

**NOTIFIED BODY OPERATIONS GROUP
(NBOG)**

**REPORT FOR THE PERIOD
TO 31 DECEMBER 2003**

Introduction

1. This report reviews the function, aims and workload of the Notified Body Operations Group (NBOG). It is NBOG's second annual report and covers its main activities in the twelve months to 31 December 2003. It has been produced in the interest of transparency and is supplemental to the frequent progress reports on the Group's activities given to the Medical Devices Experts Group (MDEG).
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@mhra.gsi.gov.uk

Background

3. Annex A provides some of the historical background to the Group's establishment and describes how it works. Suffice it to say here, that the Group was charged with the task of addressing perceived shortcomings in the performance of Notified Bodies and those organisations responsible for their designation and control. This important objective is encapsulated in its Terms of reference reproduced below:

NBOG's 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

4. When establishing NBOG, Member States agreed that membership 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.

Industry and Notified Body Participation

5. During 2002, NBOG debated several times whether or not to expand its membership to include representatives from industry and the Notified Bodies but decided against such a move. The issue was raised again early in 2003 when the Group received an official request from the EA NB-MED Group to participate in its work.
6. The issue was extensively discussed at the NBOG meeting in March 2003. This concluded with the Group expressing a clear preference for membership to

continue to be open only to representatives of national regulatory authorities. Nevertheless there was agreement that a mechanism needed to be created whereby NBOG could better explain what it was doing to all stakeholders and, if possible, seek to involve them in the production of guidance papers etc where it was felt that such involvement would add value.

7. Accordingly it was agreed that industry and Notified Bodies would be offered the opportunity to attend short meetings with the NBOG Chairman. These would ideally follow shortly after the NBOG meeting and provide an opportunity to bring these important stakeholders up to date on the work of the Group and, where appropriate, seek their input to that work.
8. Following this, and further discussion at the April 2003 meeting of the Medical Devices Experts Group, the Commission with the NB-MED Group identified an individual who, it was agreed would represent both industry and Notified Bodies at these follow up meetings. The first such meeting took place on 29 October and followed the NBOG meeting of 14 October 2003.

Work Programme

9. 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.
10. Annex C lists the various items allocated to NBOG so far. It separates items between:
 - List A - items added to the work programme at the Competent Authority meeting in Dublin in January 2004.
 - List B -Items still in progress as at December 2003
 - List C -Items completed in the year to 31 December 2003
 - List D –Items completed before 1 January 2002
11. 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 many items have been completed and others are well advanced. Many of these items, on their own, can be seen to represent fairly minor matters. However collectively they are making a real difference in the way DAs and NBs do their work. This is consistent with NBOG's aim of being a group that actually delivers and makes a difference.

NBOG Activity during 2003

12. As highlighted in our previous Annual Report, the single most important piece of work NBOG has been involved in this year has been finalising the Designating Authority Handbook. This ambitious project was aimed at describing the roles and responsibilities of DAs in relation to the designation and control of their Notified Bodies and providing simple, direct and clear advice and guidance on how those

responsibilities may best be executed. From the first it was widely believed that such a Handbook would be of value to both existing and new Member States.

13. 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. Much of this work was done electronically but the editorial group met twice during 2003.
14. The Editorial Group worked so effectively that a final draft was submitted, on time, to the NBOG meeting of October 2003 for consideration. At nearly 100 pages in length the Handbook represented a major piece of work. It drew on existing guidance in, for example, MEDDEV 2.10 and various GHTF papers as well as containing significant new advice based on Member States actual experiences. Additionally, the Handbook contained a number of checklists and other aides specially produced to help the Designating Authority carry out its tasks.
15. With only minor changes the Handbook was approved by NBOG. Following this it was submitted to the December 2003 meeting of the Medical Devices Experts Group where it was endorsed without dissent.
16. With the agreement of the Commission, and in the interests of both transparency and accessibility, the Handbook has been lodged on the Commission web site where it can be accessed by all. Additionally, the Commission has agreed to have the Handbook translated into all the languages. This will vastly increase its utility.
17. While most of NBOG's efforts during 2003 were directed at the DA Handbook it nevertheless continued to work on a variety of others items included in its work programme. Several of these, for example, guidance on possible remedial actions to be taking in response to poor performance by a NB and on the specific competencies require by NBs dealing with IVDs etc were completed and incorporated within the Handbook. At the same time it continued to develop and refine work on a series of other work items such as the preparation of guidance on a standard format for NB audit reports and the role of the NB in the vigilance system.
18. A full list of the Group's current work programme is given in Annex C.

