

**NOTIFIED BODY OPERATIONS GROUP  
(NBOG)**

**REPORT FOR THE PERIOD  
TO 31 DECEMBER 2002**

## Introduction

1. This report reviews the function, aims and workload of the Notified Body Operations Group (NBOG). It is NBOG's first such report and has been produced in the interest of transparency. For this reason the report deals with the Group's activities since its inception to the end of 2002. It is planned that subsequent reports will be issued on an annual basis.
2. 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 its current Chairman : Steve Owen at [steve.owen@doh.gsi.gov.uk](mailto:steve.owen@doh.gsi.gov.uk)

## Background

3. During the late 1990's there was increasing concern on the part of Member States, industry and others that the performance of Notified Bodies, and the Designating Authorities responsible for them, was uneven and inconsistent. If true this represented an unacceptable risk that non-compliant medical devices were being put onto the EU market thus threatening the health and safety of European citizens. But even if untrue, the simple perception of poor performance meant that public and political confidence in the European system of regulatory control was being undermined. It was in response to this concern that Member States and the EU Commission agreed with a UK request, at a meeting of Competent Authorities in Paris in July 2000, to set up NBOG.
4. Accordingly, NBOG had its first meeting in London in November 2000. Most Member States and the EU Commission attended. That meeting produced a suggested work programme and suggested Terms of Reference (see box below). Both these were endorsed by Member States at the informal meeting of Competent Authorities in Stockholm in December 2000.

NBOG's agreed Terms of Reference are::

*“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 Membership

5. Member States also agreed that, at least initially, membership of NBOG should be restricted to the EU Commission, members of Designating Authorities and interested officials from non-EU Member States such as EFTA and the EEA and the various applicant countries. It was also agreed that NBOG would be chaired by a Member State representative and hosted by the EU Commission.

6. Annex A, attached, lists the current core membership of NBOG. This is added to from time to time. For example NBOG has been pleased to see a greater representation recently from the various accession countries. We hope that this trend will continue as we are sure that all States will benefit from this wider participation in NBOG's work.
7. During the year NBOG has debated how to include industry and NBs in the work of the Group. Overall it has concluded that NBOG should continue to consist only of representatives of national regulatory bodies. Nevertheless there is widespread acceptance that the involvement of industry/NBs would be helpful in certain areas in ensuring that guidance is both sensible and practical and that implementation is facilitated. Accordingly NBOG plans to address this matter early in 2003 to see if it can establish a mechanism for the closer involvement of these important stakeholders.

### **NBOG Working Methods**

8. From its inception NBOG members determined that the Group would be one that made a difference. They intend to do this by producing meaningful and simple guidance and advice rather than simply being a "talking shop" at which issues are discussed in a general way but without reaching a final position.
9. Accordingly it was agreed that NBOG would meet no more than two or three times a year. These meetings would be used principally to allocate items from the work programme, as agreed from time to time by Competent Authorities, to individual NBOG members. These members would then be responsible for taking their items forward to a conclusion. Accordingly, the usual working method is for draft papers to be produced and circulated for comments to NBOG members electronically. This process is repeated until the whole of the Group is able to endorse the document. At this point it is issued for use.
10. In addition to providing written guidance however, the Group also believes it has a role to play in helping train, primarily, Designating Authority assessors. To this end it is active in identifying and providing training opportunities and initiating a programme of invitational audits. Further details are provided below.

### **Work Programme**

11. The work of NBOG is routinely reviewed at the informal meeting of Competent Authorities that take place every six months. (Regular updates are also given to the Medical Devices Experts Group meetings). This allows Competent Authorities to add to and amend the work programme to reflect items being completed or in response to specific issues that may arise.
12. Annex C to this report lists the various items allocated to NBOG so far for action. For each item, the lead NBOG member is shown, a brief description of what it is hoped the item will achieve provided and the current state of play given. From this it can be seen that several items have already been completed and others are well advanced. Many of these items, on their own, can be seen to represent fairly minor items. However collectively they are already beginning to make a real difference

in the way DAs do their work. This is consistent with NBOG's aim of being a group that actually delivers and makes a difference.

13. The single most important piece of work NBOG has been involved in this year, however, has been in constructing a Designating Authority Handbook. This is an ambitious project that aims to describe the roles and responsibilities of DAs in relation to the designation and control of their Notified Bodies. Additionally, the Handbook will give simple, direct and clear advice and guidance on how those responsibilities may best be executed.
14. While NBOG believe that the Handbook will be useful to all Designating Authorities, it is hoped that Accession Countries will derive a particular benefit from being able to learn from the experiences of others so far.
15. The Handbook will incorporate many of the individual items from NBOG's approved work programme as described in Annex C. Additionally, it will draw on existing guidance produced from a variety of sources such as MEDDEVs, the NB Recommendations Group, and GHTF, etc. But most of all the Handbook will draw upon the various lessons learnt and experiences gained by Designating Authorities since the mid-1990s. To this extent the Handbook perfectly matches NBOG's Terms Of Reference by "... identifying and promulgating examples of best practice ...".
16. The first draft of the Handbook was produced by the UK in mid 2002. Following discussion at NBOG a small editorial group, involving the UK, Germany, Netherlands, Ireland and Denmark, was established to take the work forward to completion. The editorial group met for the first time in December 2002 and substantial progress made.
17. NBOG hopes to be able to issue the Handbook to all Designating Authorities in late 2003. It is also hoped that, with the Commission's help, the Handbook can be translated into different languages.

