Minutes

MEETING OF THE MEDICAL DEVICES EXPERT GROUP

A FAIRE

DATE **30 June 2004** **10.00-18.00**
1 July 2004 **09.30-17.00**

PLACE **CCAB – Centre de Conferences A. Borschette - Rue Froissart, 36 1040 _ Bruxelles**

N°	Description	Document Reference	Sent on
0.0	**Approval of the Agenda**	Doc EG-003-06-04 Draft Agenda 2004 June-July 2004 V4.doc	

Review of the Directive will be reported to second day.

1.0	**Note with conclusions of the previous meeting**	Doc EG-002-06-04 Notes 29 March 2004.doc	17.05.04

2.0	**Review of MD Directives (July 1st, AM)**	Doc EG-032-06-04 Issues for Review of MDD 16 June 2004.doc	24.06.04
		Doc EG-036-06-04 Issues for Review of MDD Amended 23 June 2004.doc	23.06.04
		Doc EG-037-06-04 Other proposals to revision 23 June 2004.doc	23.06.04
		Doc EG-031-06-04 CETF proposal for review of MDD v 7.06.04.doc	23.06.04
		Doc EG-033-06-04 state of the art.pdf	16.06.04
		Doc EG-035-06-04 Biocides First Draft.doc	23.06.04

*postponed from previous meeting

A line of action for June / July MDEG has been defined

2.1. Overview

- Current legal framework is appropriate – implementation requires improvement
- Modification should not represent a major departure
- Areas for modification highlighted Annex V of the Commission communication

2.2. Action:

2.2.1. Present Documents
2.2.2. The proposal is to discuss "Substantial" issues and not "Wording"
2.2.3. Agree list of "Substantial" issues with any additions
2.2.4. Discuss if there issues are to be pursued (yea or nay)
2.2.5. Decide if meeting in September is necessary
2.2.6. Next document will be a draft proposal

2.3. Documents

2.3.1. Modifications
2.3.2. Others proposals

- Largely included in modifications in 1. above
- Or are in Directive already
- Or are part of general (ongoing) debate

2.4. "Substantial" issues

2.4.1. AIMD – which option
2.4.2. Clinical data – CETF text
2.4.3. Software (awaiting input)
2.4.4. e-labelling
2.4.5. reclassification anomalies
2.4.6. EUDAMED for custom-made devices?
2.4.7. Inclusion of knowledge of user etc. in Annex I

*postponed from previous meeting

2.4.8. Inclusion of foreseeable misuse in Annex I
2.4.9. reference to "Reprocessor" of single-use
2.4.10. utilising or incorporating

Other topics wishes to be incorporated :

- Distribution : Definitions and responsibility
- Transparency
- Clinical trials : data's assessed and approved
- Documents with regulatory binding rules other than Directive
- Medicinal products incorporated in a device (see issues 36 (proposed solution 1/ verification by NB for usefulness and 2/ then safetiness by EMEA)

The Commission came with a proposal in order to better classified medical devices:
In article 13 (1) add new :

Or
(d) in order to clarify the appropriate classification of a device a decision is required as to whether the device falls within the definition in Article 1 section 2 (a), (b), (c), (d), (e), 3, 4 and 4(a).

See compilation: Doc EG-036-06-04 Issues for Review of MDD Amended 23 June 2004

3.0	**Progress reports of the following meetings**		
3.1	**MSOG***	Doc EG-007-06-04 Class I Guidance_draft 3.doc* Doc EG-008-06-04 MSOG document - 8.2.doc* Doc EG-009-06-04 MSOG CustomMadeGuidance_draft3 - 8.2.doc*	04.06.04

There are 3 drafts guidance documents on which comments are asked for September 1st.

*postponed from previous meeting

3.1.1. GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES

Background

The document purpose is to provide a set of guidance notes to class I medical devices manufacturers who , placing under his own name the product on the European market, must act according to the national legislation transposing the 93/42/CEE Directive, which regulates medical devices.

