

GLOBAL HARMONIZATION TASK FORCE

Working Towards Harmonization in Medical Device Regulation

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NOTE: These Minutes incorporate comments on the Draft Minutes provided by Steering Committee Members during July and August 2001; and will be endorsed at the Committee's 3rd Meeting on 12 -13 October 2001.

MINUTES

STEERING COMMITTEE - 2nd MEETING

ROOM 3D
CENTRE CONFERENCE ALBERT BORCHETT (CCAB)
RUE FROISSART, 36
BRUSSELS, BELGIUM

TUESDAY, 12 - WEDNESDAY, 13 JUNE 2001

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The 2nd Meeting of the Global Harmonisation Task Force (GHTF) Steering Committee was held in Room 3D at the Centre Conference Albert Borchett (CCAB), Brussels, Belgium from Tuesday, 12 - Wednesday, 13 June 2001.

Those present were –

Steering Committee Members:

- Australia:** Ms Rita Maclachlan (Chair) - Therapeutic Goods Administration
 Mr Terry Slater - Therapeutic Goods Administration
 Mr Brian Vale (Vice Chair) - Medical Industry Association of Australia
 Mr Barry Evers-Buckland - Medical Industry Association of Australia
- Japan:** Dr Soichiro Isobe - Ministry for Health, Labor and Welfare
 Mr Masato Yoshida - The Japan Federation of Medical Devices Associations
 Mr Kenichi Matsumoto- The Japan Federation of Medical Devices Associations
- Canada:** Ms Beth Pieterston - Health Canada
 Mr Kevin Murray - Medical Devices Canada
- United States:** Dr David Feigal Jr - Food and Drug Administration
 Dr Lillian Gill - Food and Drug Administration
 Mr Robert Britain - National Electrical Manufacturers' Association
 Mr James Benson - Advanced Medical Technology Association
 Mr Michael Gropp - Advanced Medical Technology Association
- Europe:** Mr Cornelis Brekelmans - European Commission
 Dr David Jefferys - UK Medical Devices Agency
 Mr Rainer Voelksen - Swiss Federal Office of Public Health
 Dr Bryan Allman - EUCOMED and European Diagnostics Manufacturers' Association
 Mr Roland Gerard - EUCOMED
- Observers:** Dr Daisaku Sato - Ministry for Health, Labor and Welfare - Japan
 Dr Horst Frankenberger - European Federation of Precision, Mechanical and Optical Industries
- SG Chairs:** Mr Maurice Freeman, Chair - GHTF Study Group 1
 Dr Larry Kessler, Chair - GHTF Study Group 2
 Ms Kimberly Trautman, Chair - GHTF Study Group 3
- Guest:** Mr Zeger Vercouteren -Assistant Director-General, EUCOMED (for Item 9)
- Secretary:** Mr Craig Davies - Therapeutic Goods Administration

LIST OF ABBREVIATIONS

ADVAMED	Advanced Medical Technology Association
AHWP	Asian Harmonisation Working Party
CCAB	Centre Conference Albert Borchett
CEN	European Committee for Standardisation
COCIR	Coordinating Committee of the Radiological and Electromedical Industry
EC	European Commission
EDMA	European Diagnostics Manufacturers' Association
EFTA	European Free Trade Association
EUROM VI	European Federation of Precision, Mechanical and Optical Industries
GHTF	Global Harmonisation Task Force
GMDN	Global Medical Devices Nomenclature
GMDN MAPG	GMDN Maintenance Agency Policy Group
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardisation
JFMDA	The Japan Federation of Medical Devices Associations
MEDEC	Medical Devices Canada
MHLW	Ministry for Health, Labor and Welfare - Japan
MIAA	Medical Industry Association of Australia
NCA	National Competent Authority
NEMA	National Electrical Manufacturers' Association
PAHO	Pan American Health Organisation
TGA	Therapeutic Goods Administration
UK MDA	United Kingdom Medical Devices Agency
US FDA	United States Food and Drug Administration

LIST OF ACTION ITEMS

Action Item	Status
<p>1.4: GHTF Steering Committee Membership List and Contact Details</p> <p>Members to review the Steering Committee Membership List and advise any changes to the GHTF Secretary.</p>	<p>Referred to Members for noting/action, 12/7/2001</p>
<p>2.1: Global Medical Devices Nomenclature (GMDN) Maintenance Agency Policy Group</p> <p>Steering Committee industry members to further discuss the use, costs and benefits of the GMDN within their organisations and refer any feedback to the GHTF Secretary for inclusion in the agenda of the 3rd Steering Committee meeting by Friday 24 August 2001.</p>	<p>Referred to industry members for action, 12/7/2001</p>
<p>TGA and Health Canada to determine a nominee to represent GHTF on the GMDN Maintenance Agency Policy Group; and the Chair to forward this nomination to the Secretary of CEN/TC 257/SC 1.</p>	<p>Completed - 29 June 2001</p>
<p>2.3: Review and Approval of Two Study Group 4 Documents as "Final Documents"</p> <p>NEMA to provide USA industry comments on Supplement No.4 to the GHTF Chair by Friday 27 July 2001.</p> <p>GHTF Chair/Secretary refer these comments to the SG4 Chair for further consideration by the Study Group.</p> <p>The 'drafter' of Supplement No.4 to provide a response to the USA industry concerns, from a regulatory perspective.</p> <p>The proposal to approve Supplement No.4 as a "Final Document" be further considered by the Steering Committee at its next meeting.</p> <p>GHTF Secretary to re-format SG4 Supplement No.6 in "final document" format and have it posted on the GHTF website.</p>	<p>Referred to Mr Britain 12/7/01</p> <p>Comments referred to SG4 Interim Chair, 20/7/2001 Requested 20/7/2001</p> <p>Noted by GHTF Secretary for next meeting</p> <p>Completed, 9/8/2001</p>
<p>2.4: Timetable for Future GHTF Meetings</p> <p>GHTF Secretary include this item, with the above (and other) proposals in the agenda for 3rd Steering Committee meeting.</p>	<p>Noted by GHTF Secretary for next meeting</p>
<p>3: GHTF Website Management</p> <p>GHTF Secretary to include statistical information concerning the number of 'hits' to the GHTF website in future Steering Committee agenda papers.</p>	<p>Noted by GHTF Secretary for future meetings</p>
<p>4.1: Asian Harmonisation Working Party</p> <p>GHTF Chair to write to the AHWP Chair seeking further details as to the exact type of training assistance the GHTF could provide during the forthcoming AHWP Meeting.</p> <p>GHTF Chair to write to the AHWP Chair expressing the Steering Committee's concern with the use of "Working Draft" documents for training purposes; and seeking his assistance with reinforcing this point throughout the Asian region.</p>	<p>Referred to AHWP Chair by GHTF Chair - 28 June 2001</p> <p>Referred to AHWP Chair, 16/8/2001, reply received 30/8/2001</p>

