

**NOTIFIED BODY OPERATIONS GROUP  
(NBOG)**

**REPORT FOR THE YEAR  
TO 31 DECEMBER 2004**

## Introduction

1. This report reviews the function, aims and workload of the Notified Body Operations Group (NBOG) for the year to 31 December 2004. It is NBOG's third annual report. It is produced in the interest of transparency and supplements the regular progress reports on the Group's activities given to the Medical Devices Experts Group (MDEG).
2. I hope this report will be of interest to stakeholders in the medical devices sector. Further information can be obtained from its current Chairman : Steve Owen at [steve.owen@mhra.gsi.gov.uk](mailto:steve.owen@mhra.gsi.gov.uk)

## Background

3. Annex A provides the historical background to the Group's establishment and describes how it works. Its aim, however, is to help address perceived shortcomings in the performance of Notified Bodies (NBs) and those organisations responsible for their designation and control. This is encapsulated in its Terms of Reference which 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. It was also agreed that NBOG would be chaired by a Member State representative and hosted by the EU Commission. Since the group was set up it has been chaired by Steve Owen from the UK.

## Current Work Programme

5. Competent Authorities review NBOG's work programme reviewed every six months. This allows the programme to be adjusted quickly in response to specific issues that arise.
6. Competent Authorities last reviewed the NBOG work programme at their meeting in Berne in January 2005. They expressed continuing satisfaction with the way NBOG was functioning and the work it was doing. They also agreed to ask NBOG to add three new items to its work programme for 2005. These were:

- To devise ways in which an element of peer review could be introduced to the work of designating authorities and make recommendations to Member states at their next meeting in September 2005;
  - To produce a guidance paper for Notified Bodies whose client was an own brand labeller. Such paper should specifically address and clarify the extent to which the NB could take account of any certification issued by the original manufacturer's NB; and
  - To review the way in which individual NB's designated scopes are described in the Official Journal and on the Commission's web site to ensure that such descriptions are clear, consistent and accurate.
7. 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 Berne in January 2005.
  - List B -Items still being progressed by NBOG as at December 2004
  - List C -Items completed up to 31 December 2004
8. 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, represent fairly minor matters. But 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 delivers and makes a difference.

### **NBOG Activity during 2004**

9. During 2004, NBOG continued to drive forward work on all of its current work items. It effectively completed work on the production of guidance papers dealing with the role of the Notified Body in the Vigilance system, and actions to be taken by both the NB and manufacturer when – for whatever reason – a manufacturer has to change its Notified Body. Both these papers either have, or shortly will be, sent to the NB-MED group for their input before being finally signed off.
10. NBOG also devised and provided training for DA assessors. This, with the very kind hospitality of the Dutch Presidency, took place in the Hague in July 2004. Feedback from participants was that the training was relevant, useful and well delivered. The one disappointment was the relatively low attendance from those Member States that had joined the EU in May 2004 given that NBOG was asked to provide the training specifically to meet their needs.
11. During the year, volunteers among NBOG membership, were found to consider the various NB-MED documents NBOG has been asked to review. The NB-MED Recommendations Group Chairman contacted, NBOG's work in this area explained, his support obtained and an acceptable *modus operandi* devised. It was also agreed that he would attend NBOG meetings where this work item would be

discussed to allow a more effective interchange of views between NBOG and the NB-MED to take place. By the end of 2004 early views on particular papers were being circulated within NBOG for further consideration at the March 2005 meeting.

12. Work on the clinical data checklist was virtually finished by the end of the year. Only a small number of relatively minor changes now need to be made. Once this is done, the checklist can be formally approved by NBOG and added to the Designating Authority Handbook as a new annex. Similarly, work on the guidance paper describing the minimum data set to be included by NBs in their certificates of conformity is reaching a conclusion. Once a few minor changes are made to reflect member's comments, the intention is to pass the paper to NB-MED for their input.
13. NBOG continued to progress a guidance paper describing a suggested standard audit report format for NBs to use. Early drafts were circulated to NBOG during the year for comments and these are being incorporated into the final document.
14. Finally, NBOG continued its work to revise MEDDEV 2.10 to update it in light of the IVD Directive etc. A revised format has been agreed and textual changes are being made. To facilitate completion of this item a small group comprising Germany, France, Netherlands, Belgium and the Czech Republic, has been established.

### **Current Designating Authority Activities**

15. When NBOG produced its first annual report, it was keen to make transparent the work of the group itself. Additionally, it saw it as a useful vehicle to demonstrate, albeit briefly, what each Designating Authority had been doing to 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.
16. Feedback indicated 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 agreed to keep this as a permanent feature of its annual report.
17. Accordingly at Annex B is a brief narrative provided by the Member States. These describe the scale and nature of their 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).

