007

[1] See also http://ec.europa.eu/enterprise/medical_devices/working_group.htm

- 15 January 2008
- 27 June 2008
- 13 November 2008

(The Commission did not convene the group in 2005 and most of 2006).

In December 2006, Steve Owen (UK) – the founding chairman of NBOG – decided to step down and Competent Authorities elected at their Bonn meeting in February 2007 as new chairs

Dr. Rainer Edelhäuser (Chair)
ZLG – Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und Medizinprodukten
Sebastianstr. 189
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Maria Carleton (Vice-Chair)
Irish Medicines Board (IMB)
Medical Devices Department
Earlsfort Terrace
IE-Dublin 2
Ireland

Continuity in the work programme was and is a priority also for the new chairmanship.

Due to the difficulties in making documents endorsed by NBOG and the Competent Authorities publicly available on the Commission website, in 2008 the Chair created a new **NBOG website** www.nbog.eu. The website describes briefly the terms of reference, membership, work programme and working methods. Sub-sites contain NBOG's endorsed documents, national contact points, reports and news – all aiming for a better transparency regarding the work of NBOG.

The **current work programme** is attached as **Annex A**. For each item, the lead NBOG member is listed and a brief description of the intention as well as the current state of play is given.

3.2 Guidance documents

Within the reporting period, the following guidance documents have been discussed and partly finalized:

Guidance on changing Notified Bodies

The document produced by UK and Germany is directed primarily to manufacturers who, for whatever reason, are keen to change their Notified Body (NB) but are put off by perceived difficulties. The document also deals with the case of a NB being unable to continue due to e.g. reduction of scope or de-designation. Taking into account comments from NB-MED the final draft was endorsed.

The document has been published as NBOG BPG 2006-1 "Change of Notified Body".

Guidance on minimum data requirements to be provided on NBs Certificates of Conformity

The document is the answer to the wide variance of information given on certificates of conformity seen in the past, which frequently were unclear with respect to validity, conformity assessment route taken, devices covered, etc. Led by Sweden revised drafts were produced and discussed and comments from NB-MED were incorporated prior to endorsement.

The document has been published as NBOG BPG 2006-2 "Certificates issued by Notified Bodies".

Clinical data checklist

Failure by the NB to properly assess the relevance and meaning of clinical data has been identified as a major cause of concern. The Checklist produced by UK is intended to provide the DA

assessor with a useful aide memoire to help him ensure that the NB auditor is looking at the right things in the right way. The document was accepted by NBOG at the end of 2006 but prior to publication the Competent Authorities decided that the checklist needed revision in the light of directive 2007/47/EC. This is part of the current work programme and will be performed in co-operation with the Clinical Investigations and Evaluation (CIE) Working Group.

Guidance on the role of the NB in the medical device vigilance system

This work item was suggested to address the confusion evident in several areas about the need for NBs to be involved in assessing the manufacturers systems for reporting adverse events and to keep itself informed of events as they arise. Belgium and France produced various drafts, which have been intensively discussed. NBOG aimed to incorporate the guidance into the revision 5 of MEDDEV 2.12-1 but this group decided otherwise.

Therefore, after publication of MEDDEV 2.12-1 rev. 5 NBOG needed to adapt its document to the MEDDEV taking into account comments received from NB-MED and the Vigilance Working Group. A final draft was produced by France end of 2008.

Audit report format(s)

This work item aims to specify at least standard headings of items to be covered in NB audit / assessment reports and to encourage NBs to systematically address these issues in their audits or at least to explain why they were not addressed. Additionally a standard format should also help the DA when monitoring the NB.

NBOG identified that separate formats were needed for different types of Conformity Assessment Annexes and decided that Ireland will produce a document for design dossier / type testing examinations and Switzerland for quality system audit reports.

A document produced by Ireland was sent out for comments to NB-MED. NBOG agreed on the revised final draft “Guidance on Design-Dossier Examination and Report Content”, which could be forwarded to the Competent Authorities for approval.

For the document on quality system audit report content NBOG decided to wait for finalization of the GHTF SG4 work item “Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Report”. NBOG observed the development of this document but could not totally align it to European requirements.

In 2008 a decision was made to create a NBOG guidance implementing the final document GHTF SG4 N33 R16 and adopt it to European needs.

Scope of Designation

This work item is part of the peer review activities (see 3.4), especially the work item “review the designated scopes of NBs shown in the Official Journal/NANDO database” (see Annex A) and aims for harmonization of scope expressions. This is deemed necessary for better consistency within the medical device sector of the NANDO database and to minimize the “distortions” identified by the public.

NBOG identified the need to produce guidance for Designating Authorities to better define the Notification Scope of a Notified Body conducting medical devices assessments. A draft was produced by Sweden and Switzerland taking into account CEN Technical report CEN/TR 15133 : 2005 "Nomenclature – Collective terms and codes for groups of medical devices". The final draft was produced by Switzerland end of 2008 reflecting all comments received.

The following work items are still under discussion:

Guidance for Notified Bodies where their clients are Own Brand Labellers (OBL)

Aim of this work item is to provide guidance specifically on the extent to which a NB whose client is an OBL can take account of certification issued by the NB of the original manufacturer. UK and Germany had prepared a first draft for discussion. In February 2008, the Commission's Services published an interpretative document, which supported the draft document.

Discussions of a revised draft in the following meetings however, revealed that no consensus could be reached. On the one hand, OBLs do exist and have existed for many years. OBLs are legal manufacturers and therefore have to fulfil the requirements of the directive. Often these companies are just labelling the product and are not directly involved in the design, manufacture and testing. In these cases the fulfilment of requirements is demonstrated via contractual arrangements between OBL and original equipment manufacturer (OEM). On the other hand, some Member States and the Commission were very critical with regard to the common practice of admitting own-brand-labelling and feared that the guidance document would indirectly legitimise doubtful practices. Since no consensus could be reached work was stopped until a decision from the Competent Authorities on how to proceed is achieved.

Revision of MEDDEV 2.10/2

MEDDEV 2.10/2 "Designation and monitoring of notified bodies within the framework of EC directives on medical devices" needs to be adapted to the current legislation. Due to some overlap with the Designating Authorities Handbook a new structure was discussed and agreed. In order to reflect changes in standardization (especially EN ISO/IEC 17021 Conformity assessment – Requirements for bodies providing audit and certification management systems) and to take into account the revision of the GHTF Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements (SG4/N28R4) published October 2008 the work on textual changes was intermitted.

NBOG actively followed the revision of the GHTF document and provided input within the commenting period. The revision of MEDDEV 2.10/2 is now part of the project list for 2009. The revision should also take into account directive 2007/47/EC.

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

The aim of this work item is to produce guidance for the new tasks of Notified Bodies of technical file assessments on a representative basis. The document should specify how Notified Bodies should interpret the respective changes in Annexes II, V and VI of directive 93/42/EEC as amended by directive 2007/47/EC.

Due to different interpretations with respect to timing, kind and depth of assessment, reporting and sampling, first a decision by the Competent Authorities on the direction to be taken was sought. UK produced a first draft document in line with the Competent Authorities decisions taken in their meeting in Paris July 2008. It is expected that the NB will review technical files at each audit and the plan would be to review all the manufacturers' files over a certain time period. Some files will need to be assessed offsite. The draft was discussed and a revised version will go out for comments to the Notified Body Group. According to the date of application of directive 2007/47/EC – 21 March 2010 – this work item has high priority.

Guidance relating Notified Body's tasks in auditing quality systems with respect to subcontractors of medical device manufacturers

This work item is the outcome of a discussion on Own Brand Labelling (see above). Aim is to produce a guidance document on Notified Body's tasks in auditing quality systems with respect

to subcontractors of medical device manufacturers. A first draft was produced by Austria, Ireland and Switzerland. The document will be discussed in the June meeting 2009 and sent out for comments by the Notified Bodies Group NB-MED / NBRG afterwards.

3.3 Review of NB-MED Recommendations

The EU Commission's Report on the Functioning of the Medical Devices Directive (93/42/EC of 14 June 1993) issued in June 2002 made various recommendations to improve the quality and consistency of implementation. One of these was that "NB-MED[2] recommendations be subject to endorsement by the Medical Devices Expert's Group (MDEG) and enforced by national authorities responsible for the designation and monitoring of Notified Bodies". At the Dublin meeting of Competent Authorities in 2004, NBOG was asked to review the NB-MED recommendations produced so far. The intention was that this review should lead to the recommendations being formally endorsed by MDEG and made into MEDDEV documents.

NBOG received a subset of those recommendations having reached "stage 3", i.e. where the document has been accepted by the NB-MED plenary for presentation to MDEG.

Out of the recommendations produced 16 items were identified as requiring review. 2 have been assigned for review to the Market Surveillance Operation group, 3 to the IVD Working Group.

The remaining recommendations should be reviewed by NBOG:

Number	NB-MED Paper Title
NB-MED Recc 2.1/Rec 1	Representative Sample
NB-MED Recc 2.1/Rec 2	Explanation of Terms
NB-MED Recc 2.1/Rec 3	Accessories and other parts of the AIMD
NB-MED Recc 2.5.2/Rec 2	Combination of CE-marked and non-CE-marked medical devices and non-medical devices
NB-MED Recc 2.5.1/Rec 5	Technical documentation
NB-MED Recc 2.5.1/Rec4	Content of mandatory certificates
NB-MED Recc 2.5.1/Rec 6	Renewal of EC-design-examination and type-examination certificates
NB-MED Recc 2.5.2/Rec 2	Reporting of design changes and changes of the quality system
NB-MED Recc 2.13/Rec 1	CE-Marking of pre-MDD devices
NB-MED Recc 2.13/Rec 2	CE-marking of established IVD devices
NB-MED Recc 2.15/Rec 1	Voluntary certification at an intermediate stage of manufacture

[2] Notified Bodies meet on a regular basis in the framework of the Co-ordination of Notified Bodies Medical Devices (NB-MED). Typically the group meets two times a year. All NBs concerned with medical devices can attend. The NB-MED lays down its conclusions in recommendations and consensus statements.

NBOG developed a template addressing relevant items with respect to the usefulness/necessity and suitability for becoming a MEDDEV document. Volunteers (especially from CZ, DE, DK, IE, NL, SE and UK) performing the reviews were identified and according to their contributions and outcome of discussions, the agreed templates were forwarded to NB-MED.

With the adoption of the comments on NB-MED 2.5.1 Recc 5 Technical Documentation and forwarding those to NB-MED in July 2008, NBOG has finalized their initial task to review the Notified Body Recommendations mentioned above.

3.4 Peer Review Activities

In 2005, Member States agreed on the principle of introducing a system of peer review into the work of Designating Authorities and Notified Bodies. The peer review programme proposed should consist of a repeat of the Designating Authorities (DAs) benchmarking exercise conducted several years before, establishing a programme of accompanied audits, and initiating a very basic programme of case reviews where a Notified Body's designated scope was to be withdrawn or reduced. Such a system would

- identify examples of good performance and practice
- confirm consistency of approach in the designation and monitoring of NBs
- detect common problems and shortcomings
- facilitate transfer of skills between Member States
- enhance confidence amongst all stakeholders.