<p>5.1: Study Group 1</p> <p>When completed, the SG1 Chair to forward the document, "<i>Medical Devices Classification</i>" to the GHTF Secretary for inclusion in the agenda of the 3rd Steering Committee meeting.</p> <p>The SG1 Chair to forward a 'timetable for completion', etc of the current work items to the GHTF Secretary for distribution to Members out-of-session.</p> <p>5.2: Study Group 2</p> <p>The SG2 Chair to prepare a diagram describing the medical devices post-market surveillance and vigilance system (which also indicates how the SG2 guidance documents fit within the system); and forward the diagram to the GHTF Secretary for posting on the website.</p> <p>The SG2 Chair to forward a 'timetable for completion', etc of the current and proposed work items to the GHTF Secretary for distribution to Members out-of-session.</p> <p>5.2.1: Global Vigilance Exchange System</p> <p>The SG2 Chair to forward a copy of Mr Kim Dix's report on the Vigilance Exchange pilot to the GHTF Secretary for distribution to Members.</p> <p>The SG2 Chair, in conjunction with the Study Group to develop a proposal on implementation of the Global Vigilance Exchange System and forward it to the GHTF Secretary for inclusion in the agenda of the 3rd Steering Committee meeting</p> <p>5.2.2: New Study Group 2 Chair</p> <p>The GHTF Chair to write to Health Canada's, Mr Kim Dix inviting him to accept the position of SG2 Chair, effective Tuesday 16 October 2001.</p> <p>5.4: Study Group 4</p> <p>GHTF Chair to send a letter of appreciation to the SG4 Chair on behalf of the Steering Committee, acknowledging his significant contribution to the organisation and international harmonisation processes.</p> <p>GHTF Secretary to post the "SG4 Report on the Application of 'General Requirements' by Regulatory Agencies" on the GHTF website.</p> <p>5.5: Proposed Merger of SG3 and SG4</p> <p>The SG3 Chair and SG4 Interim Chair to forward their proposal on establishing a merger between the two Study Groups to the GHTF Secretary by Friday 24 August 2001, for inclusion in the agenda of the 3rd Steering Committee meeting.</p> <p>The Chair to write to all SG3 and SG4 Members advising of the Committee's decisions concerning the proposal to establish a merger between the two Study Groups and the appointment of Dr Frankenberger as the Interim Chair of SG4.</p>	<p>Referred to SG1 Chair, 12/7/2001</p> <p>Referred to SG1 Chair, 12/7/2001. Provided 3/8/2001</p> <p>Referred to SG2 Chair, 12/7/2001. Completed 20/8/01</p> <p>Referred to SG2 Chair, 12/7/2001. Provided 18/8/2001</p> <p>Referred to SG2 Chair, 12/7/2001</p> <p>Referred to SG2 Chair, 12/7/2001</p> <p>Completed, invitation sent 24/7/2001 and accepted 1/8/2001</p> <p>Completed, 24/7/2001</p> <p>Requested, July 2001</p> <p>Referred to SG3 and Interim SG4 Chair, 12/7/2001. Paper received, 30/8/2001.</p> <p>Completed - 22 June 2001</p>
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<p>5.6: Study Group Representation</p> <p>Study Group Chairs to review and amend the current Study Group membership lists in terms of the new GHTF procedural documents and provide a list to the GHTF Secretary (indicating which jurisdictions, organisations, etc each of their Members represent) by Friday 24 August 2001 for inclusion in the agenda of the 3rd Steering Committee meeting.</p> <p>Item 5 Summation</p> <p>GHTF Secretary to present the Study Group Work Plans in a standard format and post them on the GHTF website when the additional information requested during the previous items has been provided by the Study Group Chairs.</p> <p>6.1: Working Group 1 - New, Emerging Technologies/Issues/Topics</p> <p>Working Group 1's co-convenors to forward the draft guideline for handling new and emerging technologies to the GHTF Secretary by Friday 24 August 2001, for inclusion in the agenda of the 3rd Steering Committee meeting.</p> <p>6.2: Working Group 2 - Implementing Guidance Documents/Acceptance of GHTF Outputs</p> <p>For those still outstanding, Steering Committee regulators to forward their updates on the adoption of GHTF Documents to the GHTF Secretary.</p> <p>6.3: Working Group 3 - Common Method of Exchanging Regulatory Information and Mutual Acceptance of Data Requirements/Non-duplicative</p> <p>Working Group 3 to continue its work and the co-convenors submit one, new report to the GHTF Secretary by Friday 24 August 2001 for inclusion in the agenda of the 3rd Steering Committee meeting.</p> <p>6.4: Working Group 4 - Evolving Regulatory Systems</p> <p>Working Group 4 to refine its report and the co-convenors submit a revised version to the GHTF Secretary by Friday 24 August 2001 for inclusion in the agenda of the 3rd Steering Committee meeting.</p> <p>6.5: Working Group 5 - Communications</p> <p>Study Group Chairs to forward all final Meeting Summaries not currently included on the GHTF website to the GHTF Secretary.</p> <p>Item 6 Summation</p> <p>GHTF Secretary to prepare a draft GHTF Strategic Plan incorporating the suggested approaches outlined in Strategic Theme reports 1, 2, 5 and 6; and which identifies a number of key outcomes/deliverables and how these may be measured and achieved within specified timelines;</p> <p>GHTF Secretary include the draft Plan in the agenda for the Steering Committee's 3rd Meeting for further consideration, prior to presentation of the document during the Plenary Session of the 9th GHTF Conference.</p>	<p>Referred to Study Group Chairs, 12/7/2001</p> <p>On-going</p> <p>Referred to Working Group 1, 12/7/2001</p> <p>Referred to regulator members, 12/7/2001</p> <p>Referred to Working Group 3, 12/7/2001</p> <p>Referred to Working Group 4, 12/7/2001</p> <p>Referred to Study Group Chairs, 12/7/2001</p> <p>First draft prepared, 9/8/2001</p> <p>Noted by GHTF Secretary for next meeting</p>
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<p>GHTF Secretary to advise Steering Committee Members and Study Group Chairs of the improved administrative arrangements relating to the Procedural Document, "<i>GHTF Operating Procedures</i>".</p>	<p>Completed, 6 September 2001</p>
<p>7: GHTF Training</p>	
<p>The GHTF Chair to finalise the TGA's bid to an Australian Government aid agency, seeking funding to conduct a GHTF Training Program for south-east Asian regulators in Australia during March 2002.</p>	<p>Action item subject to review</p>
<p>The GHTF Chair liaises with the Study Group Chairs and Chair of the AHWP; and develops a proposed Meeting/Training schedule for consideration and endorsement during the 3rd Steering Committee Meeting.</p>	<p>On-going</p>
<p>GHTF Chair to develop a proposal for a GHTF Training Institute in conjunction with the USA regulators and Study Group Chairs; and include in the agenda of the 3rd Steering Committee meeting.</p>	<p>Action item subject to further consideration</p>
<p>8: Establishment of a Permanent Secretariat</p>	
<p>GHTF Chair, Secretary and Ms Pieterse to develop a number of options regarding the establishment of a permanent GHTF secretariat or sharing of tasks, for inclusion in the agenda of the 3rd Steering Committee meeting.</p>	<p>Completed, agenda paper included in 3rd meeting agenda</p>
<p>9: Planning for the 9th GHTF Conference</p>	
<p>Steering Committee industry representatives to identify companies who may be interested in providing sponsorship for the Conferences; and forward these details to EUCOMED as soon as possible.</p>	<p>Referred to industry members, 12/7/2001</p>
<p>GHTF Chair to write to the peak industry associations requesting sponsorship money to assist with funding various aspects the 9th GHTF Conference.</p>	<p>Completed, 7/8/2001</p>
<p>GHTF Secretary to amend the 9th Conference Program and Plenary Session agenda, circulate to Members for further comment and then post on the GHTF website.</p>	<p>Completed, 24/7/2001</p>
<p>11.1: Conflict of Interest - Steering Committee/Study Group Memberships</p>	
<p>GHTF Secretary to add "Conflict of Interest" as a 'standing item' to future Steering Committee meeting agendas.</p>	<p>Noted by GHTF Secretary for future meetings</p>

ITEM 1: INTRODUCTION**ITEM 1.1: WELCOME AND APOLOGIES**

- 1.1.1 The GHTF Chair, Ms Rita Maclachlan opened the Meeting and welcomed all Members and the GHTF Study Group Chairs to Brussels, Belgium for the second meeting of the GHTF Steering Committee. Ms Maclachlan expressed her thanks and appreciation on behalf of the Committee to Mr Cornelis (Kees) Brekelmans for making the meeting arrangements.
- 1.1.2 In particular, the Chair welcomed the following, new Steering Committee members - Dr Bryan Allman (representing EUCOMED and EDMA) and Mr Roland Gerard (representing EUCOMED). The Meeting was advised these appointments followed the resignation from the Steering Committee of Mr Michael Baker (Director-General, EUCOMED). Members noted the letter of appreciation to Mr Baker from the GHTF Chair which was included among the agenda papers.
- 1.1.3 The Chair also advised that she had accepted European industry's fourth nomination to the Steering Committee - Dr Carl Wallroth, representing EUROM VI. Dr Wallroth was unable to attend this meeting and Dr Horst Frankenberger was welcomed by the Committee, deputising for both, Dr Wallroth and Study Group 4 (SG4) Chair, Mr Robert Allen. (Dr Frankenberger is a current member of SG4). Dr Daisaku Sato (Ministry for Health, Labor and Welfare - Japan) was also welcomed to the Meeting as an observer, in place of Mr Souichi Ikegaya.
- 1.1.4 Apologies were received from -
- Mr Souichi Ikegaya - Ministry for Health, Labor and Welfare - Japan;
 - Mr Dennis Baker - United States Food and Drug Administration;
 - Dr Carl Wallroth - EUROM VI;
 - Mr Hanz-George Will - Federal Department for Health, Germany;
 - Dr Egid Hilz - COCIR; and
 - Mr Robert Allen - Chair, Study Group 4

ITEM 1.2: ADOPTION OF AGENDA

- 1.2.1 Members accepted and adopted the items presented in the agenda for this meeting and agreed that the following additional items be added to the agenda for consideration -
- a 'conflict of interest' issue, to be raised under Item 11 - Other Business;
 - discussion concerning GHTF communications with the media, to be raised under Item 6.5 - Strategic Review: Communications; and
 - discussion of issues relating to the Global Vigilance Exchange System, to be raised under Item 5.2 - Study Group 2 Work Plan.

ITEM 1.3: MINUTES FROM THE 1st STEERING COMMITTEE MEETING

- 1.3.1 The Minutes from the 1st Steering Committee Meeting were included in the agenda papers and incorporated all comments received on the draft Minutes that were circulated on 11 April 2001.

- 1.3.2 Members were reminded the Minutes had been posted on the GHTF website on 8 May 2001. There were no further comments and the Minutes were subsequently ratified by the Committee as a true record.

ITEM 1.4: GHTF STEERING COMMITTEE MEMBERSHIP LIST AND CONTACT DETAILS

- 1.4.1 The Meeting's attention was drawn to the Steering Committee's membership list and contact details which were included among the agenda papers. The Chair asked all Members to review the list and advise the Secretary of any amendments or corrections which may be required.

Action:

Members to review the Steering Committee Membership List and advise any changes to the GHTF Secretary.

ITEM 2: MATTERS ARISING FROM PREVIOUS MEETINGS

ITEM 2.1: GLOBAL MEDICAL DEVICES NOMENCLATURE (GMDN) MAINTENANCE AGENCY POLICY GROUP

- 2.1.1 At the first Meeting, Members noted that Study Group 2 (SG2) Chair, Dr Larry Kessler was asked (and subsequently agreed) to attend the first meeting of the GMDN Maintenance Agency Policy Group and to report back as to the future participation of GHTF in its membership.
- 2.1.2 Dr Kessler attended this Meeting on 14 May 2001 and was asked by the Chair to outline the details of his report to the Meeting. Copies of the report and presentation to the Steering Committee were distributed during the meeting.
- 2.1.3 Members noted the overview of the GMDN including its development, current status, future direction and potential role for GHTF. The Meeting also noted the GMDN was a common ISO/CEN project, funded by CEN and developed by a Project Council lead by the UK MDA's Mr Robert Allen. The GMDN currently contains over 14,000 terms and has been submitted to CEN and ISO members for acceptance as a technical document. The nomenclature is undergoing detailed review in certain agencies and a proposal has been referred to CEN/ISO that the Maintenance Agency Policy Group (MAPG) now further progresses this matter. The first full meeting of the MAPG is scheduled for 19-20 July 2001 and is proposed to comprise 10 CEN/ISO representatives and 1 representative from each of the European Commission, US FDA, Japan MHLW and the GHTF.
- 2.1.4 The Meeting was advised a tender offer for the MA is due to be released during August 2001 and it is anticipated the MA will be established in early 2002. The Meeting noted there are at least 2-3 potential candidates and that a significant financial investment will be required before the nomenclature will generate any revenue (approximately \$US 100,000). There should only be a small and limited financial risk to GHTF Members, CEN and ISO; but in the long term, it is considered the GMDN will be viable providing it is supported and adopted by regulatory agencies. To be useful, the nomenclature will need to be a dynamic system and have changes incorporated over time.