### **Industry and Notified Body Participation**

18. During 2004, NBOG again debated whether to open membership to industry and the Notified Bodies but decided against such a move. However, in the interests of transparency, it continues to provide the Medical Devices Expert's Working Group, at which all stakeholders are represented, with regular reports on its activities. These are supplemented by this annual report, presentations on NBOG at various conferences, articles written for various journals, etc.
19. However, following a decision by Member States to ask NBOG to review a range of guidance papers produced by NB-MED Recommendations Group, it was decided to invite the Chairman of that group (Mr John Worroll) to attend NBOG meetings to participate in that review. This has worked well.
20. John Worroll's presence at the meeting has achieved two other important goals. First, he is able to provide detailed and authoritative feedback to the NB-MED Group on NBOG's activities. Second, and arguably more importantly, NBOG has been able to use him as a conduit between NBOG and the NB-MED and, consequently, facilitate a degree of joint collaborative working. Thus during the year we have referred a number of NBOG draft guidance papers to NB-MED for their input. By this mechanism we hope that NBOG's output will be of even better quality and usefulness.

### **Acknowledgements**

21. Finally, but by no means least, I would like to thank NBOG members for their contributions to the group's very real achievements; their respective organisations that have continued to ensure that these people are available to contribute to NBOG and 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:**

Responsible for the designation and monitoring of the Austrian notified bodies is the Federal Ministry for Health and Woman's Issues. The designation and surveillance of a notified body in Austria is done according to the Austrian medical devices law and in cooperation with the Austrian accreditation body.

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 2004, there was no change in the scopes.

Each notified body was audited doing a surveillance audit conducted in cooperation with the Austrian accreditation body (part of the Austrian Federal Ministry for Economic Affairs and Labour. Actual Problems were discussed during the notified body jour fixe (twice a year). Re-evaluation according to Directive 2003/32/EC has been started and preparation for electronically submitting the certificates to our medical devices register has been done.

### **Belgium:**

The Medical Devices Service of the General Direction 111 of the Belgian Federal Public Service is responsible for the designation and monitoring of Notified Bodies in Belgium. There are currently two NBs in Belgium : Apragaz and CEBEC. They are designated only for the Medical Devices directive 93/42/EC.

During 2004 we conducted surveillance audits of both NBs. On each audit we were joined by auditors from the Belgium national accreditation service, Belcert. These audits did not identify any serious problems and whatever fairly minor deficiencies were found were corrected immediately.

We also attended the NB-Med meetings with our NBs.

### **Cyprus:**

Cyprus do not currently have any Notified Bodies for the medical devices Directives.

### **Czech Republic:**

In the Czech Republic the Czech Office for Standards, Metrology and Testing (COSMT) is responsible for the designation of notified bodies for medical devices. The designation and notification is made according to Act 22/1997 Coll. on technical requirements for products, as amended, where the designation process is called "authorization". The authorization is processed very carefully - all applicants should document the fulfilment of all criteria of the relevant medical directive.

On the 1 May 2004 - the date when the Czech Republic accessed to EU there were notified:

six NB's for Directive 93/42/EEC,

two NB's for Directive 90/385/EEC, and one NB for Directive 98/79/EC

In early 2004 COSMT checked carefully the range of designation of all the NB's with the special attention to the NB's designated according to Directive 93/42/EEC. The reason for this action were changes introduced for the conformity assessment of medical devices by Directives 2000/70/EC and 2001/104/EC and by Directive 2003/32/EC. The subject of the examination was verification of the up to date knowledge of NB's to deal with medical devices that contains as an integral part human blood or the derivatives of it or that are produced from animal tissue from TSE susceptible animals or integrate derivatives of such tissue. Where the ability was not transparently documented the range of NB's notification (authorization) was reduced.

In the year 2004 a surveillance assessment was conducted of one NB notified for medical devices (MDD) and one NB notified for active implantable medical devices (AIMD). No serious noncompliance was found and minor deficiencies were corrected immediately.

### **Denmark:**

The Ministry of Interior and Health is the Danish Designating Authority. The task of monitoring and assessing the performance of the Notified Bodies is delegated to the Danish Medicines Agency. Denmark has one Notified Body.

Directive 2003/32/EC was transposed into Danish law in May 2004. The senior management of the Danish Notified Body decided not to provide the service of conformity assessment for medical devices in the scope of the TSE Directive. The Danish Medicines Agency took note of this information. Since there was no case of non-compliance with this Directive, just no wish from the Notified Body to provide this service, the Danish Medicines Agency considered that this decision was not required to be reported to the Commission.

### Designation Activities:

Following assessment by the Danish Medicines Agency, the NB's scope was extended to include devices for determining blood groups on Annex II, List A of directive 98/79/EC.

### Surveillance Activities:

Surveillance assessments are performed according to the frequencies set in MEDDEV 2.10 rev 2 and in accordance with the directions in the Designating Authorities Handbook.

In 2004 the Danish Medicines Agency performed one surveillance assessment. Furthermore, the Danish Medicines Agency witnessed one audit and observed one CAB audit.