### **Current Designating Authority Activities**

18. When Member States asked NBOG to produce an annual report they were keen not only to make transparent the work of the group itself. Additionally, they saw it as a useful vehicle to demonstrate, albeit briefly, what each Designating Authority has currently been doing to effectively control and designate its Notified Bodies. By this means, it is hoped to re-assure stakeholders generally that all Member State are taking seriously their responsibilities in this crucial area. And further that, over time and partly at least as a result of NBOG activities, that that activity will increase and become more and more effective.
19. Accordingly at Annex B is a brief narrative provided by each Member State. These describe the scale and nature of its activities over the past 12 months to designate and control its NBs. Additionally, the narratives describe as appropriate the typical types of problems encountered with their NBs and the steps taken to ensure that these are effectively addressed. (Where it is not possible to discuss these shortcomings or corrective actions without breaching confidentiality, for

example, where a Member State has only one NB, information on the types of problems encountered and actions taken has been grouped together. This prevents any individual NB being singled out for criticism unfairly.

20. Overall Annex B gives the lie to the often expressed view that DAs do not audit or try to control the activities of their NBs. In fact just the opposite is seen to be the case. Additionally it is interesting to note, although perhaps not surprising, that many of the problems experienced are common to several Member States. Accordingly it is expected that one of the uses for the information in this annex will be to help inform NBOG as to future work items that it will propose addressing.

### **Acknowledgements**

21. Finally, but by no means least it is appropriate to thank NBOG members for their contributions to the very real achievements of the group so far, their respective organisations that have continued to ensure that these people are available to contribute to NBOG and to the Commission for making meeting rooms available and dealing effectively with the circulation of papers, production of minutes etc.

**ANNEX A : NBOG Core Membership as at 31 December 2002**

<b>Country</b>	<b>National Representative</b>
Austria	Martin Renhardt
Belgium	Philippe Bauwin
Denmark	Nicky Van Leenwen
Finland	Jarko Ihalainen
France	Isabelle Tordjman
Germany	Rainer Edelhaeuser
Greece	Theo Ktenas
Ireland	Maria Carleton
Italy	Federici Emilio
Nederlands	Lammert Meinders
Portugal	Ana Maria Miranda
Spain	Carmen Abad Luna
Sweden	Lars Olsson
UK	Rob Higgins
Switzerland	Marcus Zobrist
Norway	Ingeborg Hagerup-Jenssen
Hungary	Peter Bunytai
Slavinia	Boris Antolic
Chairman	Steve Owen

## **Annex B : Member States Round Up**

### **Austria**

In Austria, the Federal Ministry for Social Security and Generations is responsible for the designation and monitoring of the Austrian notified bodies. Two people are employed on this work in addition to external auditors as required.

Currently, Austria has designated two notified bodies, one for the directives 90/385/EEC and 93/42/EEC and one for the directives 90/385/EEC, 93/42/EEC and 98/79/EC. In the past 12 months, there was no new notification and no amendment of scopes.

Over the past 12 months Austria has conducted no NB audits.

### **Belgium**

In Belgium the Ministry of Health designates a notified body for the medical devices directives only after preliminary accreditation by the Belgian national accreditation organisation Belcert/Beltest. The experts of the medical devices department participate in accreditation audits as technical experts as well as experts of the Ministry of Economy and/or the Agency for nuclear protection in function of the type of devices concerned . Observed audits and surveillance audits made by the designating authority are co-ordinated with those of the accreditation organisation.

During 2002, Belgium notified one notified body (Apragaz ) for the 93/42 Directive with a well defined scope for which the competence of the notified body was carefully evaluated. (Apragaz was already notified under other directives for similar types of equipment). A pre-audit , an initial audit and an observed audit were made .

At the end of the year we initiated the accreditation process for a second notified body under the 93/42 Directive with the following scope: active non-nuclear medical devices. The audits will start at the beginning of 2003.

One person at the Competent Authority co-ordinates the activities related to Notified Bodies. Audit teams are formed as needed when audits must be made.