- 2.1.5 The Chair asked each Member for their comments and these are summarised in the following paragraphs. Concern was raised in relation to the establishment and on-going costs that will be incurred by the MA. Members believed the issue of translation should not be allowed to hinder implementation of the nomenclature as translation is a notoriously slow and costly exercise. In a global medical devices market, it was considered the nomenclature should be presented in the English language and that translation should be an issue for national authorities to consider and fund if deemed to be necessary. The Japanese industry representatives noted this is an important issue for that country and advised translation is already in progress.
- 2.1.6 Members considered the GHTF should support international initiatives of this nature and noted that achieving consistency in areas such as nomenclature is fundamental to the overall goal of international harmonisation. Some Members advised the nomenclature will be adopted in their jurisdictions when it becomes operational; and also recognised the benefits of adoption to both, countries with developed and developing regulatory systems. The Meeting was advised that some countries within the Asian region are already very keen to adopt the nomenclature.
- 2.1.7 While remaining supportive of the initiative, some industry members recognised (and raised some concerns) that the larger companies will ultimately provide the majority of funds for the MA as they purchase parts of the nomenclature for their large product ranges. Smaller companies, requiring limited pieces of the nomenclature would contribute substantially less. It was suggested that an 'implementation vehicle' would be needed to explain and promote the use, costs and benefits of the nomenclature to the wider industry audience. This may be achieved via training seminars or information posted on the internet, but it was agreed this issue would be discussed further at the next meeting after additional industry input was obtained.

Action:

Steering Committee industry members to further discuss the use, costs and benefits of the GMDN within their organisations and refer any feedback to the GHTF Secretary for inclusion in the agenda of the 3rd Steering Committee meeting by Friday 24 August 2001.

- 2.1.8 The Meeting was also advised of a letter to the GHTF Chair from the Secretary of CEN/TC 257/SC 1 inviting a GHTF nominee to the MAPG. In view of Dr Kessler's forthcoming retirement as SG2 Chair and other representatives already nominated to the MAPG, it was suggested that a GHTF representative be nominated from either the TGA or Health Canada. The Meeting accepted this proposal and agreed these two agencies would determine a suitable nominee from one of their organisation's to represent the GHTF.

Action:

TGA and Health Canada to determine a nominee to represent GHTF on the GMDN Maintenance Agency Policy Group; and the Chair to forward this nomination to the Secretary of CEN/TC 257/SC 1.

- 2.1.9 The Steering Committee recognised the significant achievement that has been made by the CEN/ISO sponsored development of the GMDN system. Members believe this will be a major contribution to international harmonisation among regulatory agencies, particularly in vigilance and the worldwide registration of products. The Committee also considers the nomenclature will be of particular assistance to those countries developing regulatory systems for medical devices.
- 2.1.10 The Steering Committee noted the MAPG will need to address a number of significant implementation issues including the ability of the nomenclature to meet regulatory needs, copyright/public domain issues, revenue generation to support the Maintenance Agency (MA), achieving consistency and translation into national languages.
- 2.1.11 In conclusion, the Steering Committee considered the GMDN is an initiative that should be actively supported by the GHTF and welcomes the creation of the MAPG to continue work on the nomenclature.
- 2.1.12 Members acknowledged the significant personal contribution the UK MDA's Mr Robert Allen has made to the development of the GMDN. Members asked that their appreciation and thanks to Mr Allen be formally recorded in the GHTF 'public record' (meeting minutes).

ITEM 2.2: REQUEST FOR GHTF REPRESENTATION ON THE CHAIRMAN'S ADVISORY GROUP OF IEC TECHNICAL COMMITTEE NO.62

- 2.2.1 At the first Meeting, the Steering Committee considered a letter from the Chairman of IEC Technical Committee No.62 - *Electrical Equipment in Medical Devices* inviting the GHTF to nominate a member to the Chairman's Advisory Group of TC No.62.
- 2.2.2 The Committee considered that additional information such as the meeting date, venue and the exact type of involvement being sought from the GHTF is required before any formal GHTF commitment could be given. The Committee asked the Chair to obtain these details and provide a report at the second meeting.
- 2.2.3 The Chair's letter to the IEC TC62 Chair/Secretariat (dated 11 April 2001) was included among the agenda papers. The Chair advised the Meeting that no reply to her letter had been received and this matter had been followed up with the Secretariat on several occasions.
- 2.2.4 Some Members reiterated their earlier concerns that acceptance of one invitation of this nature may lead to numerous other requests that may present difficulties for the GHTF until its 'liaison strategy' is developed as part of the draft Strategic Plan. As no response had been received from the IEC TC62 Chair/Secretariat, the Steering Committee agreed that no further action on this matter was required.

ITEM 2.3: REVIEW AND APPROVAL OF TWO STUDY GROUP 4 (SG4) DOCUMENTS AS "FINAL DOCUMENTS"

2.3.1 At the first Meeting, the Steering Committee considered (as a late item), the following Study Group 4 (SG4) documents which were provided to the Secretariat on 21 February 2001 by the SG4 Chair who requested the Committee to consider them for approval as "final documents" –

"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.4: Compilation of Audit Documentation (Clause 5.7)"; and

"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.6: Observed Audits of Conformity Assessment Bodies".

2.3.2 Given the importance of endorsing documents as "Final Documents", the Steering Committee agreed insufficient time had been allowed to give due consideration to the documents.

2.3.3 At the commencement of discussions, a USA industry representative advised the Committee of USA industry concerns with Supplement No.4. Specifically, there are concerns with the large amount of information required to be retained by auditors, the ease of 'transferability' of this volume of information, confidentiality and the requirement that auditors' hand written notes be documented and archived.

2.3.4 There are significant industry concerns with these issues, particularly the latter point as it is believed that hand written/marginal notes could be taken out of context when audit documentation is transferred to another regulatory agency. Concern was also expressed at the unbalanced membership of SG4 (ie. 12 regulators and 6 industry representatives).

2.3.5 The Steering Committee agreed not to approve Supplement No.4 as a "Final Document" and asked that the USA industry concerns with this document be referred to the Chair within 6 weeks of the meeting. The Chair would then forward these comments to the SG4 Chair for further consideration by the Study Group (and subsequent referral back to the Steering Committee for consideration at its next meeting, once the issues have been resolved). It was also agreed that if these concerns cannot be resolved within SG4, this would necessitate the Steering Committee's further deliberation of the issues from a policy perspective.

2.3.6 In the interests of receiving 'both sides of the story', the Steering Committee agreed that the SG4 representative responsible for drafting the document be requested to provide comments in response to the USA industry's concerns eg. provide an explanation from the regulatory perspective about the provision concerning auditors' hand written notes.

Action:

1. NEMA to provide USA industry comments on Supplement No.4 to the GHTF Chair by Friday 27 July 2001.
 2. GHTF Chair/Secretary refer these comments to the SG4 Chair for further consideration by the Study Group.
 3. The 'drafter' of Supplement No.4 to provide a response to the USA industry concerns, from a regulatory perspective.
 4. The proposal to approve Supplement No.4 as a "Final Document" be further considered by the Steering Committee at its next meeting.
- 2.3.7 In considering Supplement No.6, there was general agreement with this document. Comment was made that the document tended to resemble more of a mutual recognition agreement (MRA)-type document and questioned the reason or need for developing these types of documents.
- 2.3.8 The Meeting noted there were no particular concerns with the document from the European regulatory perspective and agreed that it now be progressed since the resources had already been invested in its development. Additionally, the Steering Committee did not believe this one document would set forth any expectations about developing future MRA-type documents and believed the document would serve a useful purpose by representing how GHTF auditing principles relate to MRA processes. Further comment was made that Supplement No.6 was a sound, basic document which explained a number of terms and principles that would be beneficial for those who are unfamiliar with the terminology.
- 2.3.9 After taking account of the above comments, noting there were no major objections to the document and recognising that a degree of effort and resources had already been invested in its development, the Steering Committee agreed that the following SG4 document be approved as a "final document" -

"Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - General Requirements - Supplement No.6: Observed Audits of Conformity Assessment Bodies".

Action:

GHTF Secretary to re-format SG4 Supplement No.6 in "final document" format and have it posted on the GHTF website.

ITEM 2.4: TIMETABLE FOR FUTURE GHTF MEETINGS

- 2.4.1 At the first meeting, the 'timetable for future GHTF Meetings' was raised under Other Business and it was agreed to further discuss this matter during the second meeting.
- 2.4.2 The Meeting noted it had been previously agreed to hold the third Steering Committee meeting on 12-13 October 2001 during the 9th GHTF Conference in Barcelona. There was general discussion about the number of Steering Committee meetings that would need to be held between October 2001 and December 2002; and the location of these meetings. Members noted the GHTF Chair will be rotating to Japan on 1 July 2002.

- 2.4.3 One suggestion was that the Steering Committee and GHTF Study Groups all meet in Australia during March 2002. In considering GHTF training initiatives, it was noted such a proposal would present the opportunity for Asian regulators to visit Australia and attend a GHTF training program covering the scope of each Study Group.
- 2.4.4 Members agreed to defer further discussion on this matter until the third meeting in Barcelona.

Action:

GHTF Secretary to include this item, with the above (and other) proposals in the agenda for the 3rd Steering Committee meeting.

ITEM 3: GHTF WEBSITE MANAGEMENT

- 3.1 The Chair advised this item was presented to provide Members' with an opportunity to raise any issues or suggestions they have with regard to the on-going maintenance of the GHTF website; and drew Members' attention to a recent print-out of the "What's New" page which highlighted all recent additions/amendments to the site.
- 3.2 An inquiry was made about the Secretariat's experiences to date with assuming management responsibility for the website and the transition from Health Canada. The Secretary advised the management of the website is progressing smoothly and the TGA webmaster is the person who currently updates the site at his request. The Meeting noted the website has been retained on a server operated by a California based company; and this arrangement continues to be satisfactory. The Secretary also advised the transition from Health Canada to the TGA occurred in a simple, efficient manner.
- 3.3 A Member asked whether any statistical information concerning the number of 'hits' to the GHTF website was available. The Meeting noted such information provides an indication of how effective the website is, as a communication tool. The statistical information requested was obtained on 12 June 2001, tabled the following day and was noted by Members.