Benchmarking exercise

When NBOG was originally set up, one of its first tasks was to benchmark DAs existing practices for the designation and monitoring of NBs. It did this by means of a detailed questionnaire. The results were helpful in identifying areas of both similarities and differences in the ways that DAs operated. The results triggered a lot of NBOG's subsequent work programme, in particular the production of the Designating Authorities Handbook, the observed audit programme and various training events.

The new benchmarking exercise was performed in 2007 using an updated Questionnaire for Designating Authorities on their current practices for the designation and monitoring of Notified Bodies (see Annex B). A summary of the outcome is described in 4.1.

Observed Assessments

In 2006, a pilot project for observed assessments was performed. Representatives from the Designating Authorities of Denmark and Ireland observed the assessment team of the other Designating Authority monitoring their Notified Body. The exercise revealed that this kind of observed assessments is suitable for getting an understanding of each Designating Authorities monitoring practice, their alignment and compliance with the procedures described in the Designating Authorities Handbook, building up confidence and also for sharing experience. Potential improvements of and needs for new guidance were discussed in NBOG and a peer review protocol was drafted.

The aim of the observed assessments is for the observer to comment in a constructive way on the conduct of the assessment by the observed Designating Authority (DA). This encompass items such as

- how well had the DA assessors prepared for the audit
- the conduct of the assessment itself

- the detection of any non-conformities
- the level of seriousness assigned by the assessors to the non-conformities found
- how effectively were non-conformities communicated to the Notified Body at the "close-out" meeting, etc.
- identifying examples of good practice the observer could take home with him/her, and a greater understanding of the way different DAs approached matters.

In 2007, together with the questionnaire for designation and monitoring of Notified Bodies a Peer Review Questionnaire was sent out asking for willingness to actively participate in the programme. The Peer Review Questionnaire outcome indicated that from the 24 Member States with Notified Bodies, 14 Designating Authorities were willing to be assessed through the Peer Review program.

The following Peer Reviews took place in 2008:

- Latvia conducted a Peer Review on the German DA
- Slovenia conducted a Peer Review on the German DA
- Switzerland conducted a Peer Review on the DA of the Czech Republic
- Norway conducted a Peer review on the DA of Finland
- Estonia conducted a Peer review on the DA of Sweden

A further *Questionnaire for Designating Authorities on their Willingness to Participate in NBOG Peer Review Activities in 2009* was circulated to Member States following the November 2008 NBOG Meeting. There were no responses from the following countries with NBs: Poland, Luxembourg and Romania. Cyprus and Malta did not respond, however they have not designated Notified Bodies to date.

The chart below (Fig. 1) details the outcome of the questionnaire, highlighting the following key points:

- Willingness to participate **actively**, i.e. to observe assessments performed by other Designating Authorities
- Willingness to participate **passively**, i.e. to invite representatives from other Designating Authorities observing assessments
- **Availability / willingness to** invite **experts** for training purposes **to DA / DA assessments of Notified Bodies**
- **Availability of experts to be able** to conduct assessments for other DAs

It was highlighted by the Member States that training for DA assessors was necessary to assist in the implementation of the Peer Review. This training has been tabled for June 2009 around the time of the NBOG meeting.

A new Peer Review Assessment form to assist in the conduct of Peer Review was drafted and will be piloted as part of the Peer Review Program in 2009.

Review of scopes of designations

The discussions in NBOG revealed that the current practice of describing the scope of designations presented in the NANDO database vary heavily and interested users like manufacturers and Authorities responsible for market surveillance required an improvement. Designating Au thorities were asked to review the existing scopes of their Notified Bodies and, if needed, redefine the scopes. In doing so it was evident that a level playing field, where the Notified Bodies

can fairly compete, can only be achieved applying a common set of scope expressions. Therefore NBOG proposed to Competent Authorities to work on a respective guideline (see 3.2 Scope of designations) prior to re-define the scopes.

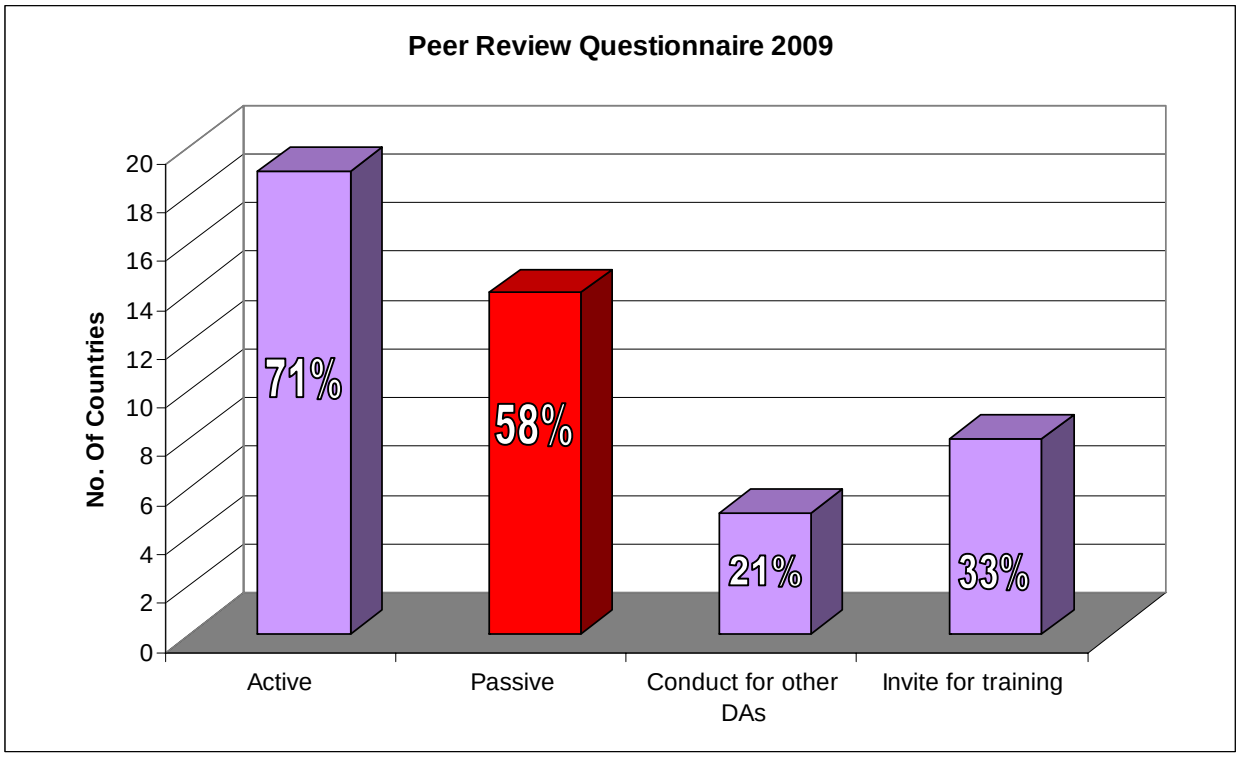

Fig. 1 Outcome of the Peer Review Questionnaire for 2009; percentage based on number of Designating Authorities having designated Notified Bodies (24)

3.5 European and International Matters – Mirror Group for GHTF activities

At the Competent Authorities Meeting in Lisbon in 2007, Member States decided that NBOG also should serve as European "mirror group" for activities of the Global Harmonization Task Force (GHTF) relating to documents being relevant for Notified Bodies.

Within the reporting period, NBOG observed thoroughly the activities, especially, of GHTF SG 4 Regulatory Auditing and commented on their documents as well as on documents of other GHTF study groups being relevant for the work of Notified Bodies and Designating Authorities, e.g.

- GHTF SG 1 (PD) N055 R6 Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer
- GHTF SG1 N41 Essential Principles of Safety and Performance of Medical Devices
- GHTF SG1 N11 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance on Medical Devices (STED) including European Commission's Note to MDEG on the GHTF STED document and its use in Europe
- GHTF SG3 (PD) N17R7 Quality management system – Medical devices – Guidance on the control of products and services obtained from suppliers

- GHTF SG4 N28 R4 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements
- GHTF SG4/N33R16 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports

NBOG also reviewed and commented on the public consultation "Recast of the Medical Device Directives" published by the European Commission in 2008.

For comments on NB-MED recommendations see 3.3 above.

4 Designating Authorities Activities

Besides the sections on background and work programme Competent Authorities decided that NBOG reports also should contain a section demonstrating, albeit briefly, what each Designating Authority had been doing to control and designate its Notified Bodies. Accordingly Member States were asked to prepare short descriptions of their assessment, designation, and monitoring system established and an overview of their operations, assessments undertaken, details of any actions/restrictions as well as any common findings. The individual responses are listed in Annex C.

4.1 Status quo of Designation – Questionnaire

The section on system descriptions is a follow-up activity of the benchmarking exercise using the updated Questionnaire for Designating Authorities on their current practices for the designation and monitoring of Notified Bodies (see Annex B) described in 3.4.

In total, 31 States – the 27 Member States, Iceland, Liechtenstein, Norway and Switzerland – were asked for information. Remarkably, all have participated in this exercise and returned the completed questionnaire. The data reflect the status in the second half of 2007 / beginning of 2008.

The questionnaire concerned the number, scope and size of Notified Bodies designated, their size in terms of personnel and certificates issued as well as their geographical activity. In addition, focus was put on the understanding of the responsibilities for assessment, designation and notification within the Member States, the activities of the Designating Authorities and if accreditation is used, the current practice of assessment and monitoring of Notified Bodies including some additional aspects e.g. on legal tools.

Unfortunately, the quality of data was less than expected, i.e. comparability and informative value are limited. Nevertheless, the data received give a good overview on the current situation of Notified Bodies being designated and controlled by the respective Designating Authorities.

Number and Size of Notified Bodies

At the time of data collection, in total 72 Notified Bodies were designated by 24 of 31 States. Figure 2 gives an overview.

All of the Notified Bodies are designated under Directive 93/42/EEC, i.e. there are no designations solely for e.g. Directive 90/385/EEC or 98/79/EC. The scope of 28 bodies comprises Directive 2003/32/EC.

The distribution shown in Figure 3 demonstrates that the majority of Notified Bodies (about 50 %) has 5 or fewer employees in the field of medical devices. 30 % have more than 10 employees. The distribution for subcontracted personnel differs. With reference to the partly huge scopes of designation it is questionable if all Notified Bodies do have sufficient scientific staff within the organization as required by Annex XI 93/42/EEC.