### **Denmark**

The Ministry of Interior and Health is the Danish Designating Authority. The task of auditing the performance of the notified body has until now been delegated to the Medical Device Agency (MDA) in England. However following a significant increase in its staff complement, the Danish Medicines Agency, is preparing to take over these tasks from the MDA and to carry them out itself in future.

Denmark currently has one Notified Body only designated under the medical devices Directives. During 2002, MDA carried out one on site surveillance audit in August and a witnessed audit in September. DGM's scope is extended under the IVDMDDD.

### **Finland**

In Finland the Ministry of Social Affairs and Health (MSAH) is responsible for designation of Finnish notified bodies for medical devices. According to the general scheme for assessment and designation, the Finnish Accreditation Service (FINAS)

working under the Ministry of Trade and Industry, performs the competence assessment and initial audits needed before application for notified body status from the relevant ministry.

The National Agency for Medicines (NAM) is responsible for monitoring the operation and competence of designated notified bodies for medical devices. In 2002 there were two persons (medical devices, *in vitro* diagnostic medical devices) involved in the monitoring. Both the persons are qualified auditors for the standard EN ISO/IEC 17025.

Finland has one Notified Body and it has been previously designated for the Medical Devices Directive 93/42/EEC by the MSAH.

In 2002 the MSAH, following an initial designation application review and a subsequent audit, conducted by FINAS, approved the designation of the Notified Body to the *in vitro* diagnostic Medical Devices Directive 98/79/EC (limited scope). The designation was dependant on completion of successful witnessed audit at a manufacturer's premises. This audit was performed by NAM in Autumn 2002.

Also in 2002, NAM continued its program of audits to the Medical Devices Directive 93/42/EEC. This included one surveillance audit on site at the notified body's office. (On site assessments have been performed at a minimum of every 12 months since 1996).

#### **FRANCE**

AFSSAPS is the competent authority and the designating authority for the directives 90/385, 93/42 and 98/79. France has one NB, G-MED, designated for all devices and all conformity assessment procedures concerning these three directives.

In 2002 a convention was adopted stating how information about the G-MED's activity and any modification of its structure is to be communicated to AFSSAPS. (Under this G-MED will submit an annual report on its activity according to the format adopted by the NBOG). Also in late 2002 AFSSAPS held discussions with G-MED to better define the procedure for the monthly notification of certificates delivered by G-MED and the procedure for withdrawal/suspension of certificates.

Apart from technical meetings concerning questions about particular certificates, AFSSAPs and G-MED meet twice a year to share information about the regulations, G-MED's activity and any difficulties encountered.

An inspection of G-MED was made by AFSSAPs on the 18 to 22 March 2002. The objectives were :

- to monitor the certification procedures implemented by G-MED
- study the methods used for the take over by G-MED of the activities of the notified body BVQI following the buy-out of the LCIE by Bureau Veritas
- to perform an initial audit concerning G-MED's application for habilitation for *in vitro* diagnostic medical devices.
- the audit covered the assessment of the system implemented by G-MED focusing on the procedures for regulatory certification (quality documentation

and examination of certification submissions filed by clients and evaluated by G-MED).

For MD inspection activity : 4 inspectors performed the inspection (2 from MD inspection unit and 2 from clinical and non clinical evaluation inspection unit). They were assisted by 2 AFSSAPS technical experts for the evaluation of specific items included in the manufacturer's certification files. On IVD side, the inspection was carried out by 2 inspectors from IVD inspection unit assisted by 2 AFSSAPS experts in this field.

### **Germany**

According to the German constitution and the medical devices act (transposition of the Medical Devices Directives), the German Laender are responsible for designating and monitoring Notified Bodies. To conduct these activities, the Laender agreed to set up two central authorities: the ZLG<sup>1</sup> (Central Authority of the Laender for Health Protection Regarding Medicinal Products and Medical Devices) in Bonn for non-active medical devices, in vitro diagnostic medical devices, and health issues, and the ZLS (Central Authority of the Laender for Safety) in Munich for active medical devices/safety issues. Within ZLG, 10 employees (7 scientific staff) are involved in the designation and monitoring of conformity assessment bodies in the medical devices area; within ZLS 2 employees are engaged in the medical devices area.

In total, 19 Notified Bodies are currently designated under the Medical Devices Directive (93/42/EEC) by either ZLG, ZLS or both. 4 of them have been designated under the Active Implantable Medical Devices Directive (90/385/EEC), and 7 of them under the In vitro Diagnostic Directive (98/79/EC). The designations and/or the underlying accreditations are specified in respect to the Annexes of the Directives and the products covered.

In 2002,

- the scope of 1 Notified Body was extended to non-active medical devices (MDD)
- the scope of 1 Notified Body was extended under the In vitro Diagnostic Directive
- the accreditation and designation of 3 Notified Bodies (1 under MDD, 2 under AIMDD) were terminated
- one application for extension to scope concerning the Human Blood Derivatives was reviewed, but put on hold due to the ongoing discussions with EMEA
- the scope of 3 Notified Bodies under MDD was reduced.