Current Designating Authority Activities

19. When NBOG produced its first annual report it was 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 been doing to effectively control and designate its Notified Bodies. Accordingly each Member State was asked to prepare a short contribution to the Annual Report and these were included as an annex to the report itself.
20. Feedback on the NBOG Annual Report indicated clearly that these short "pen pictures" were of great interest and helped re-assure stakeholders that Member

State were taking seriously their responsibilities in this crucial area. Accordingly NBOG has agreed to repeat this exercise for the period covered by this Annual Report.

21. Accordingly at Annex B is a brief narrative provided by the Member States. 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).

Acknowledgements

22. 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 - Historical Perspective

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.

Accordingly, NBOG had its first meeting in London in November 2000. Most Member States and the EU Commission attended. That meeting produced a suggested Terms of Reference and work programme. Both were endorsed by Member States at the informal meeting of Competent Authorities in Stockholm in December 2000.

In establishing NBOG, Member States were clear that it wanted it to be a Group that would make a difference. Accordingly NBOG was set up to produce simple, relevant and meaningful guidance and advice. It was specifically not to be simply a "talking shop" at which issues are discussed in a general way but without reaching a final position.

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 be responsible for taking their items forward to a conclusion. Accordingly, the usual working method for the Group is for draft papers to be produced and circulated electronically for comments. This process is repeated until the whole of the Group is able to endorse the document. At this point it is issued for use.

In addition to providing written guidance however, NBOG also 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.

Annex B : Member States Round Up

Austria :

In Austria, the Federal Ministry for Health and Women's Issues is responsible for the designation and monitoring of the Austrian notified bodies. According to the Austrian medical devices law, the designation of a notified body in Austria is only possible after accreditation by the national accreditation organisation. Two people in the ministry of health are employed on the notification procedure. The whole procedure (accreditation and notification) is done with external auditors.

Currently, Austria has two notified bodies, one for the directives 90/385/EEC and 93/42/EEC (PMG Graz) and one for the directives 90/385/EEC, 93/42/EEC and 98/79/EC (TÜV Austria). In 2003, there was no new notification and no amendment of scope.

In 2003 each notified body was audited doing a surveillance audit which was conducted together with the Austrian accreditation body. Actual problems are discussed twice a year during a notified body *jour fixe*.

Belgium:

The Medical Devices Service of the General Direction III of the Belgian Federal Public Service is responsible for the designation and monitoring of notified bodies for the MDD and AIMD directives in Belgium. (The NB notification is made after preliminary accreditation by our national accreditation body BELCERT). We intervene during the accreditation process as technical experts, concentrating on the specific aspects for medical devices while the main auditor and his team examine the more general points according to the EN 45000 series of standards. The accreditation is given only if the technical expert's report is positive.

In 2003 the following activities took place:

- Monitoring of the activities of the single existing notified body APRAGAZ by reviewing the delivered certificates
- Designation audit of a new notified body: CEBEC in February .
- Observed audit of CEBEC in December .

During both audits only minor non-conformities or observations were made and these were corrected immediately. We were quite satisfied with the way the audits were made.

Surveillance and observed audits are made together with the BELCERT auditor team and since the two notified bodies are also notified for other European directives, the audits are made by a relatively large teams of auditors (typically half a dozen).

CEBEC and APRAGAZ cover a limited scope of devices corresponding to the domains in which they had already an expertise.

We attend the NBMed meetings together with them and regularly exchange information of interest to both sides.

Denmark:

The Ministry of Interior and Health is the Danish Designating Authority. Denmark has one Notified Body. The task of assessing the performance of the Notified Body has been delegated to the Danish Medicines Agency from 1 September 2003. Since then the Danish Medicines Agency has met with the Notified Body to agree on roles and terms of reference and is now preparing the next assessment.

We are currently reviewing an application for an extension of the Notified Body's scope. The Danish Medicines Agency has so far not identified any critical issues and no specific actions have been taken.

Finland:

The Ministry of Social Affairs and Health (MSAH) is responsible for designation of 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 2003 there was one person, who is a qualified auditor for the standard EN ISO/IEC 17025, involved in the monitoring. In addition there are 6 technical staff available to assist the auditor during audits.