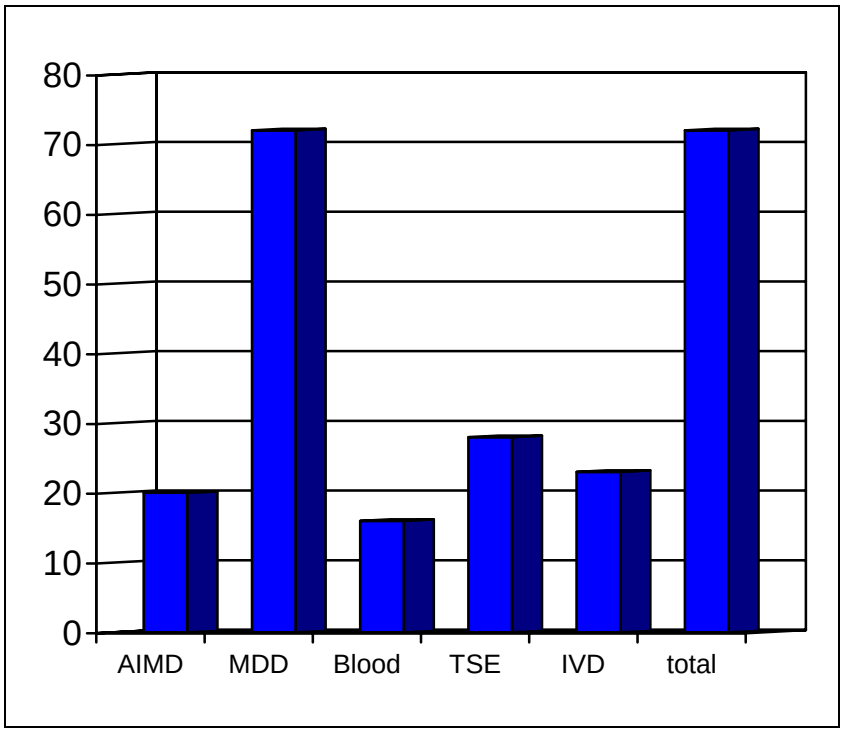

Fig. 2 *Number of Notified Bodies (y-axis) designated by 24 States in respect to the relevant medical device directives 90/385/EEC (=AIMD), 93/42/EEC (=MDD), including 2000/70/EC (=Blood), 2003/32/EC (=TSE), and 98/79/EC (= IVD)*

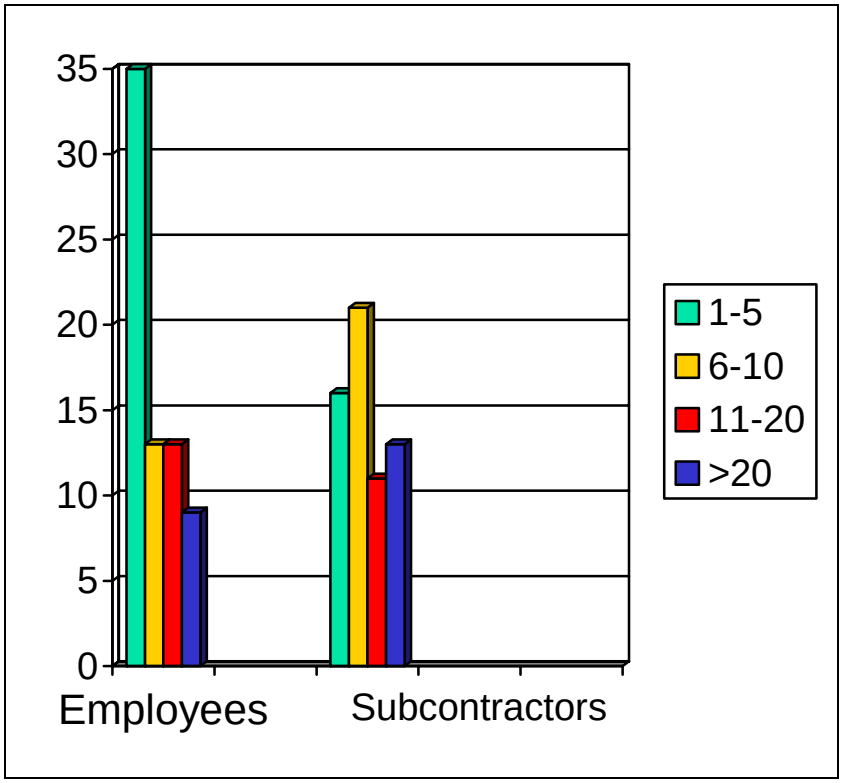

Fig. 3 *Size of Notified Bodies: Number of Notified Bodies (y-axis) in terms of internal (Employees) and subcontracted personnel (Subcontractors)*

Another distribution reflecting the size of Notified Bodies is shown in Figure 4. The figure demonstrates that there are about 40 % “small” Notified Bodies with less than 50 certificates, around 30 % “medium” Notified Bodies with 100 to 500 certificates, and only a few (around 5 %) “big players” with more than 1000 certificates.

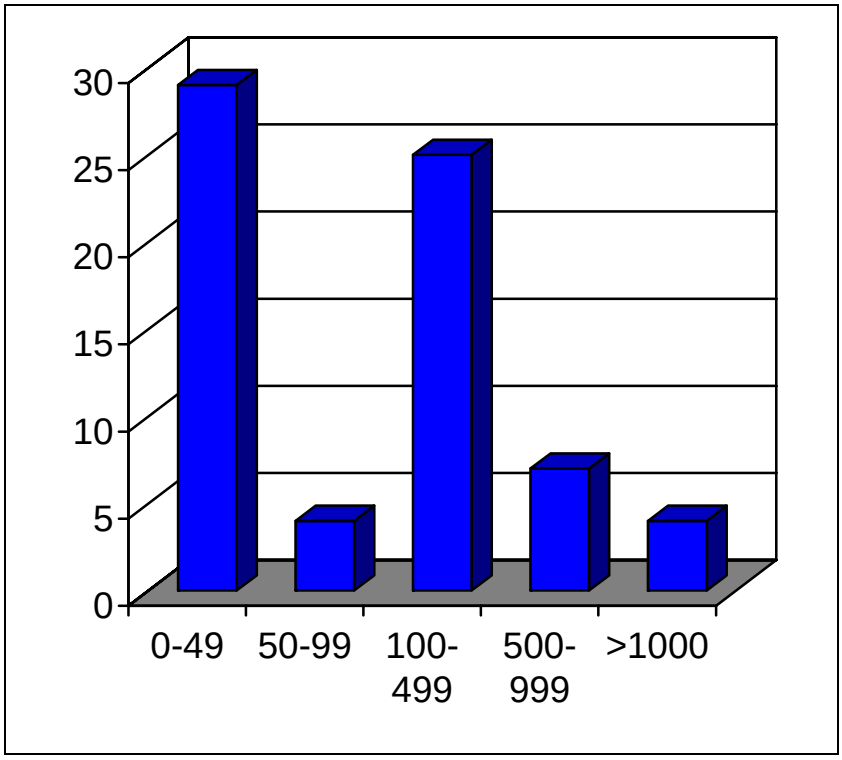

Fig. 4 Size of Notified Bodies: Number of Notified Bodies (y-axis) in terms of valid certificates issued (x-axis)

The geographical distribution shown in Figure 5 demonstrates that most of the Notified Bodies work in their domestic markets and within the European Union (about 60 %). About 1/3 each are active also in America and Asia. 13 Notified Bodies are active in addition in other regions, e.g. Africa, Australia.

The validity of data presented in Figures 4 and 5 is partly doubtful because data were not delivered for all Notified Bodies.

Designating Authorities – Current Practices

Besides questions regarding the current status of the Notified Bodies the questionnaire focused on the current practices of Designating Authorities in assessing, designating and monitoring their Notified Bodies. Most questions related to NBOG’s Designating Authorities Handbook and MEDDEV 2.10/2 Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices.

The feedback revealed that in nearly all of the Member States (about 90 %) having designated Notified Bodies the Designating Authority performs assessments. Accreditation is mandatory in only 9 of those Member States, where in two of those the Designating Authority is also accreditation body.

In 5 Member States a joint assessment by the accreditation body and the Designating Authority is performed.

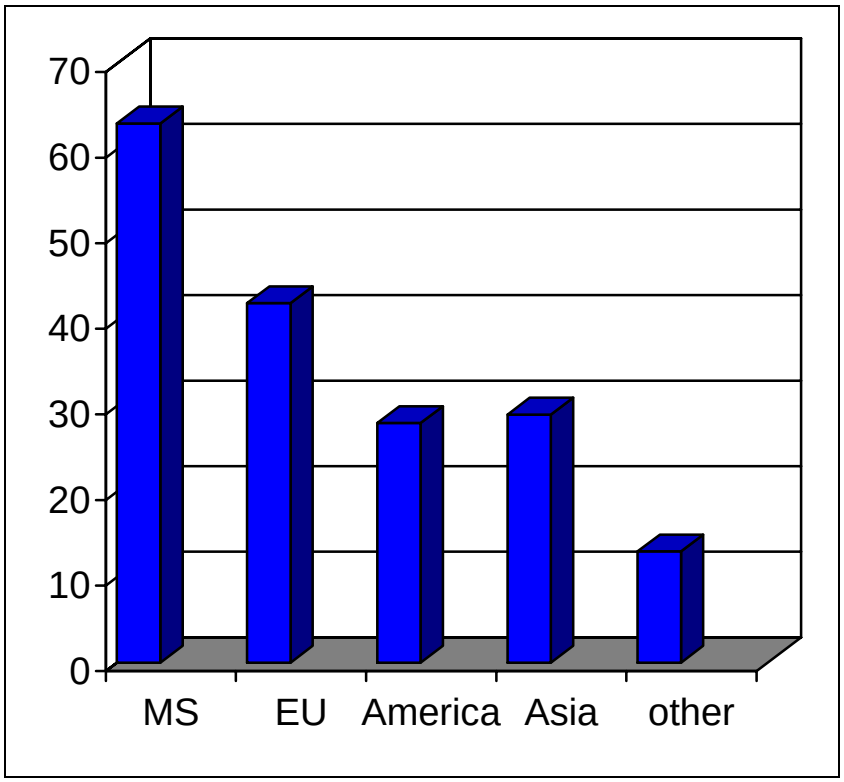

Fig. 5 *Geographical activities of Notified Bodies: Number of Notified Bodies (y-axis) in terms of geographical activity (x-axis); MS = Member State of Notified Body, EU = European Union*