Action:

GHTF Secretary to include statistical information concerning the number of 'hits' to the GHTF website in future Steering Committee agenda papers.

ITEM 4: REGIONAL HARMONISATION GROUP UPDATES

ITEM 4.1: ASIAN HARMONISATION WORKING PARTY

- 4.1.1 At the first Meeting, the Steering Committee agreed it was useful to receive updates from the regional groups and to retain these as 'standing items' for future meeting agendas.
- 4.1.2 The Steering Committee noted a report from the Chair of the Asian Harmonisation Working Party (AHWP), outlining an overview of the AHWP's recent activities (which have occurred since the first Meeting).

- 4.1.3 The Chair indicated it was commendable the AHWP are planning to undertake some training sessions during its next meeting (to be held during late July or early August 2001). Based on the proposed AHWP agenda, the Steering Committee noted there would be a significant dependence on Study Group 1 (SG1). Members believed it would be useful if the Chair wrote to the AHWP Chair seeking further advice on the exact type of involvement and assistance the GHTF could provide during the AHWP Meeting.
- 4.1.4 The Chair advised she has been invited to attend the AHWP Meeting and the SG1 Chair indicated he would be pleased to assist during the AHWP training session. The meeting noted there had been recent liaison between SG1 and the AHWP.

Action:

GHTF Chair to write to the AHWP Chair seeking further details as to the exact type of training assistance the GHTF could provide during the forthcoming AHWP Meeting.

- 4.1.5 Members were concerned to note that some GHTF "Working Draft" Documents were being used for training purposes. Several Members commented they had advised the parties involved that this practice was inappropriate as the documents remain subject to further review and amendment. As the practice appears to be continuing, the Steering Committee suggested the Chair writes to the AHWP Chair seeking his assistance to reinforce the point throughout the Asian region.

Action:

GHTF Chair to write to the AHWP Chair expressing the Steering Committee's concern with the use of "Working Draft" documents for training purposes; and seeking his assistance with reinforcing this point throughout the Asian region.

ITEM 4.2: AMERICAS WORKING GROUP

- 4.2.1 The Steering Committee noted the report provided by the Regional Advisor of the Pan American Health Organisation (PAHO), outlining an overview of the Americas Working Group's recent activities (which have occurred since the first Meeting).

ITEM 5: GHTF STUDY GROUP WORK PLANS

- 5.1.1 At the first Meeting, Members reached agreement on the processes and format for Study Group Work Plans to be referred to the Steering Committee for consideration, amendment and/or endorsement. The Committee subsequently agreed to ask each Study Group Chair to complete a Work Plan using a standard format; and submit their Plans for consideration during the second meeting.
- 5.1.2 Prior to discussing this item, the Chair highlighted the importance of an open discussion as the Work Plans will form an important component of the GHTF's strategic direction. The Chair also noted, that consistent with its functions, the Steering Committee will aim to authorise the Work Plans and provide oversight for Study Group activities (GHTF procedural document, "*Roles and Responsibilities*", Section 6.3 refers).

ITEM 5.1: STUDY GROUP 1

- 5.1.3 The SG1 Chair outlined an overview of the Study Group and its activities. SG1's scope is pre-market, technical requirements and the Study Group has considered the definition of a medical device, how to ensure safety and performance, how to meet the 'Essential Principles' and the levels of conformity assessment.
- 5.1.4 Consideration of these issues has led to the development of numerous guidance documents, with some having been finalised and others currently under development. The SG1 Work Plan was included among the agenda papers.
- 5.1.5 Based on current activities, SG1's five priorities were summarised as follows -
1. Further review of the Working Draft, "*Medical Devices Classification*" (with the aim of having a "final document" ready for consideration by the Steering Committee at its 3rd Meeting);
 2. Further review of the Working Draft, "*Definition of the term, 'Medical Device'*";
 3. Consideration of the results of the pilot study on the Summary Technical File (due 2002), followed by the resumption of work on the guidance document;
 4. Consideration of the differences in regulatory requirements for in-vitro diagnostic products and development of a subsequent model; and
 5. Further review of the Working Draft, "*Premarket Conformity Assessment for Medical Devices*".

Action:

When completed, the SG1 Chair to forward the document, "*Medical Devices Classification*" to the GHTF Secretary for inclusion in the agenda of the 3rd Steering Committee meeting.

- 5.1.6 Some Members inquired as to how SG1 could consider certain issues which were currently the subject of debate within various regulatory/political systems. The SG1 Chair advised that the Study Group recognises that regulators must resolve such matters and specifically excludes these discussions from their meetings. The Meeting was also advised that SG1 attempts to synthesise all currently available information (upon which a consensus exists); and does not include information in guidance documents which has not received regulatory approval. However, SG1 believes it is important to identify such ('non-consensus') information to assist regulatory authorities determine which provisions they do, and do not want to consider for adoption into national systems.
- 5.1.7 In concluding, the Steering Committee endorsed the SG1 Work Plan and priorities presented, but requested further information regarding SG1's estimated delivery times for work items, the number documents to be progressed and the resources required to achieve this. The SG1 Chair advised these details would be an estimate and undertook to forward the information to the GHTF Secretary for distribution to Members (for any further comment out-of-session).

Action:

The SG1 Chair to forward a 'timetable for completion', etc of the current work items to the GHTF Secretary for distribution to Members out-of-session.

ITEM 5.2: STUDY GROUP 2

5.2.1 The SG2 Chair presented a diagrammatic overview of the Study Group and its activities. SG2's scope is to -

- examine the requirements for the reporting of adverse events involving medical devices, post-market surveillance and other forms of vigilance;
- recommend ways of harmonising the requirements; and
- provide a forum for discussion of recommended harmonisation initiatives.

5.2.2 The system of adverse event reporting, post-market surveillance and vigilance; and how the Study Group's completed, current and proposed future work items/guidance documents have been developed for use throughout the various 'components' of the system were noted. The SG2 Work Plan was included among the agenda papers.

5.2.3 The Steering Committee believed the diagrammatic presentation clearly described the post-market surveillance and vigilance system; and suggested it would be useful to formalise the diagram and post it on the GHTF website as a reference source.

Action:

The SG2 Chair to prepare a diagram describing the medical devices post-market surveillance and vigilance system (which also indicates how the SG2 guidance documents fit within the system); and forward the diagram to the GHTF Secretary for posting on the website.

5.2.4 The Steering Committee noted -

1. SG2's completed projects (*ie.* documents currently posted or ready for posting on the GHTF website for public comment):
 - N36 Manufacturers' Trend Reporting on Adverse Events;
 - N20R10 Vigilance Criteria and Guidance; and
 - N30 Nationally approved reporting alternatives for known and well characterised adverse events;
2. SG2's current work items:
 - N31R4 Proposal for the Reporting of Use Errors with Medical Devices
 - N32R2 Universal Manufacturers' Data Set
 - N33R6 Manufacturer Reporting Timeframes; and
3. SG2's proposed work items:
 - N40 To Whom To Report; and
 - Postmarket Surveillance Studies.

5.2.5 The SG2 Chair explained that N40 is more of a 'visionary' document *ie.* if it is possible to harmonise approaches relating to "what", "when" and "to whom to report", it would then be possible to develop a system in which a manufacturer would generate an adverse event report, electronically forward the report to one central server and via password protection, each National Competent Authority (NCA) could then enter the server and access only those reports relevant to their own jurisdictions. The current challenge (and aim of the N40 document) is to agree upon which NCA receives which report *eg.* only the NCA where the product was manufactured and/or where the product was marketed, etc.

- 5.2.6 The Meeting noted work had not commenced on the document, N40. The Steering Committee's predecessor (the Ad Hoc Procedures Group) previously asked for this project to be kept 'on hold' while other SG2 priorities were addressed and completed. Now that the majority of these other matters have been addressed, the Steering Committee endorsed the proposal for SG2 to develop N40.
- 5.2.7 The Postmarket Surveillance Studies project commenced several years ago, but is currently in abeyance. As other SG2 priorities have now been completed, the Steering Committee endorsed the proposal to re-commence work on this project, but requested some additional information relating to timeframes, resources and a feasibility assessment.
- 5.2.8 In concluding, the Steering Committee endorsed the SG2 Work Plan and priorities presented, but requested further information regarding SG2's estimated delivery times for the current and proposed work items, the resources required and further rationale/a feasibility assessment for the Postmarket Surveillance project. The SG2 Chair advised these details would be an estimate and undertook to forward the information to the GHTF Secretary for distribution to Members (for any further comment out-of-session).

Action:

The SG2 Chair to forward a 'timetable for completion', etc of the current and proposed work items to the GHTF Secretary for distribution to Members out-of-session.

ITEM 5.2.1: GLOBAL VIGILANCE EXCHANGE SYSTEM

- 5.2.1.1 In addition to SG2's proposed work items outlined above, the SG2 Chair also sought the Steering Committee's direction on how to extend the Global Vigilance Exchange System from a pilot scheme to full implementation. The Meeting was advised this is SG2's top priority and it presents a "real" opportunity for public health/regulatory authorities to make a significant contribution to public health outcomes.
- 5.2.1.2 The SG2 Chair acknowledged the significant efforts of SG2 Member, Mr Kim Dix (Health Canada) in managing the pilot scheme. The Meeting was advised that Mr Dix had now prepared a report on the pilot and Members asked if a copy could be circulated for information. During the Meeting, a brief statistical summary was tabled, indicating that 86 reports had been received from 8 participating countries between January 1999 - September 2000; and that in response to a brief survey, 87% indicated the reports were useful and 59% indicated they preferred "active" over "passive" reporting ie. distribution via e-mail or facsimile.