Finland has one Notified Body and it has been designated for the Medical Devices Directive and the In Vitro Diagnostic Medical Devices Directive (limited scope). An application for an extension to scope under the IVD Directive was reviewed.

In 2003, NAM performed one surveillance audit on site at the notified body's office concentrating on the operation in the field of IVD Directive. No significant shortcomings were found. On site assessments have been performed by NAM at a minimum of every 12 months since 1996.

FRANCE :

Afssaps is the French competent authority and the designating authority for directives 90/385, 93/42 and 98/79. Only one notified body is notified in France, G-Med, for all medical devices and all conformity assessment procedures, relating to these three directives.

A memorandum was adopted in 2002 which lays down the means of communication, between Afssaps and G-Med, relating to the activity of G-med and the development of its organization. As part of this G-med is required to provide an annual report according to the NBOG format. In addition, the follow-up of G-med is carried out

according to the following methods (direct control by meetings, reports and /or inspections and indirect evaluation by inspection of manufacturers certified by G-Med):

- Afssaps and G-med meet two times a year in order to discuss regulatory matters, on the organization of G-med and on its international activities ;
- at the end of 2003, it was decided, to hold quarterly technical meetings with G-med in order to deal with points of doctrine concerning assessment/evaluation, classification of medical devices and quality management system auditing. In these meetings, problems identified by Afssaps during the inspections of manufacturers are discussed and if appropriate corrective actions are decided upon. Each month G-med provides Afssaps with a list of the issued / suspended / withdrawn compliance certificates ;
- finally, the withdrawal or suspensions of certificates notified by G-med are subject to a specific evaluation procedure by Afssaps, which can implement specific actions towards the concerned manufacturer in relationship with G-Med.

It is also important to mention the following points for 2003 :

- initially, G-med was the product of a merger between two testing laboratories, LCIE and LNE. In 2003, LCIE decided to sell out its activity of evaluation of medical devices within the framework of CE marking, to the LNE ;
- G-Med is a candidate to be a notified body within the regulatory framework of directive 2003/32/CE relating to the medical devices manufactured using tissues of animal origin ;
- finally, Afssaps approached COFRAC, the French accreditation organization, in order to observe surveillance audits carried out by COFRAC at G-med within the framework of its voluntary accreditations according to the NF EN 45000 standards series (especially NF EN 45012).

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. In order to conduct these activities consistently, the Laender agreed upon founding two central authorities to take over these duties, the ZLG (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, 17 Notified Bodies are currently designated under the Medical Devices Directive (93/42/EEC, MDD) by either ZLG, ZLS or both. 5 of them have also been designated under the Active Implantable Medical Devices Directive (90/385/EEC, AIMDD), and 7 of them in addition under the In Vitro Diagnostic Directive (98/79/EC, IVDMDD). The designations and/or the underlying accreditations are specified in respect to the Annexes of the Directives and the products covered.

In 2003,

- the designation of one Notified Body under the MDD was suspended following abandonment and de-designation after client transfers to other Notified Bodies
- the scope of designations of four Notified Bodies under the MDD has been reduced
- the scope of one Notified Body under the MDD was extended
- the scope of one Notified Body under the IVDD was extended.

In total, 13 assessments of Notified Bodies under the MDD, 4 assessments under the IVDD and 2 under the Active Implantable Medical Devices Directive were performed in 2003. Assessors have observed 9 audits of Notified Bodies. In addition, 24 independent laboratories for testing medical devices have been assessed during this year.

The duration of the on-site assessments of Notified Bodies varied between 1 and 3 days and the assessments were conducted by 1 to 4 assessors, depending on the size and scope of the Notified Body. Observed Audits are performed by only 1 assessor, normally. During one of the on-site assessments a representative of the Danish Designating Authority participated in the assessment.

Special emphasis was put, in 2003, on the new Directives for the reclassification of breast implants (2003/12/EC) and for medical devices manufactured utilising tissues of animal origin (2003/32/EC).