The medical devices must comply with the essential requirements established in the Annex I of the 93/42/CEE Directive, ensuring that they do not compromise the Health and Safety of patients, users and any other persons, and carry the CE mark as a guarantee of its conformity.

The manufacturer of class I medical device, a low risk device, shall follow the procedure referred to in annex VII and draw up the EC declaration of conformity required before placing it on the market. The 93/42/CEE Directive also specifies assessment requirements of clinical investigation protocols and any occurring adverse incidents evaluation.

These guidance notes do not aim to be a definite interpretation of the law and/or regulations and are for guidance purpose only.

Scope

According to the criteria established in annex IX of the 93/42/CEE Directive the manufacturer must classify his own products.

The manufacturer, after classifying their products as a class I medical devices, must act accordingly to the procedures established in the 93/42/EEC Directive namely, drawing up the EC Declaration of Conformity and prepare the appropriate technical documentation as well as informing the Competent Authority (CA) of the country in which he has his registered place of business and providing the sufficient information on the device concerned.

*postponed from previous meeting

For manufacturers who do not have a registered place of business in the European Union or in a country having an MRA with the EU, Article 14 of MDD, an Authorised Representatives (AR) is required. This entity, who have been designated by manufacturer as legal representative in the European Community, is responsible to inform the CA of his registered place of business and the device type concerned.

The present guidance also gives orientations to the manufacturers for a correct classification and how to proceed in order to comply with the article 14 of the 93/42/EEC Directive.

3.1.2. GUIDANCE NOTES FOR DISTRIBUTORS/IMPORTERS

Background

According to the medical devices directives, distributors and importers are not, directly, regulated, if they are not, simultaneously, manufacturers or authorised representatives.

According to the article 2 of the 93/42/CEE and 98/79/EC Directives the Members States shall take all necessary steps to ensure that the device may be placed on the market and put into service only if it do not compromise the safety and the health of patients, users and, where applicable other persons, when properly installed, maintained and used in accordance with its intended purpose.

Devices shall be kept so as to ensure that they maintain the quality, safety and the performance intended by the manufacturer till the end of the supply chain.

Scope

An analysis of vigilance reports showed that neither the CA nor the manufacturer always gets the information needed from the distribution chain. This resulted in an increasing number of incidents assessed as isolated problems, whilst the wider context of the problem was not always identified initially.

*postponed from previous meeting

The purpose of this guidance note to distributors and importers is to establish the necessary roles to maintain a quality management system to ensure that the quality, safety and performance of the medical devices are not affected during their distribution and to guarantee that the appropriate records are kept and made available, in the post-market surveillance.

3.1.3. GUIDANCE NOTES FOR MANUFACTURERS OF CUSTOM MADE MEDICAL DEVICES

Background

The custom-made devices manufacturer, who places under his own name the device on the European market, must act according to the national legislation, transposing the 93/42/CEE.
Directive, which regulates medical devices.

The custom-made devices must comply with the essential requirements established in the annex I of the 93/42/CEE Directive, to ensure that they do not compromise the Health and Safety of patients, users and any other persons. Whenever this is impossible, the manufacturer must indicate which of the essential requirements has not been fully met.

The manufacturer of custom-made devices, shall follow the procedure referred to in annex VIII and draw up the EC declaration of conformity before placing them on the market.
The 93/42/CEE Directive also specifies assessment requirements of clinical investigation protocols.
These guidance notes do not aim to be a definite interpretation of the law or regulations and are for guidance purpose only.

Scope

This guideline provides a general guidance for manufacturers of custom-made devices in order meet the requirements of MDD.

In relation to manufacturers who do not have a registered place of business in the European Union, article 14, of the MDD Directive, requires an Authorised Representative, designated by the manufacturer, to be their legal representative in the European Union.