The Danish Medicines Agency conducts meetings with the notified body on a regular basis to facilitate compliance with the requirements. In 2004 three such meetings were held.



Appropriate corrective actions have been taken by the Notified Body under the surveillance of the Danish Medicines Agency.

### **Estonia:**

In Estonia, the Designating Authority is the Ministry of Economics and Communications. The Executive Body is a 13-member Executive Commission, which consists of members from different ministries and agencies, including a member from the State Agency for Medicines, which is the Competent Authority for medical devices. The supervision of Notified Bodies is the responsibility of the abovementioned Commission.

The Commission performs supervision mainly by means of desk review, as regular supervision in the field is performed by the Estonian Accreditation Centre (EAK: [www.eak.ee](http://www.eak.ee)). Thus, all Estonian Notified Bodies are accredited on compliance to relevant standards.

The Commission performs field inspections on a sample basis.

Currently Estonia does not have any Notified Body in the sector of medical devices Directives. However there are a number of branch offices of Notified Bodies of other member states located in Estonia. Up until now these have covered the needs of the local medical devices industry.

### **Finland:**

The Ministry of Social Affairs and Health (MSAH) is responsible for the 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. Ideally they plan to conduct surveillance audits at 6-18 months intervals. However during 2004 there were no audits of Finnish NBs conducted.

### **France:**

AFSSAPs is both the French competent authority and designating authority for directives 90/385/EEC, 93/42/EEC and 98/79/EC. Only one notified body, G-MED, is designated in France for the entire medical device field and for all conformity assessment procedures, relating to these three directives.

A memorandum was adopted in 2002. This lays down the methods of communication, between Afssaps and G-MED, relating to the activity of G-MED and the evolution of its organization. G-MED must thus provide an annual report according to the format adopted by the NBOG. In addition, the follow-up of G-MED is carried out according to the following methods :

- Afssaps and G-MED meet twice a year to exchange views on regulatory matters, on the organization of G-MED and its international activities ;
- it was decided at the end of the year 2003, to hold with G-MED a quarterly technical meetings in order to deal with points of doctrine concerning assessment/evaluation, classification of medical devices and on quality management system auditing ;
- G-MED provides each month to Afssaps a list of the issued compliance certificates ;
- finally, the withdrawals or suspensions of certificates notified by G-MED are subject to a specific evaluation procedure by Afssaps.

It is also appropriate to mention for 2004 the following points:

- in May, having examined the capability of G-MED to assess the conformity of medical devices concerned by the 2003/32/CE directive Afssaps has confirmed to DG Enterprise the notification of G-MED in this field;
- as announced last year, LNE has taken over, alone, in 2004 the activities of G-MED until they run jointly with the LCIE. Taking into account this change Afssaps has notified to DG Enterprise LNE/G-MED with regard to the three directives 90/385/EEC, 93/42/EEC and 98/79/EC in October.

Specific technical items have been studied with G-MED during 2004 :

1. Problems identified during the inspections by Afssaps of manufacturers.
  - Breast implant classification revision : GMED has to adapt follow up audits and review the delivered certificates according to the classification update;
  - Discussions with G-MED concerning the non conformances identified by Afssaps during inspections, involving NBs in general. If relevant, corrective / preventive actions can be implemented by G-MED in order to avoid the occurrence of problems similar to those identified for other NB.
2. Information meeting organised by Afssaps addressed to manufacturers or subcontractors who sterilize MD by ETO : during this meeting Afssaps has communicated recommendations / doctrine elaborated according to the non conformances identified during the inspections on this specific subject. G-MED has been invited to participate to this meeting to develop the processes applied by the French NB for the certification of special processes.

### **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 consistently, the Laender

agreed upon founding two central authorities to take over these duties, the ZLG (Central Authority of the Laender for Health Protection with regard to 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, 11 employees (8 scientific staff) are involved in the designation and monitoring of conformity assessment bodies and laboratories 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. 6 of them have also been designated under the Active Implantable Medical Devices Directive (90/385/EEC, AIMDD). In addition, 7 are designated under the *In Vitro* Diagnostic Medical Devices Directive (98/79/EC, IVDD). The designations are specified in respect to the Annexes of the Directives and the products covered.

In addition, 46 independent laboratories for testing medical devices are accredited<sup>1</sup>. In 2004, the scope of 2 Notified Bodies under the MDD and of one Notified Body under the IVDD was extended. In 2 cases, the scope has been reduced.

To implement the requirements of the Directive on medical devices manufactured utilising tissues of animal origin (2003/32/EC) the competence of 8 Notified Bodies for conducting conformity assessment procedures for medical devices underlying this Directive was proven and confirmed. For about 60 of these products, ZLG coordinated the obtaining of necessary opinions from the European competent authorities.

In total, 13 assessments of Notified Bodies under the MDD, 6 assessments under the IVDD and 1 under the AIMDD were performed in 2004.