In total, 12 assessments of Notified Bodies under the Medical Devices Directive, 6 assessments under the In vitro Diagnostic Directive and 2 under the Active Implantable Medical Devices Directive were performed in 2002. In addition, 18 independent laboratories for testing medical devices have been assessed in this year.

One assessment of a Nbhas been observed by a representative of another member state under the "NBOG Invitational Audit programme".

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<sup>1</sup> Further information is available on [www.zlg.de](http://www.zlg.de)

The duration of the on-site assessments of Notified Bodies varied between 1 and 4 days and the assessments were conducted by 2 to 6 assessors, depending on the size and scope of the Notified Body. Observed Audits are performed by only 1 assessor.

The main problems found during the assessments of the Notified Bodies can be divided into the following categories:

#### Independence/Impartiality

- Insufficient implementation of the requirements of MEDDEV 2.10/2 regarding independence and impartiality
- Finding related bodies of the notified body offering consultancy in the area of medical devices or quality management

#### Competence

- Inadequate definition of qualification requirements for internal and external personnel
- Deficient authorisations, sometimes also insufficient procedures for authorisation

#### Application, contracting

- Contracts with manufacturer not including all necessary obligations and assurances

#### Internal procedures/Quality system

- Lack of clear and detailed definition of conditions for granting, maintaining, suspending and withdrawing certification
- Inadequate records to demonstrate the conclusions of the assessment, e.g. documentation of audit trails and esp. the decision making process
- Insufficient policies and procedures to demonstrate compliance with the regulations
- Insufficient control of documents
- Missing or improper procedures to deal with medical devices incorporating materials of animal origin (TSE/BSE)

As corrective actions, mainly adaptations of existing – or in some cases the creation of new – procedures (e.g. more precise definition of certification requirements, TSE/BSE issue) and documents (e.g. contract with manufacturer, contract with internal and external personnel, conflict of interest statement) have been agreed upon with the Notified Bodies. In some cases, the Notified Bodies have been asked to review the authorisation of their auditors/experts according to the re-defined qualification criteria, resulting in reduced scopes of authorisation. Lack of testing facilities resulted in reduction of scope. As far as individual conformity assessments were concerned, the Notified Bodies have been asked to check the respective certifications, resulting in re-work and – in some cases – suspension or withdrawal of the certificates. In one case the Notified Body was required to retrain its staff in respect to the assessment of devices incorporating materials of animal origin and to review design examinations again; this will be focus of a separate assessment in 2003.

Investigations of conformity assessments in relation to incidents respectively vigilance activities showed mainly inadequate risk analysis by the manufacturer,

faults in labelling due to non-conformities in the manufacturer's quality system, lack of valid clinical data or missing re-evaluation of products with materials of animal origin (TSE/BSE). If relevant, information from these investigations was shared with the relevant Competent Authorities.

In addition to the above Germany hold regular meetings with its NBs. For example in 2002 two regular 2-day exchange of experience meetings with Notified Bodies were held resulting in, for example, new guidance documents for "Change of Notified Bodies" and "Conformity Assessment for OEM Devices". Additionally, in our Sectoral Committees e.g. Special Accreditation Rules for the certification of quality systems have been updated and a common position in respect to the verification of manufactured products (98/79/EC Annex II List A) has been worked out. In addition Special Accreditation Rules for the scope of Human Blood Derivatives have been approved.

### **Greece**

Since 1998 the National Organisation for Medicines (EOF) has been the Competent Authority for medical devices (AIMD, MDD and IVDD). Greece has one Notified Body only. This is called EKEVYL (Research Centre for Biomaterials) and was designated in 1997 and the Ministerial Decision regarding this was published in the Government Gazette Issue B, No 262/7-4-1997. Its identification number is 0653. It is designated for both Directive 93/42/EEC and 90/385/EEC.

In addition EKEVYL has been accredited by the Hellenic Accreditation Council for operating quality management systems certification (ELOT (Hellenic Organisation for Standardisation) /EN 45012) in 2002. The scope of the accreditation includes issue of certificates based on ISO series 9002 and 46000 for companies distributing medical devices.

EOF is planning to perform audits for EKEVYL (management, quality assessment, assessors, manufacturing inspection and surveillance).

### **Ireland**

The Irish Medicines Board (IMB) was designated by The Minister for Health and Children as the Competent Authority for general medical devices, active implantable medical devices and *in-vitro* diagnostic devices in 2001. The IMB is also the Designating Authority for Medical Devices.

The Republic of Ireland has one Notified Body. This Notified Body had previously been designated for the Medical Devices Directive 93/42/EEC and for the Active Medical Devices Directive 90/385/EEC by the Department of Health and Children (DOH&C).