*postponed from previous meeting

3.2	**Clinical evaluation task force***		

The Clinical Evaluation Task Force drafted proposals for the review of Directive 93/42/EC (MDD) (see Doc EG-031-06-04 CETF proposal for review of MDD v 7.06.04.doc)

3.2a	**Post-market clinical follow-up**	Doc EG-040-06-04 PMCF v.14 Rev 18.05.04.doc	23.06.04

A document has been produced.

POST MARKET CLINICAL FOLLOW-UP OF MEDICAL DEVICES UNDER THE MEDICAL DEVICES DIRECTIVES

Rev 14 – May 18, 2004

Foreword : Rationale and Goals of PMCF

This document is intended to be a guide for manufacturers and notified bodies on how to carry out PMCF in order to fulfil post market surveillance obligation according to point 3. 1 of annex II, point 3. of annex IV, point 3 of annex V, point 3.1 of annex VI or point 4 of annex VII of medical device directive (add ref. AIMDD)

While clinical evidence is an essential element of the premarket conformity assessment process, it is important to recognize the limitations inherent to these premarket clinical investigations. The extent of the data that can be gathered in the premarket phase does not enable the manufacturer to detect infrequent complications or problems only apparent after widespread use, or /long term performance issues. As part of the manufacturer's quality system, a program of appropriate post market surveillance is key to identifying and investigating risks associated with the use of medical devices placed on the market.

Manufacturers should have general systems in place to cover PMS as well as having a defined PMS strategy for each of their products/product ranges

*postponed from previous meeting

Therefore, PMCF appears as a method of choice for this purpose. It will, for instance, enable patients' access to new therapies while establishing a review process for long term safety follow-up and detection of possible emergent risks that cannot be adequately detected by relying solely on pre-market clinical investigations (given the relatively short follow up required) or product experience /vigilance.

This documents received a large consensus.
A form and flowchart has been validated on clinical investigations.
This document will be endorsed as a MEDEV document by this MDEG meeting and will be on the EC website.

3.3	**Software working group***		

A second meeting took place in May.
Two documents are in preparation and the intention is to finalize those documents in September at the next meeting.
The first document is related to GHTF outlining.
The second document is related to Medical Devices definition to better address medical software.

3.4	**BSE/TSE**	Doc EG-039-06-04 TSE-BSE.doc	

Brief update on the activities of the Commissions TSE/BSE Working Group by Mike Cox, Chairperson.

Guidance document supporting Commission Directive 2003/32/EEC for medical devices utilising tissues or derivatives originating from animals for which a TSE risk is suspected.

At the meetings held on the 31st March 2004 and 3rd May 2004 there were representatives of Member States, EUCOMED and other invitees. The general discussions (ie transposition of the Directive, status of Notified Bodies, etc) and viewpoints on specific points (ie text of the guidance document) were considered beneficial in preparing for the forthcoming TSE Directive. The present guidance (MEDDEV 2.11/1 Rev 1) at the Commissions website has been reviewed and several further additions or amendments have been suggested. In particular it is planned to clarify the relevance of Regulation 1774, tallow derivatives and some other parts to assist interpretation.

*postponed from previous meeting

At the present time a Sub Group of the Commissions TSE/BSE Working Group is taking this work forward and the draft revision is expected after their meeting on the 23rd June 2004. The draft revision will then be discussed by the members of the Commissions TSE/BSE Working Group for their views and support to achieve a revised guidance document. This will then be followed by the final document being presented to the next MDEG meeting, for adoption as a revised MEDDEV.

…

As far as the legal appointment of Notified Bodies is concerned, a document will be circulated : Revision by the Commissions WG on TSE/BSE Draft 30 June 2004. **Application of Council Directive 2003/32/EC for medical devices utilizing tissues or derivatives originating from animals for which a TSE risk is suspected.** **Doc on web site, mettre adresse**
On one hand the national transposition is not required for the Directive to be legally in force and nor restricted a Notified Body from a country which has not transposed to be granted.
As far as the notification of Notified Body is concerned, the charge of the proof is reverse. And unless they are said by their Competent Authority they are no more notified for those types of devices, they are legally in position to assess Manufacturers.