Action:

The SG2 Chair to forward a copy of Mr Kim Dix's report on the Vigilance Exchange pilot to the GHTF Secretary for distribution to Members.

- 5.2.1.3 Some Members sought clarification as to the current status of the vigilance exchange system, as it was believed the pilot scheme could not continue without a formal assessment and position by the Steering Committee. The SG2 Chair explained that the NCA's who participated in the pilot scheme found the system to be significantly beneficial in reporting serious, worldwide adverse events about medical devices; and have essentially continued to provide reports on an informal basis.

5.2.1.4 The Steering Committee regulators agreed the pilot scheme has been highly beneficial from a public health and safety perspective and gave 'in-principle' support to proceed towards full implementation of the scheme. However, prior to achieving this, the Steering Committee agreed that it needs to consider a formal proposal from SG2 on this matter which addresses all relevant issues, including the following -

- the need for SG2 to undertake an evaluation of the pilot;
- the criteria upon which full implementation of the system will be based;
- confidentiality; and
- how to educate 'new users' of the system ie. those NCA's who have not been involved in the pilot scheme.

Action:

The SG2 Chair, in conjunction with the Study Group to develop a proposal on implementation of the Global Vigilance Exchange System and forward it to the GHTF Secretary for inclusion in the agenda of the 3rd Steering Committee meeting.

5.2.1.5 The Steering Committee then addressed the issue of the pilot scheme continuing in its current, informal manner. There was general support from all regulatory members for the informal continuation of the scheme. However, the Meeting was advised there will be a need to undertake further consultation about these matters with the European Competent Authorities. This is due to the fact that currently, only three European countries are able to receive the global vigilance reports. Informal continuation of the pilot scheme is likely to create a problem within Europe's internal market since a product which is the subject of an adverse incident report (referred to the UK MDA for example) is also likely to be supplied in other European countries which currently are not participating in the scheme.

5.2.1.6 The European regulators expressed interest in the Global Vigilance Exchange System continuing now the pilot scheme has concluded. The Meeting was advised the necessary, formal consultation would be undertaken with the 29 European Union Members, EFTA and Applicant countries with a view towards Europe-wide participation in the system.

5.2.1.7 While acknowledging the institutional constraints of Europe, the Steering Committee noted there was an on-going European interest and therefore agreed that the pilot scheme on the Global Vigilance Exchange System should continue in its current informal manner until the Committee was able to consider the SG2 proposal relating to its full implementation. Prior to the European regulators consulting within their jurisdictions, the Meeting noted they would suggest to the European Union Members, EFTA and Applicant countries that the global vigilance reports be referred to them informally via e-mail as an interim measure.

ITEM 5.2.2: NEW STUDY GROUP 2 CHAIR

5.2.2.1 The Chair reminded Members of her letter dated 23 May 2001 seeking comments on the proposal that Health Canada's Mr Kim Dix succeeds Dr Larry Kessler as the Chair of SG2. This action follows Dr Kessler's announcement that he will formally resign as SG2 Chair during the 9th GHTF Conference in October 2001.

5.2.2.2 The Chair advised that in response to her request for comments by 6 June 2001, she had received six replies, all supporting the proposal to appoint Mr Dix as the new SG2 Chair.

5.2.2.3 The Steering Committee therefore agreed with the Chair's suggestion that she now formally invite Mr Dix to accept the position of SG2 Chair, noting the transition will take effect on Tuesday 16 October 2001, during the Plenary Session of the 9th GHTF Conference.

Action:

The GHTF Chair to write to Health Canada's, Mr Kim Dix inviting him to accept the position of SG2 Chair, effective Tuesday 16 October 2001.

ITEM 5.3: STUDY GROUP 3

5.3.1 The SG3 Chair drew the Meeting's attention to the SG3 Work Plan which was included among the agenda papers. The Work Plan comprised the following current work items -

- ISO/CD 13485, Committee Draft, Quality Management Systems - Medical Devices - System Requirements for Regulatory Purposes;
- ISO/CD 13488, Committee Draft, Quality Management Systems - Medical Devices - System Requirements for Regulatory Purposes (Excluding Design Control Requirements);
- ISO 14969:200X, WD1, Quality Systems - Medical Devices - Guidance on the Application of ISO 13485 and ISO 13488;
- Quality Planning Guidance for the Medical Device Industry; and
- Risk Management.

5.3.2 The Steering Committee noted the SG3 Work Plan which outlined (for each of the above documents), a rationale, the major next steps, the primary target audience, overlap with other GHTF Study Groups, a timetable and significant impediments to progress.

5.3.3 The SG3 Chair advised the major work item is the ISO/CD 13485 document. Currently, SG3 is awaiting additional information from ISO TC210 and this work item will be progressed during the next SG3/ISO TC210 Meeting which will be held as part of the 9th GHTF Conference in October 2001.

5.3.4 Not including the Study Group's work items involving ISO TC210, the SG3 Chair asked whether the Steering Committee had any other preferences with regard to future SG3 priorities. Members accepted a suggestion from the SG2 Chair that SG3 focuses upon the Risk Management document which is viewed as being beneficial to manufacturers and will also assist with resolving some current issues of contention within SG2.

- 5.3.5 In concluding, the Steering Committee endorsed the SG3 Work Plan and priorities presented (with further work on the Risk Management document being assigned the top priority, outside of the work currently being undertaken in conjunction with ISO TC 210).

ITEM 5.4: STUDY GROUP 4

- 5.4.1 Dr Horst Frankenberger presented the SG4 Work Plan which was prepared by the SG4 Chair, Mr Robert Allen. The Chair advised the Meeting that Mr Allen has recently tendered his resignation as SG4 Chair.

Action:

GHTF Chair to send a letter of appreciation to the SG4 Chair on behalf of the Steering Committee, acknowledging his significant contribution to the organisation and international harmonisation processes.

- 5.4.2 The Meeting's attention was drawn to the SG4 Work Plan which was included among the agenda papers. The Work Plan comprised the following current work items -
- Supplement No.4: Compilation of Audit Documentation^(*);
 - Supplement No.6: Observed Audits of Conformity Assessment Bodies^(*);
 - Supplement No.x: Audit Reports;
 - SG4 Report on the Application of 'General Requirements' by Regulatory Agencies; and
 - Supplement No.xx: Guidance on the Development of Audit Strategies.
- 5.4.3 ^(*) Members noted these two documents were considered during this meeting at agenda item 2.3. The Steering Committee also noted the "SG4 Report on the Application of 'General Requirements' by Regulatory Agencies" had been finalised and agreed that the report be posted on the GHTF website.

Action:

GHTF Secretary to post the "SG4 Report on the Application of 'General Requirements' by Regulatory Agencies" on the GHTF website.

- 5.4.4 The Steering Committee endorsed the SG4 Work Plan which outlined (for each of the above documents), a rationale, the major steps and completion dates, the target audience, overlap/links with other GHTF Study Groups, a timetable, resources and deliverables; and any impediments to progress.

ITEM 5.5: PROPOSED MERGER OF SG3 AND SG4

- 5.5.1 Following the presentation of the SG4 Work Plan, the Meeting was advised that the SG4 Chair had recently suggested the Study Group's work program was nearing an endpoint. In the discussion that followed, several members raised the possibility of there being a closer linkage between SG3 and SG4.

- 5.5.2 The Meeting was advised there is distinct expertise in the two Study Groups *ie.* SG4 comprises auditing experts whereas SG3's expertise is with the specifics of quality systems requirements. In any merger of the two Study Groups, the Steering Committee would need to clearly define its expectations of the auditing experts from SG4. The Meeting also acknowledged that some existing SG3 and SG4 members may lose their positions in a new, merged Study Group.
- 5.5.3 The Meeting was also reminded of the current SG3 priorities and the SG3 Chair advised she would need clear guidance from the Steering Committee as to the extent of 'auditing' work a merged Study Group will be required to undertake. Concern was also expressed at the potential workload a merged Study Group could have imposed upon it. The Meeting agreed that any merger of the two Study Groups would not result in a doubling of the current workload; and reaffirmed that SG3's current work activities with ISO TC210 will remain the top priority for any new Study Group.
- 5.5.4 In noting the manner in which the activities and work programs of SG3 and SG4 complement each other, the Steering Committee agreed that Ms Trautman and Dr Frankenberger develop a proposal to establish a merger between SG3 and SG4.
- 5.5.5 In view of this agreement, the Steering Committee decided not to appoint a new SG4 Chair (following Mr Allen's resignation). However, the Steering Committee agreed the next SG4 Meeting scheduled for 11-13 October 2001 (during the 9th GHTF Conference) would still proceed. For this to occur and to facilitate the development of a proposal for a new, merged Study Group, the Committee unanimously agreed to appoint Dr Frankenberger as the Interim Chair of SG4. Dr Frankenberger accepted this appointment.

Action:

1. The SG3 Chair and SG4 Interim Chair to forward their proposal on establishing a merger between the two Study Groups to the GHTF Secretary by Friday 24 August 2001, for inclusion in the agenda of the 3rd Steering Committee meeting.
2. The Chair to write to all SG3 and SG4 Members advising of the Committee's decisions concerning the proposal to establish a merger between the two Study Groups and the appointment of Dr Frankenberger as the Interim Chair of SG4.

ITEM 5.6: STUDY GROUP REPRESENTATION

- 5.6.1 During the Meeting, several inquiries were made regarding the Study Group memberships and issues such as 'balance in membership' and participation by representatives from conformity assessment bodies (particularly if these representatives have not been appointed by regulatory authorities).
- 5.6.2 The Chair drew the Meeting's attention to the GHTF Procedural Documents, "*Roles and Responsibilities*" and "*Operating Procedures*", (particularly the former) which specify the requirements/criteria for participation in the GHTF Study Groups. The Chair reaffirmed that these documents would be subject to review after three years of operation, but during the current period, the 'membership rules' specified in the documents should be adhered to by all GHTF participants.