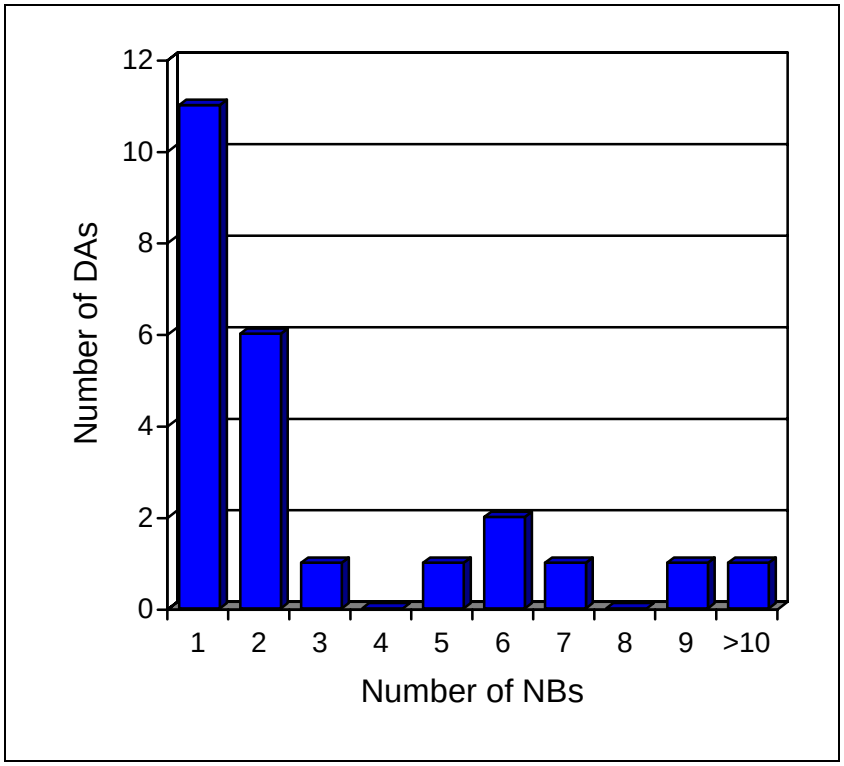

Fig. 6 *Number of Designating Authorities (DAs) being responsible for number of Notified Bodies (NBs)*

Figure 6 demonstrates that most Designating Authorities (70 %) are responsible for only one or two Notified Bodies. Only five countries have more than 5 Notified Bodies.

All Designating Authorities perform assessments prior to designation. The assessment consists of at least a document review and – for the majority – an on-site assessment. In all cases, the Notified Body's competence is reviewed. On-site assessments vary between 1,5 and 12 person days on average.

23 of the Designating Authorities (about 95 %) use MEDDEV 2.10/2, 20 (about 83 %) the DA Handbook.

Standards of the EN 45000 / EN ISO/IEC 17000 series are used by 16 (=2/3) of the DAs. 13 DAs deem these standards as not sufficient for the medical devices sector, 6 said the standards are sufficient.

Currently, not all Designating Authorities perform surveillance assessments at the Notified Bodies premises (about 85 %). The frequency of surveillance assessments varies. About 60 % are in line with the recommendations given in the DA Handbook, 20 % perform less frequent surveillance.

Observed audits are performed only by 50 %. Of those doing observed audits, 50 % limit their activities to their own territory. About 40 % are active also outside Europe. For 75 %, the frequency of observed audits is in line with the recommendations given in the DA Handbook.

The number of assessors within the Designating Authorities varies between 1 and 10 with an average of about 3.5. 2/3 of the Designating Authorities consider their resources sufficient.

In 9 countries (about 37 %) Notified Bodies are charged for designation and monitoring, for 1/3 of those total cost recovery is given.

9 (about 37 %) Designating Authorities have received compliance cases involving their Notified Bodies where it was clear that the device does not meet the requirements. Information on vigilance cases relating to devices involving conformity assessment with their Notified Body have received 13 (about 54 %) Designating Authorities.

10 (about 42 %) Designating Authorities have performed "spot checks" on their Notified Bodies.

7 (about 29 %) Designating Authorities undertook legal measures (e.g. conditions, suspension or de-designation) against their Notified Bodies for competence reasons. In the last 10 years, those have performed 15 de-designations and 14 reductions of scope.

13 (about 54 %) Designating Authorities come to know particular problems with regard to Notified Bodies located in other territories concerning manufacturers in their territory and used appropriate communication for taking measures.

Conclusion

The NBOG survey clearly reveals that despite enormous improvements in the past few years, the current practice of Designating Authorities in the medical devices area is still subject to variation. Not all DAs were using the DA Handbook.

The outcome of this NBOG survey was presented and discussed at the Competent Authorities Meeting in Brdo, Slovenia in 2008, leading to the so-called Brdo Resolution.

The Competent Authorities supported:

- implementing practices as described in the DA Handbook
- a translation of the (revised) DA Handbook into EU languages
- re-introduction of NBOG annual reports

- implementation of NBOG peer review programme (with e.g. observed assessments), which should be improved by the stronger support of all Member States
- the possibilities for commitology procedure being explored (Article 16 (2) of 93/42/EEC as amended by 2007/47/EC being a legal basis for a more unique designation and monitoring system).

4.2 Member States Round Up and common findings

In line with the decision to re-introduce NBOG annual reports and to clarify some obvious discrepancies in the returned questionnaires Member States were asked to provide a short description of the individual DA's assessment, designation, and monitoring systems established, and what their Designating Authority had been doing to control and designate its Notified Bodies.

The structured brief narratives provided by the Member States are listed in Annex C.

In the first section, name and address of the Designating Authority and their legal basis are given. The second section "Responsibilities" gives a detailed picture on who has responsibility for the respective activities. The terms used are in accordance with the DA Handbook and therefore not necessarily in line with the new definitions used in the regulation 765/2008.

In section "Number of Notified Bodies designated for" an update of the number of Notified Bodies is presented. Those figures can differ to those given in section 4.1.

The section "Designation/Monitoring" describes briefly the assessments, designations and monitoring activities performed and measures taken by the Designating Authority. In this section, some figures relate to the reporting period 2005 – 2008, some only to 2008. Where it is not possible to discuss shortcomings or corrective actions without breaching confidentiality, for example, where a Member State has only one Notified Body, information on the types of problems encountered and actions taken has been grouped together in the last section of Annex C. This prevents any individual Notified Body being singled out for criticism unfairly.

The last section "Peer assessments" describes activities under the NBOG Peer Review Programme as inviting and/or observing DA.

Clarifications or further information on the Member States contributions can be obtained from the individual national NBOG contact points[3].

5 Acknowledgments

All activities and guidance documents NBOG has produced so far would not have been possible without the commitment, willingness and contributions of all NBOG members, especially those volunteering to start drafting guidance documents and commenting on them.

Hopefully, this report shows that NBOG made real achievements so far. Many of these achievements may be small pieces on their own but together they are making a difference in the way Designating Authorities and Notified Bodies do their work.

As current Chair I would like to thank all Members and their respective organisations that have continued to ensure that people are available to contribute to NBOG as well as the European Commission for facilitating the meetings.

In the reporting period a lot of work has been done but still more is needed to ensure a consistent and competent system of designation and monitoring of Notified Bodies in the sensible medical devices sector.

[3] See http://www.nbog.eu/4.html

Only when progressing accordingly we can say NBOG is a group that delivers and makes a difference!

May 2009

Sýkorová Eva, Ing.
CA presidency

Dr. Rainer Edelhäuser
Current Chairman of NBOG

Annex A – Work Program

Work Item	Lead Country	Intention	Current State of Play
Revision of MEDDEV 2.10/2	DE	Update MEDDEV 2.10/2 to reflect various items arising from the IVD and following Directives, etc.	Revised format and structure agreed. Editorial group established; work postponed due to revision of GHTF SG4 document on regulatory auditing
Prepare guidance for Notified Bodies where their clients are Own Brand Labellers (OBL)	UK/DE	To provide guidance specifically on the issue of the extent to which a NB whose client is a OBL can take account of certification issued by the NB of the original manufacturer	Second draft prepared and discussed, no consensus reached; postponed waiting for clarification by Competent Authorities. Item needs discussion with the Commission and COEN
Review the designated scopes of individual Notified Bodies shown in the Official Journal and on the Commission's web site to ensure accuracy, clarity and consistency.	CH/DE	To ensure that NBs designated scopes are clearly and consistently described	After agreement on description of scopes all Member States need to review the current competencies of their Notified Bodies against the scopes described in the original designation letters/ NANDO database to identify any areas of inconsistency or doubt. Target date 21 March 2010
Guidance on NB's tasks of technical documentation assessment on a representative basis	UK	To ensure that NBs operate in a consistent way in applying the new requirements in Annexes II, V and VI MDD as amended by 2007/47/EC	Draft developed and discussed, going out for comments by NB-MED/NBRG
Guidance for NBs in cases their clients use suppliers / subcontractors	AT	Experience has shown that there is a big variety in the performance of NBs to include (at least critical) suppliers in their conformity assessment activities. Aim should be to develop criteria in which cases the supplier needs to be part of the NB's audit or assessment and which certifications / results of other inspections could be accepted. A close link to GHTF SG 3 should be established	Draft document to be reviewed at Jan 09 NBOG Meeting

Work Item	Lead Country	Intention	Current State of Play
Guidance on NB's Design Dossier report content	IE	Guidance to the Notified Bodies (NB) on the type of content expected of the Notified Body Design Dossier Reports of Medical Device manufacturers to ensure manufacturer's conformance to the relevant Directive and the Assessors of the Designating Authorities (DAs) on the content expected in the Notified Body's Design Dossier Report	Final draft reviewed at Nov 08 meeting
Guidance on the role of the NB in the vigilance reporting system	FR	This work item was suggested to address the confusion evident in several areas about the need for NBs to be involved in assessing the manufacturers systems for reporting adverse events and to keep itself informed of events as they arise	Final draft, comments submitted from the MDEG Vigilance group; to be finally reviewed at Jan 09 NBOG Meeting
Mirror group for GHTF	ALL	To comment on GHTF working drafts / proposed documents being relevant for Notified Bodies and Designating Authorities, e.g. STED, regulatory audit reports	Ongoing
Produce a DA Questionnaire of existing DA practices in respect to the designating and monitoring of NBs	FR/ALL	To produce a baseline of current DA activities and to identify major differences in order to plan for the Peer Review	Revised questionnaire was circulated 2007; summary of responses presented at CA Meeting February 2008 leading to the Brdo Resolution; see also section 4.1 of the report
Production of a checklist for use by a DA assessor when conducting a Peer Review	IE	To provide a simple aide memoire for use by the DA assessor when conducting a Peer Review to ensure key points are covered and assessed.	Document was drafted and discussed; to be used (pilot phase) during Peer Reviews prior to final discussion

Work items completed in the reporting period are not listed in Annex A. They are described in section 3.2.

A description of work items finalized before can be found in previous reports[4].