The deviations 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 of the body itself and its internal and external personnel

Competence

- Inadequate definition and implementation of qualification requirements for internal and external personnel
- Deficient authorisations, sometimes also insufficient procedures for authorisation
- Lack of sufficient facilities necessary for the inspections and tests required, either in-house or at subcontractors

Internal procedures/Quality system

- Deficient procedures for e.g. assessment of clinical evaluation or EC design-examination and EC type-examination
- Missing or improper procedures to deal with medical devices manufactured utilising tissues of animal origin (TSE/BSE)
- Insufficient traceability of the decision making process
- Lack of sufficient documents especially for EC design-examination and EC type-examination or audit protocols
- Inadequate planning and conducting of internal audits

As corrective actions, mainly adaptations of existing or creation of new procedures (e.g. for assessment of clinical evaluation or EC design-/EC type-examination) and documents (e.g. contract with internal and external personnel, conflict of interest statement, audit protocol) have been agreed upon with the Notified Bodies. In some cases, the Notified Bodies have been requested to review the authorisation of their auditors/experts according to the re-defined qualification criteria, resulting in reduced scopes of authorisation. 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.

In 2003, the number of information requests from other Member States according to the NBOG communication protocol has strongly increased. Investigations of conformity assessments in relation to these requests or related to incidents/vigilance cases were necessary for procedures for e.g. heart valves, hip implants, bulking agents causing saturation, coronary stents and tooth bleaching devices. If relevant, information from these investigations was shared with the Competent Authorities.

In 2003, two regular 2-day exchange of experience meetings with Notified Bodies had been held, resulting e.g. in new or revised guidance documents for the assessment of clinical evaluations and on Conformity Assessment for OEM Devices. New Accreditation Rules were created regarding the certification of quality systems for the reprocessing of medical devices and for the assessment of products manufactured utilising tissues of animal origin (TSE/BSE).

Greece :

The Minister of Health and Social Solidarity designated the National Organization for Medicines (EOF) as the competent authority for general Medical Devices, active implantable medical devices since 1998 and for in vitro diagnostic devices since 2001.

There is only one Notified Body (EKEVYL) designated for the MDD and the IVD Directives. It has been designated by the Minister of Health and Welfare in 1997, before the EOF became the competent authority for the Medical Devices (Official Gazette 262B/7-4-1997). Its identification number is 0653

The Notified Body has been accredited to the EN 45000 standards and is being audited regularly by the National Accreditation Council of Greece. The scope of the accreditation includes issuance of certificates based on ISO series 9002.

In 2003, the EOF, Division of Production and Distribution Control, conducted one audit in the Notified Body. The purpose of this audit was mainly the assessment of its compliance to GMP requirements as a Control Laboratory.

During 2003, a significant amount of time was spent by EOF's Division of Production and Distribution Control on the clarification and interpretation of the IVD directive and the MDD directive as well.

As our Agency is actually under a reorganization plan, we believe we will have a concrete schedule of audits to the Notified Body in order to assess its function, during 2004.

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 Irish Medicines Board has designated the National Standards Authority of Ireland (NSAI) as a Notified Body for the MDD, AIMD and the IVD Directives. The IMB has a total of 5 technical staff, including one auditor. Other members of the technical staff have assisted the auditor during audits in areas such as Clinical Review and competency.

In 2003, the IMB conducted 5 notified body audits (2 surveillance audits to the MDD and AIMD and a surveillance audit to the IVDD). In addition, 2 observed audits were conducted on the NB auditors to the IVDD. The IVD observed audits were prioritized, as the Notified Body was recently designated to the IVDD.

We found that a significant amount of time during the year was spent on the clarification and interpretation of the requirements of the IVD directive between the Notified Body and ourselves. There was also an increase in classification arbitration requests by the Notified Body and the manufacturer relating to both the MDD and IVD directives.

Italy :

No information provided.

Luxembourg:

No information provided.

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 2003 the Dutch Competent Authority performed two observed audits and one surveillance audit. In the surveillance audit a representative of the Danish competent authority participated as an observer as part of the NBOG invitational audit program. Surveillance audits are performed according to the frequencies set in MEDDEV 2.10 rev 2.

During the performed surveillance audits the most serious non-conformities found related to the review activities within the Notified Body organisations themselves. The most common non conformities were:

- Delays and/or inappropriate action on found non conformities
- Insufficient traceability of decisions made
- Insufficient planning of the surveillance audits
- Action against manufacturers with expired non conformities
- Training records not kept up to date

In all cases the Notified Bodies concerned have taken corrective actions. These will be reviewed in the next surveillance audits (2004).

In 2003 two regular Notified Body meetings were held in presence of the Regulating Authority from the Ministry of Health Care. Besides local aspects the main issues discussed related to affairs that were important to the Notified Bodies such as the work of NBOG and MDEG, the new directives on TSE/BSE and different classification issues.