- 5.6.3 The Meeting therefore agreed with the Chair's suggestion that the Study Group Chairs be asked to review and amend their current memberships in terms of the new procedural documents and provide a list to the Chair, indicating which jurisdictions, organisations, etc each of their Members represent. These lists will then provided for information to the Steering Committee at its next Meeting.

Action:

Study Group Chairs to review and amend the current Study Group membership lists in terms of the new GHTF procedural documents and provide a list to the GHTF Secretary (indicating which jurisdictions, organisations, etc each of their Members represent) by Friday 24 August 2001 for inclusion in the agenda of the 3rd Steering Committee meeting.

Item 5 Summation

- 5.6.4 In concluding Item 5, the Chair thanked the Study Group Chairs for their presentations and noted how it is critical to ensure the Study Group activities are focused and able to attract maximum support from the Steering Committee. The Chair reaffirmed her previous advice that the Work Plans will form an important component of the GHTF's strategic direction. The Chair noted, however, the inconsistency of the work plan presentations eg. some lacked rationale statements which were previously requested.
- 5.6.5 Previously, there was a query as to how the Work Plans will now be presented. The Steering Committee agreed with the Chair's suggestion that following receipt of the additional information requested from the SG Chairs, the Secretariat would present the Work Plans in a standard format and post them on the GHTF website.

Action:

GHTF Secretary to present the Study Group Work Plans in a standard format and post them on the GHTF website when the additional information requested during the previous items has been provided by the Study Group Chairs.

ITEM 6: GHTF STRATEGIC REVIEW - STEERING COMMITTEE WORKING GROUP OUTCOMES

- 6.1.1 The Chair introduced this item and recalled that during the first Meeting, the Strategic Review initially involved -
- an assessment of the industry and regulatory environments;
 - identification of the industry and regulatory perceptions and expectations of the GHTF; and
 - the development of a description of "key deliverables" which would define a successful GHTF in five years time.
- 6.1.2 From the Review, the Steering Committee identified seven Strategic Themes of GHTF endeavour requiring priority attention. These were subsequently condensed to six and it was agreed that refinement of the key issues and the preparation of specific proposals under each theme would be best progressed by smaller Working Groups comprising Steering Committee members only. Each Working Group was co-convened by one government and one industry representative; and each Working Group report was included among the agenda papers.

- 6.1.3 The Chair advised the aim of the current discussions would be to summarise the six reports and subsequently develop a DRAFT Strategic Plan which identifies a number of key outcomes/deliverables and how these may be achieved.

ITEM 6.1: WORKING GROUP 1 - NEW, EMERGING TECHNOLOGIES/ISSUES/ TOPICS

- 6.1.4 The Meeting's attention was drawn to the first Strategic Theme report, "*Proposal for handling new and emerging technology issues*". The medical devices sector is currently in an innovative phase with a number of new technologies being introduced into product development.
- 6.1.5 This report recommended that an internationally co-operative approach be taken to the development of voluntary guidelines which outline an understanding of the regulatory expectations for new technologies. The report reflects experience that harmonisation is best achieved via collaboration at an early stage of the process. It is intended that such guidelines outline a range of questions/points to be considered by manufacturers.
- 6.1.6 In order to progress this matter, the Committee agreed that topic selection was critical as they must be able to be addressed within reasonable timeframes. Members recognised that if the topic/s were too large and the guideline development progressed too slowly, the purpose would be defeated as the new technology will have already emerged. It was suggested that no more than two topics per year be selected by the GHTF for consideration. As an initial measure, it was also suggested this matter be progressed under the auspices of a 'pilot scheme'.
- 6.1.7 There was discussion on whether any such guidelines would be product specific or more general in nature. The Steering Committee recognised the need to utilise manufacturers' expertise in the process when a genuine breakthrough is involved. In view of confidentiality issues, the guidelines to be developed should therefore be restricted to more general topics.
- 6.1.8 The meeting considered several potential topics including "genetic testing" and "tissue engineering"; and that this process could also assist with addressing older issues which have undergone a 'change in landscape' eg. the re-use of single use medical devices and new approaches for undertaking toxicological assessments of older materials.
- 6.1.9 The Committee also acknowledged that broader expertise will be required for these topics as they expose the medical devices sector to the broader areas of therapeutic goods regulation eg. medicinal products and biologicals.
- 6.1.10 There was general consensus with Group 1's suggested approaches and the Steering Committee agreed these be included in the draft Strategic Plan. To test the report's proposal, the Committee also agreed for Group 1 to identify a number of 'new technologies', select two 'hot topics' for further consideration and proceed with the development of a draft guideline (for the Committee's consideration). The guideline would include a possible range of regulatory issues/questions which would need to be addressed by manufacturers/suppliers of the new technology.

Action:

Working Group 1's co-convenors to forward the draft guideline for handling new and emerging technologies to the GHTF Secretary by Friday 24 August 2001, for inclusion in the agenda of the 3rd Steering Committee meeting.

ITEM 6.2: WORKING GROUP 2 - IMPLEMENTING GUIDANCE DOCUMENTS/ ACCEPTANCE OF GHTF OUTPUTS

- 6.2.1 The Meeting's attention was drawn to the second Strategic Theme report, "*Implementing Guidance Documents/Acceptance of GHTF Outputs*". The Meeting was advised the report identified the following three major issues -
- **The type of deliverables**, having GHTF status, in particular, those related to the regulatory matters (principles, guidance, various 'building blocks' of pre- and post-market requirements), status reports (state of implementation, comparative reports on national systems), common projects (eg. vigilance), guidance on new, emerging technologies and documents tailor made to the needs of participating members. It was also suggested that the GHTF could be a platform in which Members could exchange information on on-going national initiatives;
 - **The acceptance and implementation of GHTF outputs by Members**, which suggested there be a 'more visible expression' of the Founding Members' commitment to the GHTF, that Members adopt some procedural arrangements at their national levels, there be systematic reporting of 'implementation decisions', Participating Members be encouraged to provide similar details, etc; and
 - **Monitoring and facilitation of Study Group activities**, including the confirmation of current Study Group requirements, national mirror groups and identification of the need for any new Study Groups.
- 6.2.2 During discussion, it was suggested that, with regard to implementation of GHTF outputs, reference to be made to the fact that each Founding Member regulator has its own consultative and legal processes to adhere to prior to GHTF documents being formally adopted.
- 6.2.3 It was also suggested that greater success with harmonisation efforts is likely to be achieved if there is focus upon administrative and regulatory requirements. The GHTF should avoid making recommendations which 'cut-across' formal legislative requirements.
- 6.2.4 To assist with facilitating this Strategic Theme, it was emphasised there was agreement from the first Meeting (Minute Item 3 refers) that the Steering Committee regulators forward their Founding Member updates on the adoption of GHTF Documents to the GHTF Secretary for posting on the website. The Chair noted that some updates were still outstanding and requested those Members to provide the information as soon as practicable.
- Action:**
- For those still outstanding, Steering Committee regulators to forward their updates on the adoption of GHTF Documents to the GHTF Secretary.
- 6.2.5 Members also commented that while reporting on those requirements which have been fully harmonised, adopted and/or implemented; it is also important to identify where differences exist and to provide clarity with regard to whether those differences are likely to be resolved or overcome in the foreseeable future.
- 6.2.6 There was general consensus with Group 2's suggested approaches and the Steering Committee agreed these be included in the draft Strategic Plan.

ITEM 6.3: WORKING GROUP 3 - COMMON METHOD OF EXCHANGING REGULATORY INFORMATION AND MUTUAL ACCEPTANCE OF DATA REQUIREMENTS/NON-DUPLICATIVE

- 6.3.1 The Meeting's attention was drawn to the third Strategic Theme report, "*Exchanging Regulatory Information and Acceptance of Assessment Results*". In addition to the first paper prepared by this Group, a supplementary paper was e-mailed to Members on 7 June 2001 and copies were also tabled during the meeting. The Meeting was advised that both documents should be considered as "first drafts" and that each outlined a similar approach to addressing the issues relevant to this strategic theme.
- 6.3.2 Benefits for regulators, industry and public health were identified. In developing the proposals, Working Group 3 also considered the direction of medical device regulation during the next five years and the need for work activities to be prioritised by the Steering Committee in order to utilise resources in the most efficient manner.
- 6.3.3 The Meeting was advised the papers represent a 'status report' on the Group's progress to date and it was suggested Working Group 3 continue its work, further refine the proposals, merge the two documents and present one, new document for consideration during the next meeting. The Steering Committee agreed with this suggestion.

Action:

Working Group 3 to continue its work and the co-convenors submit one, new report to the GHTF Secretary by Friday 24 August 2001 for inclusion in the agenda of the 3rd Steering Committee meeting.

ITEM 6.4: WORKING GROUP 4 - EVOLVING REGULATORY SYSTEMS

- 6.4.1 The Meeting's attention was drawn to the fourth Strategic Theme report, "*Evolving Regulatory Systems*". The primary purpose of the report was to address how the GHTF is able to recognise and encourage participation by countries or regions with emerging regulatory systems.
- 6.4.2 The Meeting noted the report included recommendations relating to the participation of countries with emerging regulatory systems in the GHTF processes, training and; advocacy and outreach. Members raised the following issues for further consideration -
- the extent of participation in the GHTF Study Groups by representatives from countries with emerging regulatory systems. It was noted that in order for the Study Groups to remain effective, the number of members must be relatively small and membership must be 'expertise based', not necessarily 'country based';
 - how to encourage broader involvement at Forums which can handle larger numbers eg. GHTF Conferences, regional training programs, etc;
 - requests from participating members to become full members and consequences for the composition of the various GHTF bodies;

- whether the GHTF and its Study Groups should also be developing regulatory guidance documents exclusively for countries with emerging regulatory systems, etc. The general consensus was that documents are developed for the broadest application and uptake by countries with both, established and emerging regulatory systems. It was agreed that an attempt to harmonise all regulatory systems would be too resource intensive and ultimately unsuccessful. As an alternative, it was believed consideration should be given to developing a formal consultation mechanism in order to deal effectively with countries currently developing regulatory systems; and
- while cognisant of the importance of GHTF training initiatives, the Meeting emphasised the Study Groups must not become overwhelmed as their primary purpose is to develop regulatory guidance documents.