3.5	**Workshop - Tallinn**		23.06.04

It was the last meeting for accession countries. The case studies were considered as useful.
The documents are available on EC website.

3.6	**Workshop - La Valetta**		

This meeting is in preparation.

3.7	**MRA WG**		

US :

*postponed from previous meeting

The main purpose on this MRA meeting was to analyze the MRA between US and EC
By them 3 CAB has been audited through observed audits. Two of them have been considered as agreed.
It has been agreed on both part to enter the operational phase with 6 CAB/Notified Bodies from Europe listed and 2 CAB form US.
Everything is on track for publication in Official Journal.

Australia :
A joint implementation plan has been agreed. A new text is in preparation. A single difficulty was raised on Australia point of view about the competency of NB (how they are designated, for which medical devices, …). This is still in discussion.

Canada :
Nothing happened

Switzerland, Monaco :
Operational

Japan :
Discussions will need to begin.

3.8	**MDEG - Vigilance**	Doc EG-054-06-04 Vigilance WG notes 2004-05-13 DRAFT.doc	

The main topics considered in the last meeting were :

3.8.1 Incident nomenclature

It was agreed that it is not enough for the European purposes, e.g. EUDAMED, to wait only for the work going on in ISO. That is why a task force was created, under the leadership of Tony Sant. Several Member States volunteered to take part in the work (BE, IE, UK, FR, DE, CH, PT and NO). The work will start immediately by changing e-mails.

*postponed from previous meeting

3.8.2 The revision of Vigilance MEDDEV document

Mr. Stösslein confirmed that he will take the chair of group. He had planned to have a first meeting of the group in Bonn 22nd of June.

3.8.3. GHTF SG2 mirror group issues

The secretary general of GHTF SG2, Mr. Sparti, gave a report. The work is going on to give guidance in three sectors: a) manufacturers vigilance reporting to Competent Authorities, b) exchange of reports between National Competent Authorities and c) Post Market Surveillance.

The last point, PMS questions were seen somewhat difficult to be conducted by the SG2 group. The Vigilance WG had the opinion that it should still be considered by the Steering Committee, having the meeting in Paris at the end of June, if this was the right forum for such a task.

The next meeting of SG2 will be held in Helsinki from 2nd to 4th of June, 2004.

3.8.4. EUDAMED update

Comments from the users :
It was decided that for the vigilance reports a double coding possibility will be added in the data base.
It was also decided that the Eudamed contact list will be added at the web-site.
The information how to register in EUDAMED will be resend to the Member States.

EUDAMED decision :
The decision is still going through the internal processes in the Commission. Also further talks with CEN are required to clarify their views on copyright and translation issues, as well on the legal status of GMDN Maintenance Agency.
It was not possible to give a definite time frame of the final endorsement of the Decision.

3.8.5. Closed session for Competent Authorities only

*postponed from previous meeting

3.8.5.1. Cypher Stent –case
The case was presented by the Dutch delegation, which is the leading CA in this matter. A special emphasis in the discussion was given to the warning letter from 1 April 2004, published by FDA. It was decided that Tony Sant will check the opinion of the British Notified Body involved in this matter, to give their opinion concerning the FDA Warning Letter. He will report to MDEG meeting.

It was further decided that the Dutch CA requests the company to inform all European Member States on a 3-month basis concerning the development in this FDA-case.

The Dutch CA will also request the company to send to all European Member States the results of the e-CYPHER database presented during a major Interventional Cardiology Congress (EURO-PCR), which has been held in Paris.

3.8.5.2. Exchange of reports
The German delegation introduced the issue. It was decided to continue discussion in the coming meetings about the harmonisation of vigilance reports, triggered to be sent as CA reports. Especially the safety related corrective actions should be discussed further.