In 2002 the IMB, following an initial designation application review and a subsequent audit, conducted with the assistance of the MDA, approved the designation of the Notified Body to the *in-vitro* diagnostic Medical Devices Directive 98/79/EC. The designation was conducted in parallel with the Accrediting Body in Ireland, the National Accreditation Board (NAB). The designation is dependant on completion of successful witnessed audits, accreditation by the NAB and on-going satisfactory surveillance audits.

Also in 2002, the IMB commenced its program of audits to the Medical Devices Directive 93/42/EEC and the Active Implantable Medical Devices Directive 90/385/EEC. This included observed audits on the Notified Body assessors and surveillance audits on site at the notified body's offices.

**Italy :** No information supplied

**Luxembourg :** No information supplied

### **Netherlands**

The Dutch Healthcare Inspectorate (DA) is responsible for the designation and control of two Notified Bodies under the Medical Device Directive. The Notified Bodies are designated for the MDD, AIMD and IVD directive. One of the obligations for designation for the notified bodies is an accreditation to the EN 45000 standards by the Dutch Council of Accreditation (RVA). Both Notified Bodies are accredited to the EN45000 standard and have annual site visits from the RVA.

In 2002 the Dutch Competent Authority did not perform any on-site audits at the Notified Bodies. The last audits (surveillance) were performed in the end of 2001 and the follow up of those audits were done in the year 2002. Surveillance audits are performed according the audit frequencies as set by the NBOG group in the MEDDEV 2.10 rev 2.

During the performed surveillance audits the most common non conformities were:

- Delays and/or unappropriated action taken by the NB on found non-conformities
- Insufficient planning of the surveillance audits
- Unclear status of non conformities (minor vs. major)
- Action against manufacturers with expired non conformities
- Training records were not kept up to date
- Organisational relation between ISO 9000 auditors and CE auditors not clarified

In all cases Notified Bodies have taken corrective actions to ensure an appropriate quality system and that procedures will be in place. The corrective actions will be reviewed in the next surveillance audits (2003).

In 2002 two regular Notified Body meetings were held in the presence of the Regulating Authority from the Ministry of Health Care. Besides local aspects these meetings also addressed issues such as NBOG, MDEG, new directives on blood derivates, breast implants and different classification issues.

### **Portugal**

The National Institute of Pharmacy and Medicines, INFARMED, in Portugal is both the Competent Authority and Designating Authority for non-active medical devices under the 93/42/CEE Directive and for in Vitro Diagnostic Medical Devices under the 98/79/EC Directive.

Portugal has two Notified Bodies. LEMES, Laboratory of Essays and Metrology of Health, is designated for the three medical devices Directives (90/385/CEE, 93/42/CEE and 98/79/EC) and currently has three staff members. INFARMED is a

Notified Body for non-active medical devices under the 93/42/CEE Directive. Currently this Notified Body has three full time staff members and subcontractor contracts with experts.

During 2002, one audit of the Notified Body INFARMED was undertaken. The main areas of concern that arose related to the insufficient staff employed to carry out all the necessary activities, including the reviewing of the procedures implemented. It was demonstrated, in spite of the insufficient staff, an effort to maintain their activities and comply with the implemented procedures through the participation of external experts by subcontracts.

LEMES was a joint venture between INFARMED, the National Institute of Health (INSA) and the National Institute of Blood (IPS) and began their activities as a Notified Body recently. Recently, however INFARMED and IPS decided to withdraw from LEMES and there is currently a proposal to close it down as a NB leaving INFARMED as the sole Notified Body for all directives. In these circumstances an audit of LEMES has not been conducted this year.

### **Spain**

The Ministry of Health and Consumer Affairs in Spain is the Competent Authority Within the Ministry there is the Sub-directorate of Medical Devices and it is this body that is responsible for the designation and control of Notified Bodies. The Sub-Directorate currently has three staff members engaged on these tasks. Spain has one Notified Body, the Dirección General de Farmacia y Productos Sanitarios. It is designated for all three medical devices Directives.

Over the past 12 months the Sub-directorate has considered and approved the designation of the Notified Body for the In-Vitro Diagnostic Medical Devices Directive. This followed a careful examination of the competence of the Notified Body staff; a review of the NBs internal procedures etc, an audit of the Notified Body acting under the IVD Directive and audits of the assays laboratories that will carry out specific tasks as subcontractors of the notified body.

Over the same period the Sub-Directorate conducted 3 audits of the NB (one of which was an observed audit).

### **Sweden**

The Swedish Board for Accreditation and Conformity Assessment, SWEDAC, is responsible for the designation and control of Notified Bodies under the medical devices Directives. So far SWEDAC has designated three Notified Bodies;(SEMKO AB, Medical Products Agency and Swedish National Testing and Research Institute) under Directive 93/43/EEC. No NBs have been designated for either the Active Implantable Medical Devices Directive or the In-Vitro Diagnostic Medical Devices Directive. To deal with this, and associated, work SWEDAC directly employs one technician and one lawyer/administrator. In addition it uses a technician from the Competent Authority, (The Medical Products Agency, MPA) and one technical expert from a private company.