Focussing on observed audits in 2004, assessors have observed 9 audits of Notified Bodies.

In addition, 37 laboratories for testing medical devices have been assessed during this year.

The duration of the on-site assessments varied between 1 and 3 days and the assessments were conducted by 1 to 7 assessors, depending on the size and scope of the Notified Body or the laboratory. Observed Audits were performed by only 1 assessor, normally.

During the on-site assessments of the Notified Bodies, emphasis was particularly put on the competence of the personnel, the review of the scope of designation, the judgement of the clinical evaluation by the Notified Body, and the implementation of the Directive for the reclassification of breast implants (2003/12/EC).

The deviations found during the assessments of the Notified Bodies mainly related to

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<sup>1</sup> Listing see <http://www.zlg.de/cms.php?PHPSESSID=6ad716cae8707bef096d911f6320e252&mapid=254&hmp=4>

- deficient authorisations of internal and external personnel, sometimes based on inadequate definition and implementation of qualification requirements and missing valid records
- lack of sufficient criteria for the competence of subcontracted laboratories and for the acceptance of already existing test reports
- EC design examinations without involvement of competent personnel for all relevant product aspects
- insufficient traceability of the decision making process, sometimes due to missing records on results of parts of the conformity assessment procedure
- deficient procedures and relating documents, for e.g. assessment of clinical evaluation, consultation of competent authorities with respect to medicinal substances or handling of incidents reported to the Notified Body.

As corrective actions, mainly a revision of the authorisation of the personnel, training and re-training as well as adaptations of existing or creation of new procedures and documents have been agreed upon with the Notified Bodies.

As far as individual conformity assessments were concerned, the Notified Bodies have been asked to check the respective certifications, resulting in rework and – in some cases – suspension or withdrawal of the certificates.

In 2004, the number of information requests from other Member States according to the NBOG communication protocol has again increased. Investigations of conformity assessments in relation to these requests or related to incidents/vigilance cases were necessary for procedures for e.g. breast implants, bulking agents causing saturation and coronary stents. Classification matters played an important role as a cause of investigations as well. If relevant, information from these investigations was shared with the Competent Authorities.

In 2004, two regular 2-day exchange of experience meetings with Notified Bodies were held. Issues which were discussed during these meetings were e.g. the implementation of the Directive on medical devices manufactured utilising tissues of animal origin (2003/32/EC) or batch verification for *in vitro* diagnostic medical devices. New or revised guidance documents were issued e.g. for the assessment of clinical evaluations, on harmonised standards and their impact as well as on the dealing with risk analysis.

**Greece** : Information not supplied

### **Hungary:**

The main responsibility in the practical sense for the designation and audit for Notified Bodies lies with the Hungarian Competent Authority (CA) for Medical Devices. The CA manages the secretary affairs of the Designation Committee (DC) who designates the NB's and supervises their activities. The official designation of the NB's is ruled by the ministerial decree no. 48/1999 (6.October) of the minister of health on the designation of NB's commissioned for the assessment, monitoring and certification of medical devices operated under the technical supervision of the Ministry of Health.

The designating authority shall adopt a decision after due consideration of the proposal from the DC. The designating authority shall invite members to the committee from the Ministry of Health, Ministry of Economic and Traffic, the General Inspectorate for the Consumer Protection, and from the National Accreditation Board. The members of the DC are nominated by the minister of health.

At present Hungary has two NB's for medical devices nominated in our system. One is the Institute for Hospital and Medical Engineering (ORKI), the second one is the Hungarian Electrotechnical Control Institute (MEEI).

The supervision of our NB's was performed in every year from 2001 for ORKI, and first in 2005 concerning the MEEI's activity in the year 2004. The audit program of the supervision is based on the ministerial decree no. 47/1999.(6.October) of the minister of health on the medical devices, the MEDDEV document No.2.10 Rev.1, and the accreditation standard.

The audits were performed by independent expert auditors in every case. The report of the results of the supervision contains the detailed statements and as circumstances may require the requirements of the corrective actions.

#### **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.

In 2004, the IMB verified the National Standards Authority of Ireland (NSAI) to EU Directive 2003/32/EC on medical devices utilising tissues of animal origin and related S.I. No 554 of 2003. The IMB previously designated NSAI to the MDD, AIMD and IVD legislation.

The IMB conducted 5 Notified Body audits in 2004. The audits consisted of one surveillance audit to the MDD and AIMD, one surveillance audit to the IVDD and 3 witnessed audits of NSAI Auditors to the MDD. Subcontracted auditors were targeted through the observed audits.

Following one of the surveillance audits, the IMB decided to reduce the designation scope of the Notified Body to more accurately reflect the current competency in relation to the Medical Device Directive 93/42/EEC. The amendment to the scope of the Notified Body was notified to the Official Journal of the European Commission.

The IMB continue to conduct quarterly meetings with the Notified Body to ensure a level of on-going communication.

