



FINAL DOCUMENT
Global Harmonization Task Force

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A handwritten signature in black ink, appearing to read 'Larry Kelly', is positioned above the name of the chair.

Larry Kelly, GHTF Chair

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Preface

This document was developed by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from the European Union (EU) and EFTA (European Free Trade Association), the United States of America (USA), Canada, Japan and Australia.

The original version of this document was endorsed by GHTF in September 2000 and it was foreseen at that time that the text would undergo periodic revisions. A review of this document was undertaken in 2005, 2008 and 2009. This text is the result of the most recent review to incorporate process improvements approved by the GHTF Steering Committee at its 16th meeting.

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1.0 Introduction

This document is intended to facilitate the management of GHTF activities by adequately describing the roles and responsibilities of all those involved in GHTF work.

This document establishes the different membership categories and the governing procedures for the components of GHTF.

The roles and responsibilities outlined in this document, in conjunction with the “GHTF Guiding Principles” and “GHTF Operating Procedures” and the “GHTF Strategic Directions”, are designed to be flexible, so that should the need arise, the GHTF can respond to challenges with respect to its objectives in a timely manner.

2.0 Membership

GHTF was established as a voluntary international group of medical device regulatory authorities, and medical device trade associations from Europe, the United States of America (USA), Canada, Japan and Australia, grouped into three geographical areas, namely Europe, North America and Asia-Pacific. For this purpose Europe means the European Union, and its candidate and associated countries, and countries of the European Free Trade Association (EFTA).

Participation in GHTF’s work takes place under different categories of membership – Founding Members, Regional Members, Participating Members, and Liaison Bodies.

2.1 Founding Members

Founding Members are regulatory authorities or industry representatives from Europe, the United States of America (USA), Canada, Japan and Australia. These Founding Members created GHTF and have well established regulatory systems, allowing for technological innovation whilst promoting a high level of safety and effectiveness/performance.

Founding Members will take appropriate steps to implement GHTF guidance and policies within the boundaries of their legal and institutional constraints. Regulatory authorities agree to promote the GHTF documents within their own jurisdictions and, in the course of time, seek convergence of regulatory practices. Regulators hold the ultimate responsibility for this implementation.

Founding Members participate in the Steering Committee, may propose participants for GHTF Study Groups or *Ad Hoc* Working Groups, and take part in all GHTF activities, such as plenary meetings, special topic sessions, regional meetings and GHTF training.

2.2 Regional Members

Regional Members represent the regulatory authorities and industry representatives in a formal regional grouping of economies, not otherwise represented by a Founding Member.

Regional Members have expressed support for, and have begun to take appropriate steps to implement, GHTF guidance and policies within the boundaries of the legal and institutional constraints of the participating countries. Regulatory authorities agree to promote the GHTF documents within their own jurisdictions and, in the course of time, seek global convergence of regulatory practices. Regulators hold the ultimate responsibility for this implementation.

Regional Members may propose participants for GHTF Study Groups or *Ad Hoc* Working Groups, and participate equally with Founding Members in GHTF activities, including meetings of the Steering Committee, plenary meetings, special topic sessions, regional meetings and GHTF training.

In terms of procedure:

- A regional grouping of economies wishing to become a Regional Member of GHTF should address a request to the GHTF Chair.
- The regional grouping need not be formally constituted with constituent documents but member economies must be able to be identified.
- The Chair will submit the request to the Steering Committee, which will decide whether or not to grant the requesting regional grouping Regional Member status.
- The request must contain sufficient information to allow the Steering Committee members to evaluate the interest of the regional group in GHTF's work, its level of representation of the countries and economies encompassed within the regional group, and the willingness of the member countries and economies of the regional group to implement GHTF guidance documents.

2.3 Participating Members

Participating Members are representatives of medical device regulatory authorities or medical device trade associations of countries other than the Founding Members.

Participating Members will take appropriate steps to implement GHTF guidance and policies within the boundaries of their legal and institutional constraints. Regulatory authorities agree to promote the GHTF documents within their own jurisdictions and, in the course of time, seek convergence of regulatory practices. Regulators hold the ultimate responsibility for this implementation.

Participating Members can propose participants for GHTF Study Groups or other *Ad Hoc* Working Groups the GHTF establishes, and take part in GHTF activities, such as plenary meetings, special topic sessions, regional meetings and GHTF training.

In terms of procedure:

- Any country wishing to participate in GHTF should address a request to the GHTF Chair.
- The Chair will submit this request to the Steering Committee, which will decide whether or not to grant the requesting country Participating Member status.
- The request must contain sufficient information to allow the Steering Committee members to evaluate the interest of the respective country in GHTF's work, and its willingness to implement GHTF guidance documents.

2.4 Liaison Bodies

Liaison Bodies are public health organizations, international standard-setting bodies or other groups who can contribute to or benefit from participation in GHTF.