In July 2003 the Notified Bodies delivered their annual report.

Portugal :

In Portugal there are two Competent Authorities under the medical devices Directives. INFARMED (CA) is the Portuguese Competent Authority for non active medical devices and for the in vitro diagnostic devices; INSA (CA) is the Portuguese Competent Authority for active medical devices and for active implantable medical devices. INFARMED is responsible for the control of two Notified Bodies under the Medical Devices Directives MDD and IVD.

There are two Notified Bodies: LEMES designated for the MDD, AIMDD and IVD Directives and INFARMED Notified Body (NB) designated for the MDD Directive, but exclusively, for non active medical devices. During 2003, INFARMED Notified Body (NB) was the only one who had conformity assessment activities in Portugal during 2003.

In 2003 the Competent Authority INFARMED (CA) performed one observed audit related to the Notified Body INFARMED (NB) auditors work. The main problem found concerned the follow-up by INFARMED (NB) of the annual auditing plan. This resulted mainly from problems within INFARMED (NB) related to training and human resources in regard to the range of needed technical knowledge.

Corrective actions were agreed so that the INFARMED (NB) will improve writing procedures and updated activity records and will have specific training.

Spain :

The Ministry of Health and Consumer Affairs is the DA in Spain. Within the Spanish Ministry of Health and Consumer Affairs, the unit responsible for the assessment and monitoring of Notified Bodies in order to assure the compliance of the criteria established in the Medical Devices Directives is the Subdirectorate of Medical Devices. Three members on the staff of this Subdirectorate are directly involved in the tasks of assessment and monitoring of Notified Bodies.

Spain currently has one Notified Body only; One, Española de Medicamentos y Productos Sanitarios, formerly, Dirección General de Farmacia y Productos Sanitarios. Its Identification number is 0318 and its designated scope is as under:

- Directive 90/385/EEC, since April 1993.
- Directive 93/42/EEC, since October 1994.
- Directive 98/79/EC, since December 2002.

During 2003 the Spanish DA has undertaken the following activities

I. Designation activities:

Preparation of the designation of NB 0318 for carrying out the conformity procedures referred in the Directive 2003/32/EC. In order to perform this designation, the DA has developed, in particular, the following activities:

- Evaluation of the competence of Notified Body staff.
- Review of internal procedures, reports, certificates, application forms and questionnaires of Notified Body.
- Audit to the Notified Body in the scope of in tissues of animal origin.

II. Audits:

- Number of audits conducted: 3 (2 observed audit)
- Audit findings / corrective actions proposed by the Notified Body and accepted and monitorized by DA
- Verified that all non-compliances found during the 2002 audit programme had been satisfactorily resolved.

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 two Notified Bodies under Directive 93/42/EC. No NB's have been designated for either the Active Implantable Medical Devices Directive or the In-Vitro Diagnostic Medical Devices Directive. To deal with this work, and corresponding work with Directives in other areas, 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 received no new applications for NB designation and no requests for extension of existing NB's scope.

During 2003 SWEDAC (DA) and MPA (Competent Authority for Medical Devices in Sweden) conducted one complete assessment at one of the NB's main office. The conclusion of the assessment was that the NB was missing routines regarding evaluation of the staff's competence, secure impartiality of construction review report and errand/commission of Vigilance cases. Furthermore discussions took place regarding how the NB's should verify that they have the correct competence when they accept orders within a new area. The NB has responded with suggestions for corrective actions. These were discussed at a follow up audit with positive conclusions from DA and CA and case was closed.

Regarding the second NB no specific assessment has been carried out regarding MDD. The second NB is notified for other Directives and accredited for several different areas. Within those areas where the body is accredited SWEDAC has done complete assessments. Limited assessment was done for other Directives, other than MDD. Based on those facts and previous assessments for medical devices, SWEDAC feel confident that the said NB fulfil its obligations and that the NB has good knowledge and activity.

SWEDAC has during 2003 not done any "Observed Audits". However this is planned for the year 2004.

The United Kingdom

The Devices Sector of the Medicines and Healthcare products Regulatory Agency (MHRA), formerly the 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 8 Notified Bodies designated under the Medical Devices 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 2003, one new Notified Body was designated under the MDD and three extensions to scope under the IVMDD were approved. One Notified Body has informed us that they wish to withdraw from Notified Body activities.