#### **Italy :**

The Ministry of Health and Ministry of Productive Activities are the Designating Authorities in Italy. There is not any Agency involved in the sector of MD.

At the beginning of 2004, eight NBs, designated for different classes and families of Medical Devices, were operating in Italy. During 2004, a new request for designation was examined (documental and inspective evaluation) and, finally (January 2005), the Body (ICIM) was designated.

In the period under examination, a new decree (Ministerial Decree Jul 14<sup>th</sup>, 2004) has been written and published to better implement the administrative procedures for designation.

In the last quarter of the year has started the procedure for renewal of the designation for the eight existing NB, that were close to the expiry date.

**Latvia:** Information not supplied

### **Lithuania**

The Health Ministry of the Republic of Lithuania and The State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania (CA - Competent Authority) are the designating authorities for notified bodies for the scope of medical device directives.

In the Agency we have 3 staff involved in all the procedures related to the designation and surveillance of the notified body.

For the implementation of the *Acquis Communautaire* the National Programme has been developed in 2000. For the fulfilment of the requirements of the Free movement of goods The Programme on Conformity Assessment Infrastructure was adopted in 2001. The Competent Authority had prepared the part of this Programme (PHARE financed) for the strengthening the accredited Electrical Equipment Certification Centre *Sertika* for the notified body functions.

The identification number *1609* to this body has been allocated 31.03.2005 (ENTR /C1/NMG D(05)5014. "Sertika" has been designated to carry out conformity assessment tasks under the New approach directive 93/42/EEC (EC type-examination (Annex III); EC verification (Annex IV). Lithuania also currently has one Notified Body designated under the directive 93/42/ EEC on medical devices.

**Luxembourg:** Information not supplied

### **Malta:**

The Consumer and Industrial Goods Directorate of the Malta Standards Authority is both the Competent Authority and the Designating Authority for Malta. It currently has 3 staff involved in some way or another in the designating and auditing of Maltese Notified Bodies operating under any of the New Approach Directives. This figure includes 1 staff with responsibility for Notified Body auditing.

To date, Malta has not designated any Notified Body under any of the three Medical Devices Directives, i.e. the Medical Devices Directive, the In-Vitro Diagnostic Medical Devices Directive and the Active Implantable Medical Devices Directive.

### **Netherlands :**

The Dutch Healthcare Inspectorate is responsible for the control of two Notified Bodies under the Medical Device Directives. Both Notified Bodies are designated for the MDD, AIMD and IVD directive. The notified Bodies are accredited by the Dutch Council of Accreditation (RVA) based on the EN 45011 and EN 45012 standards. The RVA audits the notified body following to their own annual scheme. The Dutch Competent Authority performs initial audits and surveillance audits taking into account the results of the RVA audits, the audits are focused on aspects in de MEDDEV2.10 not covered by the accreditation of the RVA.

Notified Body assessments are performed in line with the procedures described in the Designating Authority handbook. The MEDDEV 2.10 rev 2 is used as auditing scheme.

In 2004 both Notified Bodies have asked for an extension of the scope for medical devices falling under the TSE BSE directive 2003/32/EC. One Notified Body did not receive a positive notification and will be re-evaluated in 2005.

In 2004 the Dutch Competent Authority performed two surveillance assessments on site and one re-audit because of significant problems. The re-assessment was performed accompanied by a Notified Body auditor of another member states. This resulted additional expertise within the assessment team, aligning remedial actions and exchange of ideas of assessing notified body between member states.

During the performed surveillance assessments the most non conformities against the MEDDEV 2.10 concerned were to the review activities within the Notified Bodies themselves. The most common non conformities were:

- Delays and/or inappropriate action on found non conformities
- Insufficient traceability of decisions
- Insufficient planning of the surveillance audits
- Training records were not up to date

In all cases Notified Bodies have taken corrective actions to ensure an appropriate quality system and that procedures will be in place. In 2004 two regular Notified Body meetings were held in the presence of the Regulating Authority from the Ministry of Health Care. Besides local aspects the main issues discussed were international affairs which were important to the Notified Bodies like NBOG, MDEG, implementation of the TSE BSE Directive and classification issues.

### **Portugal :**

The Ministry of Health is the Designating Authority in Portugal.

In Portugal there are two Competent Authorities under the medical devices Directives.

INFARMED is the Portuguese Competent Authority for non-active medical devices and for *in vitro* diagnostic medical devices. INSA is the Portuguese Competent Authority for active medical devices and for implantable medical devices.

Although the Designating Authority is the Ministry of Health, the Competent Authority INFARMED performs the control of the two existing Notified Bodies.

INFARMED, the Notified Body with the codification number 0503, is designated for MDD, but non-active devices only. In the end of 2004, INFARMED Notified Body initiated the candidature process for IVD Directive. It is also important to refer that INFARMED, in 2004 was reevaluated for its capability in assessing the conformity of MD concerning the 2003/32/EC Directive.