3.8.5.3. The Swedish case of a sensor in the brain
The Swedish delegation presented a case of a patient monitor including a brain-located sensor. In some circumstances, in connection with the imaging investigations, the sensor had caused burns in the patient tissue.
The possible causes of such burns were discussed and also solutions were given by several Member States.
The Swedish delegation was grateful for the ideas presented and welcomed other Member Sates to give further feedback on similar cases.

3.8.5.. BSE/TSE issues and the Directive 2003/32
The Commission gave a report on the BSE/TSE issues. The issue is outside the vigilance system, but the report was, however, given for the sake of transparency. The report will be repeated in the coming MDEG meeting. The main message of the report was that the Member States should urgently encourage the ***Notified Bodies*** *operating in their territory to comply with the requirements of this new directive, due to a tight schedule set up by the Directive.*

3.9	**NBOG**	Doc EG-030-06-04 Draft NBOG annual report 2003.doc	23.06.04

*postponed from previous meeting

After several contacts and requests of TEAM-NB "*and further discussion at the April 2003 meeting of the Medical Devices Experts Group, the Commission with the NB-MED Group identified an individual (John Worroll) verifier orthographe 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".*

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.
Liaise 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 "xxxxxxxxx" circulated to NBOG members and comments sought.
Revise MEDDEV 2.10	Germany, Nederland's, 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, Nederland's, Germany	To provide training based on the practical application of the DA Handbook.	Nederlands 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	Revised drafts produced and discussed. Further enhancements being made.

*postponed from previous meeting

		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.	
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.

4.0	**GHTF**		

4.1	**Steering Committee Meeting, Paris, June 28 & 29**	Verbal report from Commission	

*postponed from previous meeting

In the distribution of Chairpersons, the key factor has not been on Geographic origin but on experienced persons. Today, Europe gets 2 Chairmanships on 5 study groups. It is very important to get experienced persons involved in GHTF meetings for the future.

There has been 2 new developments in the meeting.
The first change is the reports of key issue from representatives of the Regions (3 Regions are considered : America, Asian/Pacific and Europe).
The second change is the invitation of a guest speaker, in this case the chief of ISO.

It has been pointed out that rules should be supported by a rationales.

5.0	**MRAs – State of play**		

See point 3.7.

6.0	**International relations**		

6.1	**China - state of play**		

There is a possibility of a Workshop in Shanghais in autumn.

6.2	**Chinese Taipei - state of play – July's mission**		

A European delegation will be in Chinese Taipei end of July.

7.0	**Standardisation issues**	Doc EG-033-06-04 state of the art.pdf	24.06.04

There is a paper entitled "Legal aspects of standardisation in the Member States of the EC and EFTA"

7.1	**Publication of CENELEC standards**	Doc EG-049-06-04 CENELEC List 1.doc	25.06.04

*postponed from previous meeting

		Doc EG-050-06-04 CENELEC List 2.doc	25.06.04

The First list is under Medical Devices Directive.
The second list is under Active Implantable Medical Devices Directive.

7.2	**Publication of CEN standards**	Doc EG-051-06-04 CEN list 1.doc Doc EG-052-06-04 CEN list 2.doc Doc EG-053-06-04 CEN list IVD.doc	25.06.04 25.06.04 25.06.04

It is first CEN consolidated list. The list 1 concerns 93/42/EEC Directive, the list 2 the 90/385/EEC Directive and the IVD list the 98/79/EC Directive.

7.3	**Quality standards**	Doc EG-041-06-04 Quality standards - state of play.doc	23.06.04

1. EN-standards

The new EN/ISO 13485:2003 was harmonised in Europe earlier this year to represent the acceptable procedures to meet the regulatory needs for a "full quality system" as required in Europe to comply with Annex II, and includes alternative means to meet the needs for a "production quality system" to comply with Annex V, of the Medical Devices Directive 93/42/EEC (and the relevant clauses of other directives). This new standard is based on much of the contents of EN/ISO 9001:2000 but is a stand-alone document to meet the regulatory needs for medical devices.