Over the past 12 months SWEDAC has reduced the scope of one of its NBs which was unable to maintain the necessary expertise. Additionally it has considered an

application for an extension to scope from another NB. (The application was subsequently withdrawn by the applicant). Finally, it withdrew designation from the MPA when that organisation became the Swedish Competent Authority – previously the National Board for Health and Welfare Medical Products Agency acted in that role.

During the same period SWEDAC conducted two surveillance audits of its NBs at their respective offices. These identified problems such as the contents and layout of the Certificates of Conformity issued by the NB, problems in being able to specify exactly the types of expertise the NB auditors required for a particular audit and uncertainty about the depth of evaluation required by the NB of the technical documentation when conducting an Annex 2 audit. To address these problems SWEDAC has required the relevant NB to revise some of its procedures and re-train some of its personnel.

### **The United Kingdom**

The Medical Devices Agency (MDA) is both the Competent Authority and the Designating authority for the UK. It currently has 6 staff involved in some way or another in the designation and auditing of UK Notified Bodies. This figure includes 3 auditors.

The UK currently has 7 Notified Bodies designated under the Medical Device Directive, 3 designated under the In-vitro Diagnostic Directive and 1 under the Active Implantable Medical Devices Directive. Some bodies hold designation for more than one directive. Most are designated for specific Annexes under each directive.

During 2002 one notified body withdrew from designation. One extension to scope under the IVMDDD was approved and two further extensions requested which are currently being reviewed. One extension to scope under the MDD to include devices containing Human Blood derivatives was approved and one scope was reduced.

A total of 16 audits were undertaken of UK Notified Bodies during 2002. Of these, 9 surveillance audits and 4 shadow audits were under the MDD, (one surveillance audit covered both the AIMD and MDD and one covered both the IVD and MDD). One initial audit and 2 shadow audits were carried out against the IVD.

During these audits the most significant failings found related to review activities within the Notified Bodies themselves. These generally resulted from a lack of routine reviews or systematic control, resulting in problems, such as:

- Delays or inaction with Non-conformity follow-up and close out activities
- Delays in issuing certification / re-certification
- Delays in undertaking assessments (outside required time-scales)
- Unclear status of non conformities
- Manufacturers not closing non-conformities within agreed time-scales
- Insufficient reviews of Assessors qualifications / suitability for specific areas
- Insufficient initial verifications of classification of device and scope of certification
- No formal procedures covering 5 year design dossier renewal requirements to ensure completion prior to expiry of existing certification
- Insufficiently comprehensive training records

- Insufficient investigation of details and contracts verifying status of subcontractors and own brand labellers.

In all cases corrective actions were agreed to put in place systems and procedures to prevent such problems in future. The corrective actions will be reviewed for effectiveness during the 2003 audit program.

In addition to the above found evidence of unsatisfactory assessment by the NBs of manufacturer's post market surveillance procedures and vigilance reporting. Notified Bodies have re-iterated these requirements to all their assessors to address this problem. Similarly we identified a general trend of NB auditors establishing insufficient audit trails which meant that it was unclear what elements, procedures, processes and records had actually been reviewed. All notified bodies involved have reiterated the requirement for good record keeping to their assessors.

During witnessed audits, the most frequently observed issue was that elements of the quality system were either missed from the planned assessment, only partially verified or not covered in sufficient depth. In addition it is apparent that there is some confusion resulting from the transition to ISO 9001:2000, where assessors are looking at the requirements of the revised standard but failing to check sufficiently that the requirements of EN46001 and the relevant directive remain in place. Again, the relevant notified bodies have raised these issues with their assessors to ensure that they are aware of the requirements for the future.

As a result of our findings MDA also took the following formal actions taken against specific Notified Bodies in 2002:

- One notified body was banned from taking on new clients for a period whilst serious issues relating to monitoring and control were addressed. It was also required to provide monthly updates on its audit schedule until the next DA audit has taken place, to enable their auditing activities to be monitored.
- Serious concerns with review of clinical data resulted in one assessor being suspended from specific activities pending review and the Notified Body being required to re-review all Design Dossiers for which that assessor was responsible. MDA have also required that they witness the next two Design Dossier Reviews undertaken by that Notified Body.
- Following ongoing concerns regarding staff knowledge and general implementation requirements regarding Directives and NB activities, one Notified Body was advised that unless they provided suitable training in the MDD to appropriate staff the MDA would consider withdrawing their designation. The MDA required proof that this training was undertaken.
- Due to loss of specific competence, one Notified Body had its designated scope reduced.