LEMES, the Notified Body with the code number 0532, is designated for the MD, AIMD and IVD Directives.

During 2004, INFARMED Notified Body performed the audits established, regarding the monitoring of the issued certificates, complying with his internal annual plan.

INFARMED, the Competent Authority, performed one observed audit and one surveillance audit in the concerned year related to the activities of INFARMED Notified Body.

During the surveillance audit, on the site at the Notified Body's office, there were found some improvement, namely:

- Special training for the monitoring and environmental control and for the GMPs;
- Revision of some quality procedures and an introduction of a procedure related to the obligation of pre-submission meetings for the envoy of technical documentation;
- Participation in the Notified Bodies Recommendations Group;
- Elaboration of some guidelines to their clients related to the sterilization processes, parametric release and determination of endotoxins;

As a result of the last audit surveillance, INFARMED Notified Body introduced modifications in their organisation and solved the non-compliance found during 2003.

During the observed audit it was verified that the technicians involved in the audit had the appropriate knowledge not only on the regulation and in the quality systems, but also in the special procedures as the sterilization process.

#### **Poland:**

Polish accession to European Union on May 1<sup>st</sup> 2004, resulted in implementation of EU standards and regulations applied to medical devices in our country.



In Poland, the Ministry of Health and President of The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products share the responsibilities of the Designating Authority and the Competent Authority. The Ministry of Health is in charge of the appointment of Notified Bodies and their monitoring through scheduled and unscheduled audits. The President of The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is in charge of market surveillance, vigilance, clinical evaluation and registration of medical devices. These duties are carried by 3 full time staff and part time specialists employed by the Ministry and 27 people employed by the Office.

During the first 8 months of Polish EU-membership, 8 institutions applied for Notified Body status. After careful initial audits, five of them have been recommended and obtained the designation decision issued by the Ministry of Health. One institution has been rejected due to the lack of adequately experienced staff, another withdrew its application.

A total of 13 audits of Polish Notified Bodies were undertaken by the Competent Authority during 2004 – 7 initial audits and 5 surveillance audits.

Starting from 3 of November till 10 of December 2004, 5 scheduled surveillance audits of all (Polish) Notified Bodies were carried. These audits may be summaries as follows:

- to the end of 2004, only one Notified Body issued 5 CE certificates for medical devices (4 for MDD, 1 for IVD).
- certificates issued (as voluntary certificates of type examination) by another Notified Body had certain formal mistakes. Also medical devices manufacturer's documentation was insufficient. These elements were found during the audit and presented in audit's report. The Notified Body has been obligated to immediate correction of the pointed elements. January 2005 was designated as the deadline for these corrections.

In addition, 2 unscheduled audits were taken in the second half of 2004. There were the following reasons for them:

- close monitoring of the Notified Body which had been issued voluntary certificates with mistakes;
- verification of information on significant conflict of interest which had been present at one of the Notified Bodies and which had been hidden during the scheduled audit. Considering all circumstances, the notification for the audited institution – ITAM has been withdraw.

All 4 Notified Bodies have summarised their year 2004 activities pending adequate reports addressed to (Polish) Ministry of Health.

### **Slovenia:**

According to the regulation on medical devices, the designating authority for Notified Bodies in the Republic of Slovenia is the Minister of the Economy who, with the consensus of the Minister for Health, is responsible for the designation of Notified Bodies. The regular monitoring of Notified Bodies is performed by the Slovenian accreditation body, while the Ministry of the Economy carries out special monitoring.

The Slovenian accreditation body assesses the qualification of Slovenian Notified Bodies according to the Act on accreditation and keeps the Ministry of the Economy informed about the status of the Notified Body. The Notified Body might have four different status: it may keep the accreditation, the accreditation may be temporarily deprived, the accreditation may be recalled or it may be in the course of the proceeding.

In the year 2004 the Slovenian accreditation body carried out the regular monitoring of our Notified Body (SIQ 1304) in accordance with the accreditation rules. The Slovenian Notified Body SIQ holds the following accreditation:

EN 45011 – certification body (Slovenian Accreditation (SA), DaTech)  
EN 45012 – certification body for quality systems (SA)  
EN ISO/IEC 17025 – testing lab (SA, DaTech)

The Slovenian accreditation body has informed us that on the basis of the monitoring performed in 2004, SIQ has fulfilled the criteria for keeping the status of accredited organ.

### **Slovak Republic:**

In the Slovak Republic, the Ministry of Health of the Slovak Republic is the legislative body responsible for the whole area of medical devices. The Directive 90/385/EEC, 93/42/EC and 98/79/EC are involved in the Government decrees nos. 572/201, 572/2001 and 569/2001. It has designated the State Institute for Drug Control (SIDC) the competent authority for all MD, IVD and active implantable medical devices. SIDC, as the competent authority is responsible for putting medical devices onto the market. This involves the registration, code assignment and supervision of dossiers. SIDC is also the competent authority for notification and registration of adverse effects and assessment of clinical trial notifications.