EN/ISO 13485:2003 was made available to the CEN members in July 2003 and is intended to replace the two standards listed below, which must be withdrawn by July 2006:

- EN ISO 13485:2000 "Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001 *(revision of EN 4600).*
- EN ISO 13488:2000 "*Quality systems - Medical devices - Particular requirements for the application of EN ISO 9002 (revision of EN 46002).*

*postponed from previous meeting

Note: This new version of EN ISO 13485 incorporates the two alternative scopes of quality systems applications as previously covered in EN ISO 13485:2000 ("full quality system") and EN:ISO 13488:2000 ("production quality system").

Summary

EN ISO 13485:2003 is a stand-alone document to meet the European regulatory needs of a quality system for either a "full quality system" or a "production quality system".

This standard replaces both of the following:

- EN ISO 13485:2000 together with ISO 9001:1994 ("full quality system") and

- EN ISO 13488:2000 together with ISO 9002:1994 ("production quality system").

The latter two standards will cease to provide presumption of conformity with relevant Essential Requirements on 31st July 2006 (at the end of the agreed **transition period**).

2. Guidance documents

Guidance documents on the implementation of quality system for medical devices were published in 1994/1995. At that time the guidance documents were developed by a CEN/CENLEC Working group and several technical committees and this resulted in a total of 3 documents

- EN 724:1994 "*Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices*",
- EN 928:1995 "*In vitro diagnostic systems - Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices*"
- EN 50103:1995 "*Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry*"

With the new edition of EN ISO 13485:2003, all those guidance documents are outdated.

*postponed from previous meeting

However, an ISO technical committee has now drafted a Technical Report: ISO TR 14969 '*Quality systems –Medical devices – Guidance on the application of ISO 13485:2003*' being suitable for consideration as a replacement for EN 724, EN 928 and EN 50103.

CEN/TC 205 '*Non-active medical device'* which developed the EN 724:1994 and CEN/TC 140' *In vitro diagnostic medical devices'* which developed EN 928:1995, passed resolutions to withdraw these documents and to replace these guidelines through adoption of the ISO TR 14969 as a CEN/TR to be transposed under CEN/CLC/WG QS "*CEN/CENELEC Coordinating working group on quality supplements*" work program. Justification for adoption of the ISO TR 14969 is under consideration.

References

1. EN 46001:1993 Specification for application of EN ISO 9001 to the manufacture of medical devices.
2. EN 46002:1993 Specification for the application of EN 9002 to the manufacture of medical devices.
3. EN 724 Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices.
4. EN 928 Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices.
5 EN 50103 Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical devices industry.
6. EN 29001:1987 Quality systems - Model for quality assurance in design/development, production installation and servicing.
7. EN 29002:1987 Quality systems – Model for quality assurance in production and installation.
8. ISO 13485:1996 .Quality systems – medical devices – particular requirements for the application of ISO 9001.
9. ISO 13488:1996 BS EN ISO 13488:2001 Quality systems – medical devices – particular requirements for the application of ISO 9002.
10 ISO 14969:1999 -.Quality systems – Medical devices – Guidance on the application of ISO 13485 and ISO 13488.
11. ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.
12. EN ISO 13485:2000 Quality Systems – Medical Devices – Particular requirements for the application of EN ISO 9001 (revision of EN 46001:1996) (identical to ISO 13485:1996).

*postponed from previous meeting

13. EN ISO 13488:2000 Systems – Medical Devices – Particular requirements for the application of EN ISO 9002 (revision of EN 46002:1996) (identical to ISO 13488:1996).

7.4	**EN 60601-1-8:2003**	Oral information	

7.5	**PrEN 14820**	Doc EG-034-06-04 100604_LetterToAntonioLacerda_prEN14820_Final1.doc	23.06.04

Letter from Ann O' Connor (Medical Devices Director) on prEN 14820 Single-Use Containers for Human Venous Blood Specimen Collection

… "raised concerns about the proposed harmonised standard for single-use containers for human venous blood specimen collection (prEN 14820), which recently went to the CEN/TC 140 Committee for formal vote.