### **Switzerland**

Switzerland has submitted a list of 6 candidate Conformity assessment Bodies to the Joint Committee set up under the Bilateral Agreement between the EU and

Switzerland in June 2002. The Committee process for compiling and adopting the CABs was still ongoing at the end of 2002.

The Swiss Designating Authority, Swissmedic, Swiss Agency for Therapeutic products, employs a staff of four auditors working jointly with auditors of the Swiss Accreditation Service. During 2002 it conducted 1 witnessed audit, 1 surveillance audit, 1 initial audit and 2 training events for candidate Conformity Assessment Bodies. (The training events covered topics such as new legal requirements for CABs (Swiss and EU), risk based audit strategy and validation requirements with a special emphasis being placed on IT systems.

### **Norway**

There are 4 staff working in the Norwegian competent authority responsible for all matters concerning the medical devices Directives including the designation and control of Notified Bodies. Norway currently has three Notified Bodies designated under the Medical Devices Directive.

During 2002, the CA conducted various audits. Common problems found mainly related to competence matters ie what can/should be requested with regards to medical competence of NB staff and what activities can be sub-contracted by the NB. (In addition various detailed points on how the Directive was to be correctly interpreted were found and discussed). All these matters were discussed at length and the NB concerned asked to provide detailed documentary evidence concerning the degree of medical competence it claimed to have.

### **Summary of main audit findings arising from those Member States with only one Notified Body.**

As stated in paragraph 19, Page 4 of this report the following table summarises some of the main problems identified, and corrective actions taken, by those Member States having one NB only. Information has been summarised in this way to prevent NBs being unfairly criticised or disadvantaged. Accordingly it should not be assumed that any of the problems listed below relate to any particular NB.

<i><b>Types of problems found</b></i>	<i><b>Corrective actions</b></i>
<i>Lack of compliance with procedures for the review of technical information and manufacturing procedures to evaluate compliance with the essential requirements of the directives.</i>	<ul style="list-style-type: none"> <li>a) <i>Review procedures of the Notified Body</i></li> <li>b) <i>Training course about these procedures to all staff.</i></li> <li>c) <i>Exclusion of some technical experts and auditors from specific tasks.</i></li> <li>d) <i>Re-assessment and periodical audits for manufacturers and products involved.</i></li> <li>e) <i>Testing or re-testing of products involved.</i></li> </ul>
<i>Insufficient staff employed to carry out the conformity procedures applicable to some type of products.</i>	<ul style="list-style-type: none"> <li>a) <i>Incorporation of new qualified people to the staff.</i></li> <li>b) <i>Some tasks subcontracted to</i></li> </ul>

	<i>external experts</i>
<i>Failure to verify the implementation of previously agreed corrective actions by the manufacturer or their efficacy</i>	<ul style="list-style-type: none"> <li>a) <i>Training courses about audits to the auditors.</i></li> <li>b) <i>Periodical audits to verify the implementation and efficacy of corrective actions to manufacturers involved.</i></li> </ul>
<i>Failure to maintain comprehensive training records of staff</i>	<i>Creation of such records</i>
<i>Lack of clear evidence of auditor competence, inadequate systems in place to periodically review auditor performance by the NB</i>	<i>Creation of systems within the NB to address these points.</i>
<i>NB own internal procedures not being followed or not reflecting actual practice.</i>	<i>NB auditors reminded of procedures or procedures updated.</i>
<i>Inadequate control of subcontractors; inadequately written contracts between NBs and sub-contractors.</i>	<i>NB procedures reviewed and updated; contracts amended.</i>
<i>Audit reports and assessment reports not detailed enough.</i>	<ul style="list-style-type: none"> <li>a) <i>Review of procedure about reports and records.</i></li> <li>b) <i>Notified Body internal audits specifics to verify the implementation of this procedure.</i></li> </ul>

## NBOG Progress Report

### ANNEX C : NBOG WORK PROGRAMME

Work Item	Lead Country	Intention	Current State of Play
Produce a DA Questionnaire of existing DA practices in respect to the designating and monitoring of NBs	UK	To produce a baseline of current DA activities and to identify major differences	Questionnaire issued in June 2001. Replies collated and presented to Competent Authorities at their meeting in Madrid in January 2002.
Production of Designation and monitoring checklist based on MEDDEV 2.10/2	UK	To synthesis down the particular requirements of MEDDEV 2.10/2 into an easy to use checklist. This could be used by DAs to compare their current activities with those described in the MEDDEV and, by highlighting differences or omissions, suggest possible changes.	Checklist completed and circulated to all DAs September 2001. To be included in DA Handbook.
Production of a Communication protocol.	UK	To agree a means for DAs to communicate effectively with each other about possible problems with a particular Notified Body's performance. Use of the Protocol would ensure that the issue was sent to a named individual who would then be responsible for progressing the issue to a conclusion within agreed time limits and for reporting the outcome back to the question's originator.	Protocol produced and agreed. The protocol has been in use now since October 2001. To be incorporated into DA Handbook.
Establish an Invitational Audit Programme	Nederlands	This programme would set up a mechanism whereby a DA assessor from County A could observe an assessor from Country B conducting a Notified Body assessment. This would have the benefits of helping train Country A's assessor, providing objective insights into the activities of County B's assessor and encouraging networking between DA assessors generally.	Programme established. Named contact points in each Member State identified. Assessors from several Member States have used the programme. Feedback show the programme is meeting its objectives very well.
Production of a checklist for use by a DA assessor when	UK	To provide a simple aide memoire for use by the DA assessor when auditing a NB to ensure that all key	Completed. To be incorporated into DA Handbook.