6.4.3 The Steering Committee asked Working Group 4 to further refine its report to address the above issues, incorporate the suggestions raised by Members; and present a revised report to the next meeting.

Action:

Working Group 4 to refine its report and the co-convenors submit a revised version to the GHTF Secretary by Friday 24 August 2001 for inclusion in the agenda of the 3rd Steering Committee meeting.

ITEM 6.5: WORKING GROUP 5 - COMMUNICATIONS

- 6.5.1 The Meeting's attention was drawn to the fifth Strategic Theme report, "*Communications*". The Meeting noted the report identified the following major issues and that these may require further consideration before the end of the five year Strategic Plan -
- the identification of "internal" and "external" GHTF Stakeholders;
 - a range of communication modes;
 - the reasons for communication;
 - a proposal for a GHTF Communications Protocol;
 - proposals for publicising GHTF documents such as Meeting Minutes, Press Releases and the Strategic Plan; and
 - several proposals for future consideration eg. publication of GHTF Annual Reports, GHTF quarterly or biannual reports, development of a GHTF website bulletin board, etc.
- 6.5.2 Members agreed there needs to be consistency in the GHTF communications process and that the organisation needs to be more pro-active with regard to publicising its various activities and achievements. In particular, press releases to be issued after Steering Committee meetings should be as extensive as possible, providing all relevant and consolidated information to the press.
- 6.5.3 Acknowledging that Members cannot commit the GHTF, the Committee agreed that Members can communicate on GHTF matters and promote GHTF activities.
- 6.5.4 In relation to communications, the Chair drew the Study Group Chairs' attention to the fact that not all Meeting Summaries have been kept up-to-date on the website. The Chair asked the Study Group Chairs to review their relevant web pages and where Meeting Summaries were missing, to forward the final versions to the GHTF Secretary for inclusion on the website.

Action:

Study Group Chairs to forward all final Meeting Summaries not currently included on the GHTF website to the GHTF Secretary.

- 6.5.5 There was general consensus with Group 5's suggested approaches and the Steering Committee agreed these be included in the draft Strategic Plan.

ITEM 6.6: WORKING GROUP 6 - ORGANISATION/INFRASTRUCTURE

- 6.6.1 The Meeting's attention was drawn to the sixth Strategic Theme report, "*Organisation/Infrastructure*". The Meeting was advised the report outlined a number of options/suggestions with regard to addressing the following issues - how to support the 'deliverables'; establishment of a permanent secretariat (discussed further under Item 8); Study Group work planning, membership and expertise; document control; monitoring/evaluation (including the need for a tracking system); and funding.
- 6.6.2 There was general consensus with Group 6's suggested approaches and the Steering Committee agreed these be included in the draft Strategic Plan.
- 6.6.3 The Meeting noted an additional report addressing the issue of Study Group work and documentation infrastructure. This proposed a number of amendments to the Procedural Document, "*GHTF Operating Procedures*". Members acknowledged that the GHTF procedural documents would be subject to review after three years of operation, but there were no objections to a suggestion that a number of matters represented sound administrative practice and should be implemented immediately.
- 6.6.4 These matters are outlined below and their reference points to the document, "*GHTF Operating Procedures*" were highlighted among the second meeting agenda papers (Item 6.6, Paper C refers) -
- "The Study Group Chairs will inform the GHTF Chair of all projected Study group meetings for a running twelve (12) month period. The information shall include projected meeting dates, locations, and documents that will be the subject of the meetings. The GHTF Chair shall post the meetings with the above information on a section of the GHTF web site called "Calendar of SG Meetings for the Next Twelve (12) Months." It shall be the responsibility of the SG Chairs to update the GHTF Chair following each SG meeting; and the GHTF Secretary to then update the web site accordingly";
 - "All new work items with their rationale will be posted by the GHTF Chair on the GHTF web site under each appropriate Study Group. New work items will be deleted from the web site if the Steering Committee subsequently eliminates a work item or a Proposed Document is posted. The rationale shall be posted on the web site as a preamble to all new work items, Proposed and Final Documents";
 - "All Proposed Documents, including their rationale as preambles, will be posted on the GHTF website by the Chair within three (3) weeks of approval as a Proposed Document";
 - "It is the responsibility of the GHTF Chair to post the comment period due date on the web site";

- "Once endorsement of a Final Document is obtained, the Chair will make the necessary arrangements to have it available in hard copy format and in electronic format, including the rationale as a preamble, on the GHTF website"; and
- "New Work Item and Rationale Documents

New Work Item (NWI) and Rationale (RAT) Documents identification codes are to include identification of the authoring group, ie. "SG2" for Study Group 2 or "SC" for Steering Committee, followed by "RAT" in parenthesis for Rationale Document and "NWI" in parenthesis for New Work Item Document each followed by an oblique and then the document number (N) that will be assigned to subsequent Working Drafts and Proposed and Final Document.

Examples: SG2 (NWI)/N21
 SG3 (RAT)/N7
 SC (RAT)/NI".

- 6.6.5 Other very minor amendments (eg. paragraph numbering changes) which were also indicated are not outlined above as they are best implemented when the procedural documents are subject to review.

Item 6 Summation

- 6.6.6 The Chair noted the valuable preceding discussions and thanked each of the Working Group's Chairs for their significant contributions. Members agreed that the suggested approaches outlined in the Strategic Theme reports developed by Group's 1, 2, 5 and 6 be included in a draft Strategic Plan for consideration at the next Meeting and presented for information during the Plenary Session of the 9th GHTF Conference on Tuesday 16 October 2001.
- 6.6.7 The Meeting also agreed that further consideration would be given to the amended reports to be provided by Working Group's 3 and 4, with a view towards also including these in the draft Strategic Plan.

Action:

1. GHTF Secretary to prepare a draft GHTF Strategic Plan -
 - incorporating the suggested approaches outlined in Strategic Theme reports 1, 2, 5 and 6; and
 - which identifies a number of key outcomes/deliverables and how these may be measured and achieved within specified timelines;
2. GHTF Secretary include the draft Plan in the agenda for the Steering Committee's 3rd Meeting for further consideration, prior to presentation of the document during the Plenary Session of the 9th GHTF Conference; and
3. GHTF Secretary to advise Steering Committee Members and Study Group Chairs of the improved administrative arrangements relating to the Procedural Document, "*GHTF Operating Procedures*".

ITEM 7: GHTF TRAINING

- 7.1 At the first Meeting, the Steering Committee agreed that further consideration of a policy relating to GHTF training and any formal requests for training should be deferred until the 2nd Meeting, in light of the Strategic Review currently being undertaken.
- 7.2 During the first meeting, the Chair advised of a funding proposal being developed by the TGA for consideration by an Australian Government aid agency and undertook to provide a draft copy to the Committee. On reflection, it was decided to defer the proposal until the Steering Committee had a further opportunity to discuss the entire GHTF Training issue.
- 7.3 Although the Strategic Review is progressing well, it was recognised another 12 months may pass before the GHTF Strategic Plan is finalised. The Chair therefore suggested that the TGA proceeds with developing the funding proposal in an attempt to receive training funds under the auspices of the GHTF. The Chair advised that any funds received would primarily be utilised to cover the costs of south-east Asian regulators attending a training program in Australia. The Steering Committee endorsed this approach and agreed for the TGA to proceed with its funding bid under the GHTF's auspices.
- 7.4 To facilitate this, the Meeting also agreed with a suggestion from the Chair that a training program be held in Australia sometime during March 2002, in conjunction with meetings of the Steering Committee and Study Groups. The Committee agreed that the Chair further discusses this matter out-of-session with the Study Group Chairs and Chair of the Asian Harmonisation Working Party (AHWP); and develop a proposed Meeting/Training schedule for consideration at the next Meeting.

Action:

1. The GHTF Chair to finalise the TGA's bid to an Australian Government aid agency, seeking funding to conduct a GHTF Training Program for south-east Asian regulators in Australia during March 2002.
 2. The GHTF Chair liaises with the Study Group Chairs and Chair of the AHWP; and develops a proposed Meeting/Training schedule for consideration and endorsement during the 3rd Steering Committee Meeting.
- 7.5 The Meeting also discussed an earlier proposal from the SG2 Chair. The GHTF Ad Hoc Procedures Group considered this proposal relating to a training organisation being established for the global vigilance exchange program. At the first Meeting, the Steering Committee agreed it would further discuss this matter with the SG2 Chair at the second meeting once a work plan for Study Group 2 had been considered.
- 7.6 There was acknowledgment that the broadening of the initial proposal to cover all GHTF activities should be further examined. It was suggested the Steering Committee give consideration to establishing a "GHTF Training Institute". There is on-going interest in GHTF activities but due to time and resource constraints, it is not always possible for Steering Committee or Study Group Members to accept requests to conduct training. It was also suggested this may be resolved via a permanently staffed and funded Institute.

- 7.7 To progress this idea, the Meeting considered any such Institute be built from the "inside out" *ie.* ask the Study Group Chairs to identify which of their guidance documents would be ready for such an approach; and from this, develop an entire training program in a methodical manner.
- 7.8 Some Members also explained that as a complement or an alternative to GHTF training, promotion of GHTF documents and relevant training is a natural activity in the area of bilateral and regional co-operation in the field of medical devices between Members and third countries. Conferences and programs in which GHTF documents are explained do not for that reason alone qualify as GHTF training events.
- 7.9 The Meeting also noted issues such as identifying what people need to learn, having a process for disseminating relevant documentation/supporting material and how to make some relatively 'dry' topics more interesting or practical-based would need to be addressed. The issue of funding was also raised and the Committee acknowledged it is extremely difficult for training programs to be fully self-sufficient. However, Members agreed that recouping some expenses would be desirable and it was suggested the US FDA's Quality Systems Inspection Technique may be a model worth considering.
- 7.10 The Committee agreed this proposal be further investigated and a strategy developed for consideration during the next meeting. To assist in this process, the Study Group Chairs agreed to identify which guidance documents could currently be utilised by a formal training institute.