[4] See http://www.nbog.eu/5.html

The following new items are agreed for NBOGs Work Programme at 21st Meeting of Competent Authorities for Medical Devices Brdo, Slovenia:

Work Item	Lead Country	Intention	Current State of Play
Revision of the checklist for clinical evaluation due to the revision of the MDD	UK	To update the current checklist in line with 2007/47/EC. This work should be performed in cooperation with CIE	Co-ordination of work established
Revision of the DA Handbook	TBD	After adoption of the DA Handbook 2003 the Commission was asked to translate it into all EU languages to promote use	Translations have been provided only into the French and German language. No further translations have been done. Discussion revealed that updating would be necessary; this is to be seen in conjunction with the next work item
Elaboration of criteria on the assessment, designation and monitoring of NBs, which could be used as basis for the procedure laid down in the new Article 16 (2) MDD	TBD	With regard to the stage of adoption of the changes of the new approach this should be seen as a mid-term activity after having received the Commission's interpretation	First thoughts developed; further discussion with CAs necessary

Annex B – Questionnaire for Designating Authorities …

… on their Current Practices for the Designation and Monitoring of Notified Bodies (EC Medical Devices Directives)

MEMBER STATE	
DESIGNATING AUTHORITY	
ADDRESS	
NAME	
TEL	
FAX	
E-MAIL	

Please send the completed questionnaire back until DD MM YYYY to

Please complete the questionnaire to indicate your current practices with Notified Bodies.

1 How many Notified Bodies do you have responsibility for under the

A	90/385/EEC – AIMDD	
B	93/42/EEC – MDD	
C	– incl. 2000/70/EC "blood derivatives"	
D	– incl. 2003/32/EC "TSE"	
E	98/79/EC – IVDD	
F	Total number of Notified Bodies designated	

2 Please indicate below who has responsibility for the following activities concerning your Notified Bodies (eg your national accreditation body, yourself, jointly etc)[5]

A Assessment[1]

B Accreditation (if used)
Please indicate if accreditation is used voluntarily ☐ or is required (mandatory) ☐

[5] See NBOG Designating Authorities Handbook for further explanation of terms; please be specific in use also on further questions where those terms occur

C Designation
D Notification
E Monitoring

3 How many scientific staff (university degree or comparable degree in relevant studies, e.g. medicine, natural science, engineering) do your Notified Bodies in the medical devices area have (please indicate relevant number of Notified Bodies)

A	employed internally	1 – 5	☐
		6 – 10	☐
		11 – 20	☐
		> 20	☐
B	subcontracted	1 – 5	☐
		6 – 10	☐
		11 – 20	☐
		> 20	☐

4 How many certificates are issued by your Notified Bodies in the medical devices area? Please indicate relevant number of Notified Bodies; counting of valid certificates only.

0 – 49	☐
50 – 99	☐
100 – 499	☐
500 – 999	☐
> 1000	☐

5 What is the geographical distribution of certificates issued? Please indicate relevant number of Notified Bodies.

Member State	☐
Europe	☐
Asia	☐
America (total)	☐
Others	☐

		Y	**N**
6	Do you assess the Notified Body prior to designation?	☐	☐
7	Does the pre-designation assessment take the form of a	**Y**	**N**
A	document review?	☐	☐
B	Notified Body visit?	☐	☐
8	Is the competence of the Notified Body personnel reviewed	**Y**	**N**
A	prior to designation?	☐	☐
B	at/after Notified Body audits?	☐	☐

		Y	N
9	Do you perform an Initial Assessment of the Notified Body on-site?	☐	☐
	If yes, on average, how many man days are Initial Assessment performed in?		

		Y	N
10	In relation to MEDDEV 2.10/2 are the following elements covered in your assessments covered in questions 6 and/or 9 above		
A	General Requirements	☐	☐
B	Independence Requirements	☐	☐
C	Impartiality Requirements	☐	☐
D	Competence Requirements	☐	☐
E	Internal Procedures and Facilities	☐	☐
F	Confidentiality Requirements	☐	☐
G	Liability insurance	☐	☐
H	Subcontracting	☐	☐
I	Quality system	☐	☐

		Y	N
11	Do you perform an assessment of the testing facilities of your Notified Bodies?	☐	☐
	If yes,		
	– also for subcontractors?	☐	☐
	– in all areas/scopes of Directives (see 1 A-E)?	☐	☐
	– does it take the form of an accreditation according to EN ISO/IEC 17025 / EN ISO 15189?	☐	☐

Please indicate areas assessed

12 Please indicate any specific clauses of MEDDEV 2.10/2 which you are not currently applying (Continue on a separate sheet if necessary)

		Y	N
13	Do you use European Standards of the EN 45000 / EN ISO/IEC 17000 series for your assessment/accreditation/designation?	☐	☐

If yes, please indicate standards for (including subcontractors)

Module B (e.g. MDD Annex III)	
Module D (e.g. MDD Annex V)	
Module E (e.g. MDD Annex VI)	
Module F (e.g. MDD Annex IV)	
Module H (e.g. MDD Annex II)	

		Y	N
14	Are the requirements in the EN 45000 / EN ISO/IEC 17000 standards used sufficient?	☐	☐

		Y	N
15	Do you use the NBOG Designating Authorities Handbook for your assessment / designation? If yes, please provide a short feedback, e.g. what is missing, which parts are used / not used. Continue on a separate sheet if necessary.	☐	☐

		Y	N
16	Do you perform Surveillance Assessments? If yes, please comment on sampling activities (e.g. do you review client files, design dossiers submitted by the manufacturer, testing); continue on a separate sheet if necessary.	☐	☐

17	How many man days are Surveillance Assessments generally performed in?	☐

		Y	N
18	Please indicate what is assessed at Surveillance Assessments:		
A	Assess operational activities to ensure compliance with NB procedures	☐	☐
B	Assess operational procedures to ensure NBs compliance with the relevant directives	☐	☐
C	Review of client cases (to include assessments and product evaluations)	☐	☐
D	Review the composition of, and competence of the assessment team	☐	☐
E	Review of customer complaints and vigilance issues	☐	☐
F	Other (Please specify)		

19	On average when are Surveillance Assessments conducted on each Notified Body? (Please tick as appropriate)	
A	every 6 –12 months	☐
B	every 12 – 18 months	☐
C	every 18 – 24 months	☐
D	> 24 months	☐

20 Please indicate the nature of the most common problems identified during Initial and / or Surveillance Assessments. Continue on a separate sheet if necessary.

		Y	N
21	Do you carry out observed audits (i.e. observing the Notified Body undertaking an audit at the manufacturer's site)? If no go to Q26.		

		Y	N
22	Do you carry out observed audits		
A	– outside of your own country?		
B	– outside of Europe?		
	If yes,		
C	– do you inform the Competent Authority/Designating Authority before carrying out observed audits/assessments outside of your own country?		
D	– in all cases?		
E	– only Authorities of countries outside the EU/EFTA?		

		Y	N
23	Please indicate what is assessed at an Observed Audit:		
A	Operational activities to ensure Notified Body compliance with its procedures		
B	Operational activities to ensure NBs compliance with the relevant directives and guidance (eg GHTF, MEDDEV)		
C	Competence of the assessors		
D	NBs assessments of technical documentation, including design dossiers if applicable		
E	NBs review of manufacturers customer complaints / vigilance issues		
F	Other (Please Specify)		

24 What is the average frequency of Observed Audits for each Notified Body? (Please tick as appropriate)

A	every 6-12 months	
B	every 12-18 months	
C	every 18-24 months	
D	>24 months	

25 Please indicate the most common problems identified during Observed Audits.

26 What are your requirements for the competence and expertise of your assessors carrying out assessments of Notified Bodies?

27 How many assessors/auditors/inspectors would be available for the assessment and surveillance of NBs

		Y	N
28	Do you make a charge for designating and monitoring your Notified Bodies?		
	If yes, do you fully recover your direct costs?		
29	Do you consider that you have enough resources to designate / monitor Notified Bodies?		
30	Have any Notified Bodies applied for extensions to scope?		
31	Have you received any compliance cases involving the Notified Bodies you have designated where it is clear that the products do not meet the requirements?		
	If yes, do you investigate compliance cases with the Notified Body?		
32	Have you received any vigilance cases relating to products involving conformity assessment with a Notified Body you have designated?		
	If yes, do you investigate relevant Notified Body activity with regard to the involved products?		
33	Have you performed any “spot checks” on Notified Bodies?		
34	Do you have the legal means to instruct Notified Bodies to withdraw a certificate?		
35	Have you taken any measures (e.g. conditions, suspension or de-designation) against your Notified Bodies for competence reasons?		

If yes,

– how many de-designations have you performed in the last 10 years?

– how many reductions of your Notified Bodies’ scopes have you performed in the last 10 years?

		Y	N
36	Have you come to know particular problems with regard to Notified Bodies residing in other Member States concerning manufacturers on your territory?		
	If yes, have you taken any measures?		

If yes, please specify (Continue on a separate sheet if necessary)

For Notified Bodies under Directive 98/79/EC only

		Y	N
37	Have you defined technical requirements for the verification of manufactured products (e.g. 98/79/EC Annex IV section 6) by Notified Bodies?		

If yes, please specify (Continue on a separate sheet if necessary)

38 Please enter any further comments that you feel are necessary/useful. Continue on a separate sheet if necessary

Additional Comments:

DATE:

NAME:

Annex C – Member States

Austria

Designating Authority	Federal Ministry of Health
Address	Radetzkystrasse 2, A-1030 Vienna Austria
Legal basis	Austrian Medical Devices Law, BGBL. Nr. 657/1996 i.d.g.F.
Responsibilities for	
Assessment	Federal Ministry of Health together with the national accreditation body (Federal Ministry for Economic Affairs) The assessment and monitoring is done in conjunction with the Austrian accreditation body (Federal Ministry for Economic Affairs) according to the Austrian Medical Devices Law (BGBl. Nr. 657/1996 i.d.g.F.) and the Austrian Accreditation Law (BGBl. Nr. 468/1992 i.d.g.F.) using the relevant standards.
Accreditation (if used)	Federal Ministry for Economic Affairs Accreditation is mandatory
Designation	Federal Ministry of Health
Notification	Federal Ministry of Health
Monitoring	Federal Ministry of Health together with the national accreditation body (Federal Ministry for Economic Affairs)
Number of Notified Bodies designated for	
– 90/385/EEC	2
– 93/42/EEC	2
– 98/79/EC	1
– **total number** of bodies	2
Designation/Monitoring	
New designations 2005 – 2008	n.a.
Number of Assessments in 2008	0
Procedures in line with	EN ISO 17011, DA Handbook
Duration of assessments	Initial assessments: 5 days, surveillance: 1 day
Number of assessors/size of assessment teams	In total: 5, size of assessment team: 2
Description of nonconformities found	
Measures taken	
Exchange of experience	Notified Body Jour Fixes two times per year

Peer assessments	
Activities	

Belgium

No information provided

Bulgaria

No information provided

Cyprus

Designating Authority	Ministry of Commerce, Industry & Tourist
Address	1421 Nicosia, Cyprus
Legal basis	Law 30(I) / 2002 and its amendments
Responsibilities for	
Assessment	Approval Committee Representatives from: 1. Ministry of Commerce, Industry and Tourist 2. Medical devices Competent Authority 3. Cyprus Organisation for the Promotion of Quality
Accreditation (if used)	Accreditation is voluntary
Designation	Cyprus Organisation for the Promotion of Quality
Notification	Cyprus Organisation for the Promotion of Quality
Monitoring	Cyprus Organisation for the Promotion of Quality
Number of Notified Bodies designated for	
– 90/385/EEC	0
– 93/42/EEC	0
– 98/79/EC	0
– **total number** of bodies	0
Designation/Monitoring	
New designations 2005 – 2008	N/A
Number of Assessments in 2008	N/A
Procedures in line with	N/A
Duration of assessments	N/A