monitoring the activities of a NB.		points are covered and assessed.	
Provide training for DA assessors on auditing NBs	UK	Lay on a training event which allowed different DAs to describe how they audited their NBs. The event would explain the various stages, from preparation to close out, by reference to actual experience gained from the “tutors” who themselves would be DA assessors.	Training Day held in September 2001 for DA assessors. Event was judged to be very successful by those participating.
Guidance on possible remedial actions a DA could take in response to identified poor performance by a NB.	Nederlands	The guidance should ideally provide a means of grouping problems into Major, Minor or Trivial categories. Examples of each would be provided. For each category a range of possible remedial actions could be given which DAs could use when considering the need for corrective action by a NB in response to identified shortcomings. To this extent the aim of the guidance would be to encourage DAs to take effective and consistent actions when faced with an under performing NB.	Guidance completed. To be incorporated into DA Handbook.
Notified Body Annual Reports	France	To encourage transparency the aim was to agree with NBs that they issue publicly available annual reports on their activities. These would also provide some basic, and non-confidential, statistics.	Draft suggestions produced and sent to NB-MED for comments. None yet received.
DA Handbook/Best Practice Guide	UK	The Handbook is designed to give practical advice and guidance to DAs on their roles and responsibilities for the designation and monitoring of NBs. It should be of special value to new DAs in the applicant countries. It is hoped that the Handbook will be completed in the Summer/Autumn of 2003.	First draft produced and discussed. Editorial group established to take project forward. Met in December 2002 and made good progress.
Produce guidance on the specific competencies required by NBs dealing with : a) IVDs b) Devices incorporating human blood or plasma; and	a)Germany b)Denmark	To provide practical help to DAs by identifying specific skills and resources NBs would need to operate in each of these respective areas.	Early drafts produced. Eventually to be incorporated into the DA Handbook.

c) Devices incorporating animal tissues	c)France		
Guidance on minimum data requirements to be provided on NBs Certificates of Conformity	Sweden	The aim is to provide standard templates of what information the Certificate of Conformity should contain. The work item is meant to address the wide variance between Certificates currently seen which frequently makes it difficult to judge, for example, what devices are covered, periods of validity, conformity assessment route taken, etc.	Revised drafts produced and discussed. Further enhancements being made.
Guidance on the role of the NB in the vigilance reporting system.	Belgium/ France	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.	Early drafts produced and issued to NBOG members for comment.
Guidance on changing NBs	Germany/ UK	This guidance would be addressed primarily at manufacturers who, for whatever reason, are keen to change their NB but are put off by perceived difficulties.	Drafts produced and discussed. Final draft awaited shortly.
Guidance for DA assessors on how to prepare for an audit of an NB.	UK	All experienced assessors agree that preparation is vital if an audit of a NB is to be comprehensive and useful. The guidance is intended to highlight what the DA assessor needs to do before conducting the audit itself and includes the importance of identifying, obtaining and studying relevant documentation prior to the audit.	Draft prepared and discussed. Currently being revised. To be incorporated into the DA Handbook.
Production of a checklist relating to the verification of clinical data used by the manufacturer to demonstrate compliance for use by DA assessors when conducting audits of NBs.	UK	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 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.	Early draft prepared. To be discussed by NBOG and then amended. Will be incorporated within the DA Handbook.
Preparation of a standard audit report format for use by NB auditors.	Ireland	Separate formats will be needed for each type of Conformity Assessment Annex. The aim is that specifying at least the standard headings of items to	First draft awaited.

		be covered in the audit report will 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 auditing the NB.	
Hold a training event for DA and NBs on the assessment of clinical data.	UK/Commission	To help provide DA and NB assessors/auditors with a basic understanding of the importance of having clinical data to support a manufacturer's claims and the need to check its relevancy, accuracy and interpretation..	To be discussed
Produce a NBOG Annual Report	UK	To demonstrate a commitment to transparency and provide information on the work of the group.	Draft completed and issued to NBOG members for various contributions. Hope to issue final version end of February 2003.