A total of 14 audits were undertaken of UK Notified Bodies during 2003. Of these, 8 were surveillance audits covering the MDD (two of them also covered the IVDMD and one also covered the AIMDD). The remaining 6 audits were witnessed audits (four covering the MDD and two covering the IVDMD).

During these audits, the most significant or widespread findings were partly associated with audits carried out by the Notified Bodies, and partly with the internal controls of the Notified Bodies themselves, such as:

- New certification issued after client transfer from one Notified Body to another but before a review of client compliance status had been carried out.
- Certification issued to companies without any assessment or review of certification status of their major manufacturing subcontractors.
- Certification issued to start-up companies before representative samples of their devices had gone through the production process.
- Insufficient initial verification that products were medical devices under the directives.
- Insufficient verification that applicants were the manufacturers as defined by the directives.
- Insufficient documentation of reviews and decisions taken by Notified Bodies.
- Insufficient audit records to demonstrate width and depth of audit, particularly regarding regulatory requirements.
- Audit findings not progressed and closed out in a timely manner.

In all cases corrective, as well as preventive, actions were agreed and put in place. All such actions will be verified for implementation and effectiveness during the 2004 audit programme.

In addition to the above, audits have confirmed an increasing trend in attempts to CE-mark borderline products, particularly in areas bordering general fitness and well-being, 'miracle cures' and general laboratory equipment. Cases of insufficient review of the medical claims made for such products have been seen during recent audits. As a result, all affected Notified Bodies have raised the issues with their reviewers and assessors to ensure that they are aware of the requirements for the future.

As a result of our findings MHRA also took the following formal actions against specific Notified Bodies in 2003:

- Identification of large gaps in expertise for one Notified Body resulted in a suspension of them carrying out any assessments in these areas.
- Following concerns that important subcontractors had not been assessed one Notified Body was advised that unless they conducted an audit of this subcontractor within one month the MHRA would consider withdrawing their designation or reduce their scope. After a period of extensive monitoring by the MHRA, the Notified Body decided to withdraw from its activities as a Notified Body. The withdrawal is due to be completed shortly after a period of client transfers to other Notified Bodies.

Switzerland

Switzerland has six Conformity Assessment Bodies (CAB, NB) designated under the MRA with the EU. They are all active for the Directives 93/42/EEC. One of them is designated for the Directive 90/385/EEC as well, and none is designated for the Directive 98/79/EC yet. The Swissmedic team responsible for CAB designation

includes three auditors. Swissmedic has audited jointly with the Swiss Accreditation Service three CABs in the year 2003. Main corrective actions requested from CABs included:

- To improve co-ordination among the team members during the audit for the purpose of optimising effectiveness.
- To improve in the demarcation of products (manufacturer of MD and other related products).
- To procure additional medical expertise to assist in design dossier reviews.
- To improve the records of the decision making process for the certificate in order to be able to present the evidence that all steps of this process have been followed.

The audit duration was between one and three days, the main focus this year was the observation of the CAB's auditing followed by reviewing the audit results as documented by the CAB as well as their decision process leading the manufacturer's certification. Two CABs were successful in amending their scope under the Directive 93/42/EEC. They qualified after a review of their updated qualification documentation. In one case Swissmedic observed an audit in order to decide.

Additionally, a one day training for CAB staff was provided by Swissmedic in 2003.

Norway

The Directorate for Health and Social Affairs is the Competent Authority for Norway, and also responsible for auditing Notified Bodies. Norway has three Notified Bodies designated under Directive 93/42/EEA.

The Notified Bodies delivered their annual reports in April 2003.

All Notified Bodies are accredited under the EN 45000 standards, and hence receive regular visits from the national accreditation body (Norwegian Accreditation - NA). The Directorate for Health and Social Affairs has met with NA in 2003 in order to share findings and experiences and clarify how to best coordinate our actions and cooperate in the future.

Request from other Member States have been raised with the Notified Bodies. One request led to temporarily suspension of a certificate by the NB involved, but none of them led to formal action against any NB.

There seems to be an increased number of cases relating to misuse of notified body number. Both the Competent Authority and the NBs themselves have received several requests from other CAs relating to products/manufacturers that turn out to be unknown to the NB who's number appears on the CE-mark. The NBs themselves have also discovered several examples of misuse of their notified body number. In these cases the NB informs both the Directorate for Health and Social Affairs as well as the CA in the country where the manufacturer misusing their NB number has his business address.