Number of assessors/size of assessment teams	N/A
Description of nonconformities found	N/A
Measures taken	N/A
Exchange of experience	N/A
Peer assessments	
Activities	N/A

Czech Republic

Designating Authority	Czech Office for Standards, Metrology and Testing
Address	Gorazdova 24, P.O. BOX 49, 128 01 Praha 2, Czech Republic
Legal basis	the Organisation of the State Administration
Responsibilities for	
Assessment	Czech Office for Standards, Metrology and Testing
Accreditation (if used)	Czech Accreditation Institute – see http://www.cai.cz Accreditation is not mandatory but is required before assessment and the body shall be under surveillance and should be periodically reaccredited
Designation	Czech Office for Standards, Metrology and Testing
Notification	Czech Office for Standards, Metrology and Testing
Monitoring	Czech Office for Standards, Metrology and Testing
Number of Notified Bodies designated for	**to the 1st January 2009**
– 90/385/EEC	2
– 93/42/EEC	5 4 including 2000/70/EC « blood derivatives » 4 incl. 2003/32/EC « TSE »
– 98/79/EC	1
– **total number** of bodies	5
Designation/Monitoring	
New designations 2005 – 2008	6 designations – change of the scope of the designations
Number of Assessments in 2008	3 assessments – no subsidiaries
Procedures in line with	Partly according to Blue Guide, partly according to MEDDEV 2.10/2 rev. 1, partly according to EN ISO/IEC 17011, partly according to DA Handbook

Duration of assessments	For the scope of one Directive – 1 person-day as minimum, 3 person-days as maximum, 2 person-days as average
Number of assessors/size of assessment teams	2 to 7 (when the audit is connected with audits to other New Approach Directives)
Description of nonconformities found	Different nonconformities, mainly formal part of applications or certificates – one case of not properly chosen sampling plan at statistical verification according to Annex IV MDD
Measures taken	Different measures that are agreed by the Director of the Testing Department of COSMT – for using of statistical methods in the conformity assessment a guide in Czech language was developed
Exchange of experience	4 meetings every year with NBs (and CA and manufactures) from the Czech Republic focused on exchange of information from EU (NBOG and so on) and on exchange of experiences at conformity assessment, application of legislation and so on
Peer assessments	
Activities	Inviting DA in November 2008 for all three MD Directives – audit lasted 3 days

Denmark

Designating Authority	The Danish Medicines Agency (on behalf of The Ministry of Health)
Address	Axel Heidesgade 1, 2300 Copenhagen S, DK
Legal basis	Law 1046 on medical devices
Responsibilities for	
Assessment	The Danish Medicines Agency
Accreditation (if used)	DANAK Accreditation is voluntary
Designation	The Ministry of Health
Notification	The Ministry of Health
Monitoring	The Danish Medicines Agency
Number of Notified Bodies designated for	
– 90/385/EEC	0
– 93/42/EEC	1
– 98/79/EC	1
– **total number** of bodies	1
Designation/Monitoring	
New designations 2005 – 2008	0

Number of Assessments in 2008	1
Procedures in line with	DA Handbook
Duration of assessments	3 days
Number of assessors/size of assessment teams	2-3
Description of nonconformities found	See common findings
Measures taken	Conditions given to rectify nonconformities
Exchange of experience	Interpretation of legislation in general, weekly-monthly contact
Peer assessments	
Activities	One active, one passive (both Ireland)

Estonia

Designating Authority	Ministry of Economic Affairs and Communications
Address	Harju 11, Tallinn 15072
Legal basis	Product Conformity Attestation Act
Responsibilities for	
Assessment	Estonian Accreditation Centre
Accreditation (if used)	Estonian Accreditation Centre Accreditation is mandatory
Designation	Ministry of Economic Affairs and Communications
Notification	Estonian Accreditation Centre
Monitoring	Estonian Accreditation Centre
Number of Notified Bodies designated for	
– 90/385/EEC	0
– 93/42/EEC	0 0 including 2000/70/EC « blood derivatives » 0 incl. 2003/32/EC « TSE »
– 98/79/EC	0
– **total number** of bodies	0
Designation/Monitoring	
New designations 2005 – 2008	0
Number of Assessments in 2008	0
Procedures in line with	N/A

Duration of assessments	N/A
Number of assessors/size of assessment teams	N/A
Description of nonconformities found	N/A
Measures taken	N/A
Exchange of experience	N/A
Peer assessments	
Activities	18. Sept. 2008. Observation of SWEDAC (Sweden) assessing Intertek Semko AB (0413)

Finland

Designating Authority	National Agency for Medicines on behalf of Ministry of Health and Social Security
Address	PO Box 55 00301 Helsinki
Legal basis	Medical Devices Act (1505/94) modified, Amended by Act 680/1999, Act 345/2000 and Act 892/2001
Responsibilities for	
Assessment	National Agency for Medicines on behalf of Ministry of Health and Social Security
Accreditation (if used)	FINAS (Finnish Accreditation Service) Accreditation is voluntary (our present NB has the accreditation)
Designation	Ministry of Health and Social Security (legal designation)
Notification	Ministry of Health and Social Security (legal notification)
Monitoring	National Agency for Medicines on behalf of Ministry of Health and Social Security
Number of Notified Bodies designated for	
– 90/385/EEC	None
– 93/42/EEC	1
– 98/79/EC	1
– **total number** of bodies	1
Designation/Monitoring	
New designations 2005 – 2008	None
Number of Assessments in 2008	n.a.
Procedures in line with	DA Handbook (if applicable)

Duration of assessments	2 days in 2008
Number of assessors/size of assessment teams	2 each
Description of nonconformities found	See common findings
Measures taken	None
Exchange of experience	Apart from Peer Review Program no organised exchange of information (some unofficial discussions, though)
Peer assessments	
Activities	One Peer Review Audit in 2008 (assessed by the Norwegian DA)

France

No information provided

Germany

Designating Authority	ZLG Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten also on behalf of ZLS Zentralstelle der Länder für Sicherheitstechnik Bayerisches Staatsministerium für Arbeit und Sozialordnung, Familie und Frauen Referat II6 / ZLS Winzererstraße 9 D-80797 München (in charge of Notified Bodies for active medical devices only)
Address	Sebastianstrasse 189 D-53115 Bonn
Legal basis	German Act on Medical Devices (Medical Devices Act)
Responsibilities for	
Assessment	ZLG/ZLS
Accreditation (if used)	ZLG/ZLS Accreditation is mandatory
Designation	ZLG/ZLS
Notification	Federal Ministry of Economics and Technology
Monitoring	ZLG/ZLS
Number of Notified Bodies designated for	
– 90/385/EEC	6

– 93/42/EEC	16 1 including 2000/70/EC « blood derivatives » 8 incl. 2003/32/EC « TSE »
– 98/79/EC	5
– **total number** of bodies	16
Designation/Monitoring	
New designations 2005 – 2008	1
Number of Assessments in 2008	20 on-site assessments (including subsidiaries in the U.S. and China) and observed audits
Procedures in line with	DA Handbook, MEDDEV 2.10/2, EN ISO/IEC 17011
Duration of assessments	2 – 15 days, average 6 – 8
Number of assessors/size of assessment teams	available in total: 5 at ZLG, 2 at ZLS; assessment team: 2 – 5; observed audits: 1 assessor
Description of nonconformities found	The nonconformities found during the assessments of the Notified Bodies mainly related to – deficient authorisations of internal and external personnel, sometimes based on inadequate definition and implementation of qualification requirements and missing valid records – EC design examinations without involvement of competent personnel for all relevant product aspects – insufficient traceability of the decision making process, sometimes due to missing or too little conclusive records on results of parts of the conformity assessment procedure – deficient procedures and relating documents, for e.g. assessment of clinical evaluation, consultation of competent authorities with respect to medicinal substances or handling of incidents reported to the Notified Body – incomplete compliance with procedures – inadequate content of certificates and failures in their registration in the German data base on certificates – insufficient regulations on impartiality.
Measures taken	As corrective actions, mainly a revision of the authorisation of the personnel, training and re-training as well as adaptations of existing or creation of new procedures and documents have been agreed upon with the Notified Bodies. As far as individual conformity assessments were concerned, the Notified Bodies have been asked to check the respective certifications, resulting in rework and – in some cases – suspension or withdrawal of the certificates. For several Notified Bodies, the scope of the designation has been restricted or conditions for the designation have been issued.

Exchange of experience	Meetings twice a year; provision of information and documents by e-mail on a regular basis several times a year; individual discussions with single Notified Bodies
Peer assessments	
Activities	1 assessment by a German assessor in and on behalf of Slovenia; participation of an assessor from Latvia in 1 assessment in Germany, 2 other DAs invited

Greece

No information provided

Hungary

No information provided

Iceland

No information provided

Ireland

Designating Authority	Irish Medicines Board
Address	Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.
Legal basis	Statutory Instrument numbers 304 and 444 of 2001
Responsibilities for	
Assessment	IMB
Accreditation (if used)	Accreditation is not mandatory
Designation	IMB
Notification	IMB
Monitoring	IMB
Number of Notified Bodies designated for	
– 90/385/EEC	1
– 93/42/EEC	1 including 2000/70/EC « blood derivatives » including 2003/32/EC « TSE »
– 98/79/EC	1
– **total number** of bodies	1
Designation/Monitoring	
New designations 2005 – 2008	No new designations were performed between 2005 and 2008.
Number of Assessments in 2008	3 surveillance audits and 2 observed audits

in 2008	
Procedures in line with	DA Handbook and MEDDEV 2.10-2 Rev 1
Duration of assessments	Surveillance audits– minimum 4 person days, maximum 16 person days, average 9 person days. Observed audits– minimum 1 person day, maximum 2 person days.
Number of assessors/size of assessment teams	Surveillance audits– up to 2 auditors and 3 technical assessors. Observed audits– 1 auditor.
Description of nonconformities found	See common findings
Measures taken	In all cases, containment actions were taken to identify any potential affected product on the market. In addition, corrective actions were implemented to prevent recurrence of the root cause. These actions are tracked to closure by the IMB and followed up at audit. More recently, we have started tracking and trending audit findings from notified body audits and have shared this information with the notified body involved. In cases where we identify that a corrective action has not eliminated the root case, and the non-compliance has recurred, we meet with the notified body and talk through the root cause. The aim of this approach is to promote effective CAPAs. Aside from surveillance and observed audits, we have conducted pro-active audits of the notified body to follow-up on a poor audit performance. Periodic desk reviews to reconfirm the designation scope are on-going.
Exchange of experience	- Certificate withdrawals/suspensions- approximately 10 per year - Request for follow up of vigilance issue at NB audit- approximately 2 – 3 per year - Classification request/arbitration - < 5 per year - Regular meetings with NB - 4 per year - Participation in NB training event/information days- approximately 1 per year.
Peer assessments	
Activities	Peer review assessment conducted of Danish Medicines Agency in 2006 with subsequent review by DMA of IMB audit in 2007. Recommend that this programme become mandatory and potentially with active participation of peer reviewers in audits/ increased cooperation between MS audit teams for specific technical areas.