Action:

GHTF Chair to develop a proposal for a GHTF Training Institute in conjunction with the USA regulators and Study Group Chairs; and include in the agenda of the 3rd Steering Committee meeting.

ITEM 8: ESTABLISHMENT OF A PERMANENT SECRETARIAT

- 8.1 At the first Meeting, Members noted the (former) Ad Hoc Procedures Group had discussed the establishment of a permanent GHTF Secretariat, but agreed the Therapeutic Goods Administration (TGA) would re-visit this issue upon assumption of the GHTF Chair in January 2001.
- 8.2 During the first Meeting, the Steering Committee noted this issue will be addressed by one of its Working Groups under the terms of the GHTF Strategic Review. The Committee therefore agreed to defer further consideration of this matter until the second meeting where discussion could continue in conjunction with the Strategic Theme report prepared by Working Group 6 (Item 6.6 refers).
- 8.3 The Meeting was advised Working Group 6 did not develop a specific recommendation as to whether the GHTF should have a permanent secretariat or continue to rotate the secretariat amongst the founding member countries every 18 months. To assist further discussion, the Group identified a number of "pros" and "cons" for establishing a permanent secretariat:

"Pros"

- The disruptive process of moving the Secretariat every 18 months would be discontinued;
- There would be an advantage to a long term contracted web site service;
- Founding Member regulators would not have the burden of the administrative duties of the Chair and Secretariat;
- The Steering Committee which is now in place would act as the Secretariat's Board of Directors; and
- With a permanent staff, the Secretariat could take on more duties/responsibilities, eg. monitoring, evaluating, promoting and advocating deliverables; and possibly assuming responsibility for arranging the Global Medical Device Conference.

"Cons"

- A source of revenue to fund the Secretariat must be found;
- Unlike ICH, the GHTF Conference will never be able to substantially fund the Secretariat;
- The location of the Secretariat could be an issue eg. North America vs Europe;
- Hiring and retaining Secretariat staff, employee benefits program, human resource support, etc; and
- A permanent Secretariat may not be a priority among all manufacturers since the regulators are presently assuming responsibility for the activity.

8.4 In the discussion that followed, it was suggested that a permanent secretariat could possibly be established within existing structures (without the need to create a separate organisation). For example, an industry association headquarters could be partitioned to establish a Secretariat office which would then be jointly funded by all industry and government Founding Members.

8.5 The Meeting also noted another suggestion that it may be possible to establish a list of activities to be shared between a 'core group' (which would be situated with the current Chair) and other Members located in different regions, in particular industry representatives, who could thus take on more responsibilities. This approach would create a GHTF liaison point in different parts of the world, but it would need to be recognised that the current GHTF Chair would accept most of the responsibilities.

8.6 The Meeting agreed with a suggestion from the immediate past GHTF Chair, that she liaise with the current Chair and Secretary to develop a range of secretarial tasks and a number of options regarding the establishment of a permanent secretariat or sharing of tasks. These options would then be considered during the 3rd Steering Committee Meeting.

Action:

GHTF Chair, Secretary and Ms Pieterse to develop a number of options regarding the establishment of a permanent GHTF secretariat or sharing of tasks, for inclusion in the agenda of the 3rd Steering Committee meeting.

ITEM 9: PLANNING FOR THE 9TH GHTF CONFERENCE

- 9.1 At the invitation of the Chair, Mr Zeger Vercouteren (Assistant Director-General, EUCOMED) joined the meeting for discussion of this item and was asked to provide an update on progress with arrangements being made for the 9th GHTF Conference (11-16 October 2001) which will precede the 9th Global Medical Devices Conference.
- 9.2 The Meeting was advised that the London based company, IBC Global Conferences had been contracted to assist with the registration and other logistical details for both conferences. The Meeting also noted that Study Group 3 will now meet in conjunction with ISO TC210 from Saturday 13 - Monday 15 October 2001.
- 9.3 The registration fee for the GHTF Conference is 200 Pound Sterling and registration will be undertaken via a secure website established by IBC. Regulators wishing to attend both Conferences will be charged a special fee of 450 Pound Sterling.
- 9.4 The Meeting was advised a key factor in the success of the Conferences will be the ability to attract commercial sponsorship. Industry representatives were asked to identify member companies or companies whose activities are related to the medical devices industry, that may be interested in providing some commercial sponsorship for the Conferences.
- 9.5 It was also noted, that consistent with the last GHTF Conference, the GHTF Chair will be seeking financial sponsorship from the peak industry associations to assist with various aspects of this Conference's costs.

Action:

1. Steering Committee industry representatives to identify companies who may be interested in providing sponsorship for the Conferences; and forward these details to EUCOMED as soon as possible.
 2. GHTF Chair to write to the peak industry associations requesting sponsorship money to assist with funding various aspects the 9th GHTF Conference.
- 9.6 The Meeting then considered the draft agenda for the conference's Plenary Session which was also included among the agenda papers. The Meeting agreed that the Plenary Session be reduced to half a day and the remainder of that day be comprised of four parallel training sessions aligned to the GHTF Study Groups. The Meeting also agreed to replace the Special Topic on a "World Update on Tissue Regulation" with a topic on "New and Emerging Technologies".

Action:

GHTF Secretary to amend the 9th Conference Program and Plenary Session agenda, circulate to Members for further comment and then post on the GHTF website.

ITEM 10: INFORMATION ITEMS

ITEM 10.1: REPORT FROM ISO TC210 CHAIRMAN'S ADVISORY GROUP MEETING AND TC210 PLENARY

- 10.1.1 The Chair advised the Meeting that the Chairman of ISO TC210 invited her to attend the recent TC210 Meeting and Plenary session which were held in Japan from 9-13 April 2001. Members were reminded the Memorandum of Understanding between the GHTF and ISO TC210 was accepted by the GHTF Membership during the Plenary Session of the 7th Conference on 29 June 1999.

10.1.2 The Chair advised she asked the TGA's Deputy Chief GMP Auditor (who is also Australia's SG3 and TC210 representative) to attend the 9-13 April 2001 meeting on her behalf. The Steering Committee **noted** the report which was included among the agenda papers and highlighted those TC210 Resolutions which specifically refer to the GHTF. The full list of TC210 Resolutions approved at the Plenary Session were also included among the agenda papers for Members' information.

ITEM 11: OTHER BUSINESS/LATE PAPERS

ITEM 11.1: CONFLICT OF INTEREST - STEERING COMMITTEE/STUDY GROUP MEMBERSHIPS

11.1.1 The Chair drew the Meeting's attention to a potential conflict of interest issue surrounding membership of the Steering Committee and GHTF Study Groups. The Meeting was advised that some representatives who have been appointed to the Steering Committee have agreed not to participate in the work of the Study Groups. Where currently involved, those representatives have agreed to withdraw from the Study Groups.

11.1.2 The Chair advised it has been suggested that dual membership of the Steering Committee and one or more Study Groups may lead to a conflict of interest. The Meeting noted there are established procedures for identifying and handling conflict of interest issues within committees. Members were advised the critical point is the identification, subsequent handling and appropriate documentation of any 'conflict'; and not the fact that one may or may not have existed in the first place.

11.1.3 Members agreed that 'conflict of interest' be added as a standing item at the beginning of each subsequent meeting agenda. This would provide the opportunity for the Chair to ask Members to identify any perceived or direct 'conflicts' they may have in relation to any agenda item; and subsequently allow the full Committee (less the potentially affected member/s) to address any issues on a case-by-case basis (prior to the commencement of the Meeting proper).

Action:

GHTF Secretary to add "Conflict of Interest" as a 'standing item' to future Steering Committee meeting agendas.

11.1.4 In concluding, a majority of the Steering Committee agreed that it would not prevent any of its Members from participating in the Study Groups and where a 'dual membership' situation existed, the Committee also agreed it would not force its Members to resign from the Study Group.

11.1.5 However, the Steering Committee also agreed that it would not seek to impose this decision on any organisation from a Founding Member country that has decided to apply different requirements upon their own representatives.

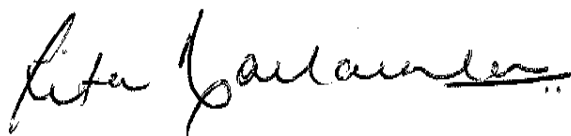
ITEM 11.2: 10TH GHTF CONFERENCE

11.2.1 The Steering Committee noted the announcement from the Japanese representatives that the 10th GHTF Conference would be held at the Toshi Center Hotel, Tokyo, Japan from 25-28 May 2003. This conference will be followed by the 10th Global Medical Devices Conference at the same venue on 29-30 May 2003. Members accepted the time schedule allocated to both conferences.

ITEM 12: NEXT MEETING

- 12.1 The Steering Committee reaffirmed an earlier agreement that its third meeting would be held at the Hotel Rey Juan Carlos I in Barcelona from Friday 12 - Saturday 13 October 2001, as part of the 9th GHTF Conference.
- 12.2 The Chair closed the meeting at 5.15pm, thanked all participants for their attendance and contributions to the meeting's achievements; and looked forward to welcoming members to the Steering Committee's third meeting in Barcelona.
- 12.3 The Chair especially thanked Mr Brekelmans and his staff; and Mr Michael Baker of EUCOMED and his staff, for their assistance in Brussels with the meeting arrangements, the Steering Committee Welcoming Reception on 11 June 2001 and Dinner on 12 June 2001.

Meeting record prepared by Mr Craig Davies, GHTF Secretary (Australia).



Rita Maclachlan
GHTF Chair; and
Director
Conformity Assessment Branch
Therapeutic Goods Administration



Craig A Davies
GHTF Secretary
Conformity Assessment Branch
Therapeutic Goods Administration