According to Slovak law a Slovakian Notified Body can only be designated after it has been accredited by the Slovak National Accreditation Service (SNAS). The Slovak Office of Standards, Metrology and Testing (UNMS SR) is responsible for the designation and monitoring of NBs in the Slovak Republic. Evaluation and audit of NB activity comes under the jurisdiction of the UNMS SR and SNAS.

There are 4 NBs in the Slovak Republic:

- No 1293 – EVPU a.s. Nova Dubnica (SKTC 101), Gajova 4, 811 09 Bratislava, designated for all medical devices and directives 90/385/EEC, 93/42/EEC and 98/79/EC.
- No 12398 – CEROT s.r.o, Bratislava (SKTC 144) for directive 93/42/EEC (CEROT besides the technical trials of optical medical devices also provides counselling services for medical requirements.
- No 1297 – VUZ, Bratislava (SKTC 115) for directive 93/42/EEC
- No 1296 – VUTCH-CHEMITEX s.r.o for directive 93/42/EEC

Since the Slovak Republic joined the EU until 31 January 2005, EVUP has notified to the competent authority (SIDC) a recognition of 154 certificates (of these 21 were for Slovak producers). CEROT (until 31 March 2005) notified 10 certificates (of these 6 were Slovak producers) The remaining two NBs have not so far notified any certificates.

## **Spain :**

The Ministry of Health and Consumer Affairs. Spain is the Spanish Designating Authority. 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 Subdirección General de Productos Sanitarios (SGPS). Three members on the staff of this Subdirectorate are directly involved in the tasks of assessment and monitoring of Notified Bodies.

Spain has one Notified Body currently designated ie. “Agencia Española de Medicamentos y Productos Sanitarios” (AEMPS), formerly, Dirección General de Farmacia y Productos Sanitarios. Its identification number is 0318 and its designated scope is:

- Directive 90/385/EEC, since April 1993. No amendments in 2004.
- Directive 93/42/EEC, since October 1994. No amendments in 2004
- Directive 98/79/EC, since December 2002. No amendments in 2004.
- Directive 2003/32/EC, since 27<sup>th</sup> January 2004. Designation in 2004

During 2004 the Spanish DA has undertaken the following activities:

### I. Designation activities:

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. Follow-up of the Notified Body activities:

- Direct control by meetings to discuss regulatory matters in order to deal with points concerning classification of medical devices, borderline devices, assessment and quality management system auditing.
- Indirect control by inspection of manufacturers certified by the NB when there is a surveillance or vigilance issue.
- The withdrawal or suspensions of certificates notified by the NB are subject to a evaluation procedures by the AEMPS and in some cases specific actions has been taken towards the manufacturers.

- Number of audits conducted: one surveillance audit on site at the notified body's office. The few problems found have been addressed.

### **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 has no new applications for NBs. One NB asked for a small extension of its scope.

During 2004, SWEDAC (DA) and MPA (Competent Authority for Medical Devices in Sweden) conducted one complete assessment at one of the NB's main office. The NB extended its scope with Non active surgical implants Class IIb; Joint replacement implants and Implants for osteosynthesis. The conclusion of the assessment was that the NB was competent for the extension. Regarding the quality system the quality manual needed to be updated with job descriptions, CV etc. Some written routines was not followed by the NB regarding document control. The NB has responded with suggestions for corrective actions. The corrective actions are at the moment reviewed by CA.

Regarding the second NB the assessment had to be postponed to 2005

SWEDAC is planning during 2005 to do at least one "Observed Audit".

### **The United Kingdom**

The Medicines and Healthcare products Regulatory Agency (MHRA) is both the Competent Authority and the Designating authority for the UK. It currently has 5 staff involved in some way or another in the designation and auditing of UK Notified Bodies. This figure includes 3 staff with responsibility for Notified Body auditing.

The UK currently has 7 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 and device scopes under each directive. During 2004, one Notified Body withdrew from operating as a UK Notified Body under the Medical Devices Directive.

A total of 13 audits were undertaken of UK Notified Bodies during 2004. Of these, 8 were surveillance audits covering the MDD (two of them also covered the IVDMDD

and one covered the AIMDD). The remaining 5 audits were witnessed audits (four covering the MDD and one covering the IVDMD).)

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

- IVD standard reference material not included in audits of calibration activities.
- Insufficient initial verification that products were medical devices under the Directives.
- Insufficient documentation of decisions taken by Notified Bodies.
- Insufficient sampling across the whole system to verify that an element of the audit plan had been adequately covered during an audit.
- Acceptance of inadequate clinical data during Design Examinations.

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 2005 audit programme.

Monitoring of the Notified Bodies also included investigations into two instances where problems reported during witnessed CAB audits may have affected assessors that were also used by UK Notified Bodies. Where this was confirmed, the Notified Body took extensive action to resolve the problems.