Italy

Designating Authority	1) Ministry of Labour, Health and Social Affairs 2) Ministry of Ministry of Economic Development
Address	1) Via Giorgio Ribotta, 5 00144 Roma 2) Via Sallustiana, 53 00187 Roma
Legal basis	D. Lgs. 507/92 (AIMD) D. Lgs. 46/97 (MD) D.M. 318/98 (NB-MD) D. Lgs. 332/2000 (DMDD)
Responsibilities for	
Assessment	1) Ministry of Labour, Health and Social Affairs 2) Ministry of Economic Development
Accreditation (if used)	1) Ministry of Labour, Health and Social Affairs 2) Ministry of Economic Development
Designation	1) Ministry of Labour, Health and Social Affairs 2) Ministry of Economic Development
Notification	1) Ministry of Labour, Health and Social Affairs 2) Ministry of Economic Development
Monitoring	1) Ministry of Labour, Health and Social Affairs 2) Ministry of Economic Development
Number of Notified Bodies designated for	
– 90/385/EEC	1
– 93/42/EEC	10 1 including 2000/70/EC « blood derivatives » and 1 including 2003/32/EC « TSE »
– 98/79/EC	0
– **total number** of bodies	10
Designation/Monitoring	
New designations 2005 – 2008	2
Number of Assessments in 2008	3
Procedures in line with	DA Handbook
Duration of assessments	6 person-days (average)
Number of assessors/size of assessment teams	5 assessors in our organization 3 (size of the assessment team)

Description of nonconformities found	- situations where the NB has issued a certificate of conformity based on an inadequate/improper assessment - inadequate scrutiny of clinical data - failure to operate within its designate scope - failure to identify the correct conformity assessment route, including incorrectly classified devices - failure to identify the correct classification - audit reports poorly written - inadequate/absence of procedures (concerning , for example, training auditors, evaluation clinical data, resolution and prevention of conflicts of interest and assurance of the impartiality of assessment and verification staff, demarcation between 93/42/EC and other directives)
Measures taken	Reduction of scope
Exchange of experience	Involving NBs in consequence of audit at manufacturer by CA inspectors (about 120 exchanges), periodical meeting with NBs in the Ministry of Labour, Health and Social Affairs (one-two per year).
Peer assessments	
Activities	We are planning a peer review with IR

Latvia

Designating Authority	Medical devices Board for Latvia Health Statistics and Medical Technologies State Agency authorized by Health Ministry of Latvia Republic
Address	12/22 Duntes street, Riga, Latvia, LV-1005
Legal basis	Minister Cabinet regulation No 581 from 02.08.2005, with Ammendment No 585 from 22.07.2008
Responsibilities for	National accreditation Bureau - LATAK
Assessment	LATAK
Accreditation (if used)	Accreditation is mandatory
Designation	CA
Notification	CA
Monitoring	LATAK
Number of Notified Bodies designated for	
– 90/385/EEC	0
– 93/42/EEC	0
– 98/79/EC	0
– **total number** of bodies	0

Designation/Monitoring	
New designations 2005 – 2008	0 - from year 2005-2008
Number of Assessments in 2008	0
Procedures in line with	not/applicable in meaning to national NB
Duration of assessments	not/applicable
Number of assessors/size of assessment teams	not/applicable
Description of nonconformities found	not/applicable
Measures taken	not/applicable
Exchange of experience	not/applicable
Peer assessments	
Activities	not/applicable

Liechtenstein

No information provided

Lithuania

Designating Authority	Ministry of Health
Address	Vilniaus str. 33, LT-01506 Vilnius, Lithuania
Legal basis	Governmental regulation No. 674 adopted in 2006
Responsibilities for	
Assessment	National Accreditation Bureau jointly with State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania (On behalf of Ministry of Health)
Accreditation (if used)	Accreditation is mandatory
Designation	Ministry of Health
Notification	Ministry of Economy
Monitoring	National Accreditation Bureau jointly with State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania (On behalf of Ministry of Health)
Number of Notified Bodies designated for	
– 90/385/EEC	0
– 93/42/EEC	1
– 98/79/EC	0
– **total number** of bodies	1

Designation/Monitoring	
New designations 2005 – 2008	0
Number of Assessments in 2008	0
Procedures in line with	Partly according MEDDEV 2.10/2 rev. 1 and DA Handbook LST EN 45011, LST EN 17025
Duration of assessments	1 day
Number of assessors/size of assessment teams	2-3 persons
Description of nonconformities found	
Measures taken	
Exchange of experience	Some discussions on the interpretation of legislation
Peer assessments	
Activities	

Luxembourg

No information provided

Malta

No information provided

Netherlands

Designating Authority	Ministry of Health, Welfare and Sport
Address	P.O. Box 20350 2500 EJ The Hague
Legal basis	Act on Medical Devices
Responsibilities for	
Assessment	Dutch Healthcare Inspectorate
Accreditation (if used)	The Dutch Accreditation Council (RvA) ISO/IEC 17021 Accreditation is mandatory
Designation	Ministry of Health, Welfare and Sport
Notification	Ministry of Health, Welfare and Sport
Monitoring	Dutch Healthcare Inspectorate

Number of Notified Bodies designated for	
– 90/385/EEC	2
– 93/42/EEC	2 including 2000/70/EC « blood derivatives » incl. 2003/32/EC « TSE »
– 98/79/EC	2
– **total number** of bodies	2
Designation/Monitoring	
New designations 2005 – 2008	1 IVD KEMA
Number of Assessments in 2008	1
Procedures in line with	DA Handbook
Duration of assessments	2 days
Number of assessors/size of assessment teams	3
Description of nonconformities found	- shortcomings in the registration of competence personnel - issue independence requirements - shortcomings information requirements CE dossier
Measures taken	No
Exchange of experience	Regularly meetings Notified Body, Dutch healthcare Inspectorate exchange of information, 4 times a year, frequent e-mail and tele-phone conferences
Peer assessments	
Activities	0

Norway

Designating Authority	Directorate of Health (i.e. formally the Ministry, but in practise the Directorate does all the work, the audits etc)
Address	PO Box 7000 St Olavs plass, 0130 Oslo, Norway
Legal basis	National regulation implementing the MD directives as well as national regulation on Notified Bodies in general: Lov 12. januar 1995 nr. 6 om medisinsk utstyr Forskrift 15. desember 2005 nr. 1690 om medisinsk utstyr Lov 16. juni 1994 nr 20 om tekniske kontrollorgan som har til oppgåve å gjennomføre samsvarsvurderingar
Responsibilities for	
Assessment	Directorate of Health

Accreditation (if used)	Norwegian Accreditation (=the national accreditation body) Accreditation: Has been voluntary for the bodies already designated. Will be mandatory in case of new designations.
Designation	Ministry of Health, based on recommendation etc from the Directorate of Health
Notification	Ministry of Trade notifies Brussels, based upon request from the Directorate of Health
Monitoring	Directorate of Health
Number of Notified Bodies designated for	
– 90/385/EEC	0
– 93/42/EEC	3 1 including 2000/70/EC « blood derivatives » 1 including 2003/32/EC « TSE »
– 98/79/EC	0
– **total number** of bodies	3
Designation/Monitoring	
New designations 2005 – 2008	None
Number of Assessments in 2008	2 on-site assessments
Procedures in line with	DA Handbook and internal procedures
Duration of assessments	4 person-days per surveillance audit on site
Number of assessors/size of assessment teams	2-3 assessors, assessment team 3-4 persons (due to internal training + sometimes includes legal expert in the audit team)
Description of nonconformities found	Incomplete training records of NB staff. Lack of written documentation of the auditing of subcontractors. Failure to comply with their own internal procedures.
Measures taken	Not needed to take measures – non-conformities have been dealt with by corrective actions
Exchange of experience	Mostly exchange of e-mails (many!), phone calls and a few meetings
Peer assessments	
Activities	Observed FI on surveillance audit at the premises of VTT (= the NB in Finland) in December 2008

Poland

Designating Authority	Ministry of Health Drug Policy and Pharmacy Department Medical Device Division

Address	15, Miodowa Street PL-00-952 Warsaw Poland
Legal basis	Act of 20 April 2004 on Medical Devices
Responsibilities for	
Assessment	Ministry of Health
Accreditation (if used)	Accreditation is voluntary
Designation	Ministry of Health
Notification	Ministry of Economy
Monitoring	Ministry of Health
Number of Notified Bodies designated for	
– 90/385/EEC	since 01.01.2005 to 31.12.2008 – 1 NB
– 93/42/EEC	since 01.01.2005 to 10.03.2005 – 4 NB since 10.03.2005 to 13.05.2005 – 5 NB since 13.05.2005 to 07.11.2007 – 6 NB since 07.11.2007 to 31.12.2008 – 5 NB 0 including 2000/70/EC « blood derivatives » 0 incl. 2003/32/EC « TSE »
– 98/79/EC	since 01.01.2005 to 07.01.2008 – 3 NB since 07.01.2008 to 31.12.2008 – 1 NB
– **total number** of bodies	since 01.01.2005 to 07.11.2008 – 6 NB since 07.11.2008 to 31.12.2008 – 5 NB
Designation/Monitoring	
New designations 2005 – 2008	2 (10.03.2005 and 13.05.2005)
Number of Assessments in 2008	4
Procedures in line with	DA Handbook, MEDDEV 2.10/2
Duration of assessments	Minimum 4 person-days Maximum 5 person-days Average 4 person-days
Number of assessors/size of assessment teams	4-5 person
Description of nonconformities found	Small nonconformities in procedures accepted by Notified Bodies

Measures taken	Notified Bodies are obliged to implement after-control recommendations, and, as fast as it is possible, to announce it Ministry of Health
Exchange of experience	Mutual training for Notified Bodies once a year.
Peer assessments	
Activities	

Portugal

No information provided

Romania

No information provided

Slovakia

No information provided

Slovenia

Designating Authority	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)
Address	Ptujska ulica 21, SI-1000 Ljubljana
Legal basis	Medical Devices Act (Official Gazette of the Republic of Slovenia no. 101/99, 70/00, 7/02, 13/02-Zkrmi, 67/02, 47/02-ZdZPZ, 31/06-ZZdr-1)
Responsibilities for	
Assessment	JAZMP
Accreditation (if used)	Slovenian Accreditation (SA) Accreditation is mandatory
Designation	JAZMP
Notification	
Monitoring	JAZMP
Number of Notified Bodies designated for	
– 90/385/EEC	0
– 93/42/EEC	1
– 98/79/EC	0
– **total number** of bodies	1
Designation/Monitoring	
New designations 2005 – 2008	0

Number of Assessments in 2008	1
Procedures in line with	Mainly DA Handbook
Duration of assessments	3 days + 1 (overview of corrective actions)
Number of assessors/size of assessment teams	3
Description of nonconformities found	See common findings
Measures taken	0
Exchange of experience	Follow-up of corrective actions
Peer assessments	
Activities	In 2008 we invited a German expert to perform the assessment of the Slovenian NB (SIQ) and we (the JAZMP experts) were the observers.