…

We believe that the omission of a standardised colour coding system for sample collection receptacles from this harmonised standard provides a level of unnecessary risk for patient safety. We would therefore appreciate the opportunity to raise this issue for discussion at the upcoming MDEG meeting in June".

The French Competent Authority raised the same concern, as well as UK, Portugal
It is proposed a Competent Authorities contribution to go further on this standardization.

8.0	**JCTLM Activities (July 1st – PM)**	Presentation by Robert Wielgosz Doc EG-038-06-04 Joint Committee for Traceability in Laboratory Medicine (JCTLM).pdf	23.06.04

*postponed from previous meeting

In response to the need to establish lists of available higher order reference materials, available higher order reference measurement procedures and reference and reference measurement laboratories for laboratory medicine a joint Committee for Traceability in Laboratory medicine (JCTLM) has been established by the Bureau International des Poids et Mesures (BIPM), together with International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the International Laboratory Accreditation Cooperation (ILAC).

A major driving force for the establishment of the Joint Committee has been the implementation of the European Directive 98/79/EC on *in vitro* diagnostic medical devices, which included the requirement for the traceability of values assigned to calibrators and control materials for *in vitro* diagnostic devices to be assured through available reference measurement procedures and/or reference materials of higher order.

The JCTLM has established a framework which lays down a process whereby reference materials and reference measurement procedures are examined with respect to conformity with appropriate international documentary standards (ISO 17511, 15193 and 15194), and whereby reference material properties are verified by measurements made in institutes with demonstrated competence in the field.

The outputs of the framework are databases of available higher order reference materials and higher order reference measurement procedures as well as reference laboratories that can be used by the IVD industry and other users to meet requirements for traceability for *in vitro* diagnostic and laboratory medicine measurements.

Two lists of Higher Order Reference Materials and Reference Measurement Procedures are published
(http://.bipm.org/en/committees/jc/jctlm/jctlm-db/)
Recopier contenu du SUMMARY, voir Website

9.0	**Reclassification of total joint implants – State of play**		

10.0	**EUDAMED- Commission Decision – State of play**		

*postponed from previous meeting

As far as the nomenclature is concerned, the EC decision is to let that nomenclature available freely in all EC languages . An agreement is in discussion with CEN.

11.0	**Authorised representative : "Guidelines on the role and responsibilities"**	Waiting for text	

12.0	**Study on Competitiveness**	State of play	

Meetings took place. The study is mainly based on patents. The aim is to highlight the answer to requirements of both Member States and Industry.

13.0	**AOB**		

13.1	**Dental amalgam**		

No progress has been made and there is no reason to re-opened the debate. Dental amalgam does not seem to provoke unacceptable risks for the general population although it exists allergy. The decisions taken earlier are endorsed.

13.2	**Handling new and emerging technologies, follow-up***		

A task force on electronic labeling is created. There will be a call for volunteers. All stakeholders are eligible for participation. Because of rooms availability no meeting could take place before November. The documents will be available on the Commission web site. The volunteers will have access to these documents in order to go ahead with information before the meeting.

13.3	**EUROM VI / COCIR´s document on User Guidance**	Doc EG-027-06-04 User Guidelines.COCIREUROM6.final.pdf	04.06.04

*postponed from previous meeting

13.4	**Bar code – Traceability - France**	Doc EG-004-06-04 France- codes barres - tracabilité - GHTF.doc	04.06.04

France followed by others countries had expressed interest for problem about traceability and the need of harmonizing practices through European countries and even to the all world.
Today, US is using systems based on EAN (21CFR201,606,610), Japan using another system and Europe come up with a trend of using EAN code for traceability.
The request is to put this subject on the table for GHTF European presidency.

*postponed from previous meeting