As a result of our findings MHRA also took the following formal actions against specific Notified Bodies in 2004:

- One Notified Body has been closely monitored due to unacceptably high levels of audit program delays to ensure sufficient resources are put in to rectify the situation.
- Following the identification of gaps in the expertise of one Notified Body and its suspension from carrying out assessments in particular areas, the restrictions were maintained in place while the Notified Body prepares evidence for a revised scope.

## **Switzerland**

Switzerland has five Conformity Assessment Bodies (CABs) designated under the MRA with the EU. They are all active for the Directives 93/42/EEC. One CAB is designated for the Directive 90/385/EEC as well. The Swissmedic team responsible for CAB designation includes three auditors. Swissmedic has audited jointly with the Swiss Accreditation Service one CAB in the year 2004. Main corrective actions requested from the CAB included:

- To specify explicit validation requirements to be audited (including design validation).
- To improve the internal certification process after the audit by listing in detail the applicable standards and legal requirements.

The duration of the witness audit was one day.

Swissmedic provided a training for CAB staff on the topics Post Marketing Studies and EUDAMED.

**Norway:**

The Directorate of Health and Socioal 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. No NBs are designated for the AIMD or the IVDMD Directive.

The Notified Bodies all delivered their annual reports by April 2004.

All Notified Bodies are accredited under the EN 45000 standards, and hence receive regular visits from the national accreditation body (Norwegian Accreditation – NA).

Requests from other Member States have been raised with the NBs, without any of them leading to any formal action against any NB. A number of examples of misuse of the notified body number has been revealed, related in particular to one of the NB. These issues are handled by the NB itself.

The competence of the one NB having certificates for products covered by directive 2003/32/EEA was reviewed. Surveillance audits of all three bodies were foreseen to be completed in the autumn of 2004, but had to be postponed. Preparations started in 2004, and the audits themselves took place in winter 2005.

**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>
NBs understaffed or lost particular (and crucial) competencies
Product verification incorrectly conducted
Non-compliances from previous audits not correctly closed-out
Major non-conformances not closed out satisfactorily by the manufacturer prior to the Notified Body issuance of the certificate.
No review of sterilization validation or any queries relating to the sterilization on file
Documentation of Clinical review was insufficient
Details of certificates suspended or withdrawn not available

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 2005 Berne meeting of Competent Authorities.**

Work Item	Lead Country	Intention	Current State of Play
Construct proposals for the introduction of an element of peer review into the Designating Authorities work on the designation and control of Notified Bodies	All	To encourage a greater consistency in the way different Designating Authorities designate and control their national notified bodies and, in the process increase mutual confidence.	NBOG has enthusiastically endorsed the principle of peer review but is realistic about the practical difficulties facing its introduction. Various options have been identified. These are to be further developed with a view to putting initial proposals to the next CA meeting in September 2005
Review the designated scopes of individual Notified Bodies shown in the Official Journal and on the Commission's web site to ensure accuracy, clarity and consistency.	All	To ensure that NBs designated scopes of authority are clearly and consistently described.	All Member States are currently reviewing the described scopes of designation against the scopes described in the original designation letters of the NB to identify any areas of inconsistency or doubt.
Prepare guidance for Notified Bodies where their clients are Own brand labellers	Germany and the UK	To provide guidance specifically on the issue of the extent to which a NB whose client is a OBL can take account of certification issued by the NB of the original manufacturer.	Germany and the UK are preparing a first draft which will then be issued to NBOG members for discussion and comment.

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

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	Each paper assigned a volunteer lead assessor. Preliminary comments already issued to NBOG for consideration. Agreed to invite the Chairman of the NB-Recc Group to attend NBOG meetings for this particular item.
Revise MEDDEV 2.10	Germany, Netherlands, Belgium, France and the	Update MEDDEV 2.10 to reflect various items arising from the IVD Directive, etc.	Revised format and structure agreed. Textual changes now being made for circulation to NBOG early in 2005.



	Czech Republic		
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 before being sent to NB-MED for comment..
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. Minor amendments to be reflected in the paper and then sent to NB-MED 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.	Final draft produced and agreed by NBOG. Sent to NB-MED for comment.
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.	Revised drafts produced and circulated for comments. Further revisions now being made.

**List C : Items completed prior to December 2003**

<b>Work Item</b>	<b>Lead Country</b>	<b>Intention</b>	<b>Comments</b>
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 described in the MEDDEV and, by highlighting differences or omissions, suggest possible changes.	Checklist completed and incorporated into the DA Handbook.
Produce guidance on the specific competencies required by NBs dealing with : a) IVDs a) Devices incorporating human blood or plasma; and b) 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.

Organise and provide training for DA assessors	UK, Ireland, Netherlands, Germany	To provide training based on the practical application of the DA Handbook	Training event provided in the Hague in July 2004.
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	Netherlands	This programme would set up a mechanism whereby a DA assessor from Country 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 Country 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.