Spain

Designating Authority	MINISTERIO DE SANIDAD Y CONSUMO (MSC) (MINISTRY OF HEALTH AND CONSUMPTION).
Address	PASEO DEL PRADO 18-20.- 28071 MADRID
Legal basis	Real Decreto 634/1993, de 3 de mayo, sobre productos sanitarios implantables activos; Real Decreto 414/1996 de 1 de marzo por el que se regulan los productos sanitarios; Real Decreto 1662/2000, de 29 de septiembre, sobre productos sanitarios para diagnóstico in Vitro.
Responsibilities for	
Assessment	Medical Devices Subdirection (MDS)
Accreditation (if used)	Non used
Designation	MSC
Notification	MSC
Monitoring	Medical Devices Subdirection (MDS)
Number of Notified Bodies designated for	
– 90/385/EEC	1
– 93/42/EEC	1 incl. 2003/32/EC « TSE »
– 98/79/EC	1
– **total number** of bodies	1
Designation/Monitoring	
New designations 2005 - 2008	0

Number of Assessments in 2008	One Notified Body on-site assessment and one observed audit.
Procedures in line with	DA Handbook
Duration of assessments	2/3
Number of assessors/size of assessment teams	2/3
Description of nonconformities found	See common findings
Measures taken	N.A.
Exchange of experience	MDS and the Spanish Notified Body meet several times a year in order to deal with points concerning vigilance cases, classification of medical devices, borderline devices, assessment and quality management system auditing.
Peer assessments	
Activities	N.A.

Sweden

Designating Authority	SWEDAC
Address	Box 878, SE-501 15 Borås
Legal basis	Authority
Responsibilities for	
Assessment	Yes
Accreditation (if used)	Accreditation is voluntary
Designation	Yes
Notification	Yes
Monitoring	Yes
Number of Notified Bodies designated for	
– 90/385/EEC	none
– 93/42/EEC	2 including 2000/70/EC « blood derivatives » incl. 2003/32/EC « TSE »
– 98/79/EC	none
– **total number** of bodies	2

Designation/Monitoring	
New designations 2005 – 2008	none
Number of Assessments in 2008	2
Procedures in line with	ISO 17011+17021+17025, EN 45010+45011+45003 + LVFS 2003:11 (MDD 93/42/EEG)
Duration of assessments	4 days
Number of assessors/size of assessment teams	2 persons
Description of nonconformities found	12
Measures taken	none
Exchange of experience	none
Peer assessments	
Activities	By Estonian State Agency of Medicines and Estonian Accreditation Centre

Switzerland

Designating Authority	Swissmedic, Swiss Agency for Therapeutic Products
Address	Hallerstrasse 7, 3000 Bern 9
Legal basis	Swissmedic is the central Swiss supervisory authority for therapeutic products. It is a public service organization of the federal government.
Responsibilities for	
Assessment	Swissmedic together with the Swiss Accreditation Service (SAS) conducting joint assessments
Accreditation (if used)	Swiss Accreditation Service (SAS) Accreditation is mandatory
Designation	Yes
Notification	Swissmedic send the notification application of a new or changed scope (by using the official notification form) to the national State Secretariat for Economic Affairs (SECO). SECO, the responsible Authority for notification in Switzerland, forwards the form to the commission.
Monitoring	Yes, Swissmedic monitors together with the Swiss Accreditation Service (SAS), conducting joint assessments and witness audits.
Number of Notified Bodies designated for	
– 90/385/EEC	0

– 93/42/EEC	5 0 including 2000/70/EC « blood derivatives » 0 incl. 2003/32/EC « TSE »
– 98/79/EC	1 (limited to devices for the measurement of blood sugar)
– **total number** of bodies	5
Designation/Monitoring	
New designations 2005 – 2008	The number of bodies remained unchanged for the mentioned period. Scope changes: 93/42/EEC (3 extension), 90/385/EEC (1 cancelled), 98/79/EC (1 new)
Number of Assessments in 2008	3 (all in Switzerland)
Procedures in line with	EN ISO 17011 (SAS), DA – Handbook (Swissmedic), ISO/IEC 17021:06, EN ISO 19011:02
Duration of assessments	One day
Number of assessors/size of assessment teams	2 - 3 persons (at least one responsible for designation and one for accreditation)
Description of nonconformities found	- insufficient SOPs concerning: impartiality, outsourcing, notification of certification modifications, check of auditors training records, competence of management and personnel - insufficient monitoring of outsourced services and ensuring of the competence of their auditors and technical experts - inappropriate use of auditors and technical experts for activities outside their predefined competence - insufficient knowledge of the designated scope
Measures taken	- suspension of the scope according to the directive 90/385/EEC - reduction of the scope according to the directive 93/42/EEC - reduction of the auditors field of application by limiting predefined competences - obligation to conduct certification activities together with defined external experts - obligation to improve the insufficient SOPs
Exchange of experience	- Swiss bodies have to submit an annual report with certification activities in the medical devices field. - The annual meeting with all members is an additional opportunity to exchange experience. - In the case of particular questions, Swissmedic is open minded for all stakeholder, considering the important limitation by separation of power (a fundamental aspect of the new approach).

Peer assessments	
Activities	Swissmedic was only involved in one peer review assessment until now (as ODA). The result was insofar particular, that week points of the Notified Body (NB) in the peered MS seem to be comparable with those of the Swiss ones. Realizing that, the ODAs expectation of assessing the parts of the auditors' competence and the qualification of outsourced parts were considerable high. The ODAs recommendation is to check the auditors' quality management system knowledge not only according to ISO 9001 and to assess particular competence according to devices of which the NB issued certificates. In addition, the NB shall be able to demonstrate that the personnel involved in outsourced activities, have been initial assessed and monitored by expecting a level of competence comparable to that of the NB. And it has to be apparent, that the entity conducting the outsourced parts has for these parts a quality system established, sufficient to fulfil the entire quality system requirements of the NB.

United Kingdom

Designating Authority	Medicines and Healthcare products Regulatory Agency
Address	Market Towers, 1 Nine Elms Lane, London SW8 5NQ, UK
Legal basis	Statutory Instruments 2002 No. 618 (Consolidated legislation), 2003 No. 1697 (Amendments to cover the re-classification of breast implants and additional requirements covering devices utilising materials from TSE susceptible animal species) and Medical Devices Regulations 2007 No. 400 (Amendment to cover the re-classification of total hip, knee and shoulder joints).
Responsibilities for	
Assessment	MHRA
Accreditation (if used)	UKAS (accreditation for NBs is voluntary at present)
Designation	MHRA
Notification	MHRA
Monitoring	MHRA
Number of Notified Bodies designated for	
– 90/385/EEC	1
– 93/42/EEC	7 in total 1 including 2000/70/EC « blood derivatives » 4 incl. 2003/32/EC « TSE »
– 98/79/EC	3
– **total number** of bodies	7

Designation/Monitoring	
New designations 2005 – 2008	No new designations 5 scope extensions
Number of Assessments in 2008	14 in total, 7 of these were on-site surveillances. 7 observed audits, 3 of these abroad (USA), 2 were carried out by auditors subcontracted to NBs. MHRA do not assess affiliates, since they have no NB responsibilities.
Procedures in line with	DA Handbook
Duration of assessments	2-9 person days, average 4.6 person days
Number of assessors/size of assessment teams	3 regulatory assessors, 80+ technical/clinical specialists Team size 1- 4 persons
Description of nonconformities found	On-site surveillance: Missing documents in client records, no evidence that a product is a medical device, wrong classification, insufficient audit records, insufficient clinical data and evidence of device equivalence, poor auditor training records, backlog of audits due to lack of NB auditing resources. Observed audits: Insufficient sampling and depth of audit, time management issues, failing to establish that manufacturer had carried out their regulatory responsibilities (for example under Article 12 and Article 14), failing to establish that manufacturer kept up to date with regulatory changes etc.
Measures taken	1 reduction in designated scope, 4 temporary suspensions for part of the scope, 2 suspensions of individual assessors pending re-training, 2 permanent reductions in individual auditor scopes, requests for immediate corrective actions, requests for corrective and preventive actions. In some cases, follow-up assessments or special (additional) surveillances have also been imposed, combined with a number of specific conditions for continued operation.
Exchange of experience	Meetings between NBs and MHRA twice each year, ad-hoc meeting with individual NBs (at a total rate of 2-3/year), email notifications of regulatory news items, annual collection of NB statistical data regarding certification, and general contact by email and telephone. Specific NB assessor training events have also been undertaken by the MHRA, on average once/year.
Peer assessments	
Activities	One confirmed for January 2009, 2-3 others being planned for 2009

Common findings

In this section, the individual responses of Member States having only one Notified Body are summarized:

- Assessments: These related to shortcomings in the documentation of certain details of the file review e.g. final label/IFU review
- Audit documentation does not contain sufficient information on the fulfillment of the quality management system requirements
- Certificate Issuance: Findings included inaccurate certificate details relating to items such as dates, scope and product
- Competence: Inconsistencies were found in ensuring that audits/product reviews were allocated to staff with all the necessary competencies
- Current practice of the NB activities partly not in line with the established quality system
- Delays on auditing surveillance of manufacturers
- Deviation from Notified Body internal procedures by the notified body employees.
- Insufficient contractual relationship with applicants; applications do not include the relevant declarations and undertakings to be provided by the manufacturer
- Lack in “good audit practice”
- Lack in “good documentation practice”
- Lack in authorisation of personnel, e.g. insufficient criteria, rational for defining the scope for each of the assessment personnel is missing
- Lack in documentation of the responsibilities and reporting structure, non-consultancy requirements
- Lack in internal procedures, notification to DA, clinical data, non-conformities open, interpretation of legislation, maintenance of audit competences
- Minor non-conformities in filing and general administration
- Missing training in medical devices area
- NB does not have clear process descriptions for the various conformity assessment activities within the scope of its designation, e.g. application process, contract review, procedures to evaluate manufacturer's compliance with the chosen annexes, procedures for assessment of clinical data, procedures relating to the issue, withdrawal and suspension of certificates, procedures for the provision of information
- NB was not able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements to cover liabilities
- No traceable documentation that audit/assessment documentations are reviewed and found sufficient/acceptable prior to the issuing of certificates
- Open non-compliances: It was found that a number of non-compliances identified at previous audits were not appropriately closed out or resolved
- Promotional materials of NB offers activities, which are not in line with the requirements
- Training: For a number of auditors, trainings records for witnessed audits could not be produced