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

As stated in paragraph 21 of this report the following table summarises some of the main problems identified 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>Types of problems found</i>
<i>NB auditors competence not related to the technologies being assessed by NB</i>
<i>Training of NB auditors inadequate</i>
<i>Clinical data review by NB inadequate</i>
<i>Performance evaluation review by NB inadequate with poor audit trail</i>
<i>NB not conducting Internal audits of its own activities</i>
<i>Certificate issued outside of the NBs designated scope</i>
<i>Product family and range poorly defined on certificate</i>
<i>Poor or no audit of sub contractors</i>
<i>Inadequate assessment of specialised functions such as sterilisation, decontamination etc</i>
<i>Superficial analysis of clinical dossiers</i>
<i>Inappropriate choice of which annex to affix CE marking under</i>
<i>Delays in agreed evaluation timetable between the NB and the manufacturer in order to carry out the evaluation procedures and audits.</i>
<i>Inadequate time being allowed to NB audit staff to prepare for audit</i>

Corrective actions were taken in all instances to address the above shortcomings.

ANNEX C : NBOG WORK PROGRAMME

List A : The following new items were added to NBOG's Work Programme at the January 2004 Dublin meeting of Competent Authorities.

Work Item	Lead Country	Intention	Current State of Play
Review guidance papers produced by the NB Recommendations Group	To be determined	To review and update as necessary all Guidance Papers produced over several years prior to their being presented to MDEG for formal endorsement	Preliminary meeting with the Chairman of the NB-Recc Group being arranged to scope and prioritise the work.
Liase with GHTF Study Group 4	All	To ensure that the views are NBOG are adequately reflected in the various guidance papers being produced	SG4's draft paper entitled "xxxxxxxx" circulated to NBOG members and comments sought.
Revise MEDDEV 2.10	Germany, Netherlands, Belgium, France and the Czech Republic	Update MEDDEV 2.10 to reflect various items arising from the IVD Directive, etc.	Preliminary draft prepared by Germany already circulated for comments.
Organise and provide training for DA assessors	UK, Ireland, Netherlands, Germany	To provide training based on the practical application of the DA Handbook.	Netherlands to determine likely number of attendants and, with the Commission, investigate the possibility of funding being made available.

List B : Items still remaining from NBOG's current work programme

Work Item	Lead Country	Intention	Current State of Play
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.	Revised drafts, incorporating comments made, issued to NBOG members for further 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.
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.	Draft prepared and circulated to NBOG for comments. Ultimate intention is for the checklist to 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 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.	First drafts produced and circulated for comments. Further revisions now being made.

List C : Items completed during the year to December 2003

Work Item	Lead Country	Intention	Comment
DA Handbook	UK	Designed to give practical advice and guidance to DAs on their roles and responsibilities for the designation and monitoring of NBs.	Endorsed by NBOG in October 2003 and MDEG in December 2003. Now on Commission web site.
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 for use by DAs to compare their current activities with those	Checklist completed and incorporated into the DA Handbook.

		described in the MEDDEV and, by highlighting differences or omissions, suggest possible changes.	
Produce guidance on the specific competencies required by NBs dealing with : a) IVDs b) Devices incorporating human blood or plasma; and c) Devices incorporating animal tissues	a)Germany b)Denmark c)France	To provide practical help to DAs by identifying specific skills and resources NBs would need to operate in each of these respective areas.	Completed and incorporated into the DA Handbook.
Guidance on possible remedial actions a DA could take in response to identified poor performance by a NB.	Nederlands	The guidance attempts to group problems into Major, Minor or Trivial categories. Examples of each provided. For each category a range of possible remedial actions suggested for DAs to consider. To this extent the aim of the guidance is to encourage DAs to take effective and consistent actions when faced with an under performing NB.	Completed and incorporated into the DA Handbook.
Guidance for DA assessors on how to prepare for an audit of a 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.	Completed and incorporated into the DA Handbook.

List D : Items completed prior to January 2003

Work Item	Lead Country	Intention	Comments
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 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. 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 monitoring the activities of a NB.	UK	To provide a simple aide memoire for use by the DA assessor when auditing a NB to ensure that all key points are covered and assessed.	Completed and incorporated into DA Handbook.
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.