Liaison Bodies are urged to co-operate in promoting GHTF guidance documents work to their members, as appropriate, and to consider GHTF guidance in their own work.

Liaison Bodies may nominate observers for GHTF Study Groups, or other *Ad Hoc* Working Groups which the GHTF establishes, and take part in GHTF activities, such as plenary meeting, special topic sessions, regional meetings and GHTF training, on a meeting by meeting basis.

In terms of procedure:

- Any organization or entity wishing to become a Liaison Body of GHTF should address a request to the GHTF Chair.
- The Chair will submit this request to the Steering Committee, which will decide whether or not to grant the requesting organization or entity Liaison Body status.
- The request must contain sufficient information to allow the Steering Committee members to evaluate the interest in GHTF's work and their willingness to promote GHTF guidance.

3.0 Observers

Founding Members, Regional Members and Liaison Bodies may nominate observers to the Steering Committee as well as to Study Groups and *Ad Hoc* Working Groups. Observers of Liaison Bodies may attend only the open section of the Steering Committee meeting. Such nominations must be made for specific meetings and must be addressed to the GHTF Chair for the Steering Committee, to the Study Group Chair for participation in Study Groups or to the Chair of an *Ad Hoc* Working Group for participation in an *Ad Hoc* Working Group. Participation depends on the agreement of the respective Chair after informing the GHTF Chair.

Other members (Participating Members) may nominate observers to Study Groups or *Ad Hoc* Working Groups. Requests must be addressed to the Study Group Chair or *Ad Hoc* Working Group. Participation depends on the agreement of the Chair after consulting with the GHTF Chair.

4.0 GHTF Operational Structure

GHTF carries out its activities through the Steering Committee, the Study Groups, *Ad Hoc* Working Groups under the leadership of the GHTF Chair.

4.1 GHTF Steering Committee

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The role of the Steering Committee is to steer, provide policy and strategic direction in order to ensure that GHTF work continues over time to fulfil its goals and objectives. Its role is to:

- provide strategic planning,
- allocate GHTF resources as required,
- assign and provide oversight of new work items,
- actively monitor progress of assigned work items,
- adopt GHTF guidance documents, and monitor their implementation,
- authorize and promote training events as required.

4.1.1 Steering Committee Composition

The GHTF Steering Committee comprises representatives from the Founding Members and the Regional Members. The GHTF Steering Committee is composed of:

- (A) up to four regulatory and up to four industry representatives from among the Founding Members in each of Europe, North America (the USA and Canada) and Asia (Australia and Japan); and
- (B) up to two representatives of regulators and up to two industry representatives from each Regional Member.

The geographic area holding the Chair may decide that the Chair and/or Vice Chair are not included in that number. In this case, the Chair and/or Vice Chair may not act as spokespersons for their geographic area.

Each geographic area is responsible for the selection of its representatives. Industry association representatives should broadly represent industry.

When a Study Group document comes before the Steering Committee, any Steering Committee member who also currently serves on that Study Group will not participate in the discussion, unless invited by the Chair.

Study Group Chairs participate in GHTF Steering Committee meetings by invitation of the GHTF Chair.

Representatives of Participating Members and Liaison Bodies may be invited by the GHTF Chair, in agreement with the Steering Committee, to attend Steering Committee meetings on specific agenda points.

At its discretion, the GHTF Steering Committee may consult Members or outside parties in order to gather information and solicit external advice relevant to matters pending before the Committee. (see 4.1.3.)

4.1.2 Functions

In order to fulfil its role, the Steering Committee is responsible for:

- (A) supporting the development of the GHTF regulatory model,

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- (B) monitoring and modifying as needed the institutional rules and procedures of GHTF and in particular the composition of the Steering Committee,
- (C) granting status of Regional Members, Participating Members and Liaison Bodies,
- (D) encouraging the participation of countries and economies other than those of the Founding Members and those represented by the Regional Members, to work together within their regional context,
- (E) establishing and discharging Study Groups, and discussing and allocating work items and work priorities,
- (F) establishing and discharging *Ad Hoc* Working Groups, and allocating work items and work priorities,
- (G) appointing and renewing Study Group Chairs and Vice Chairs,
- (H) appointing and renewing *Ad Hoc* Working Group Chairs and Vice Chairs,
- (I) endorsing final GHTF guidance documents, and encouraging their implementation,
- (J) overseeing GHTF activities, in particular
 - establishing the scope and milestones for work items
 - ensuring timely Study Group and *Ad Hoc* Working Group progress against milestones,
 - preventing duplication of Study Group and *Ad Hoc* Working Group activities and those of other external organizations,
 - identifying and resolving problems that might delay project completion,
- (K) reviewing GHTF policies and procedures at regular intervals and ensuring that GHTF documents are updated regularly,
- (L) providing assistance in the planning of the GHTF Conference and other meetings and approving GHTF Conference agendas,
- (M) providing support and/or guidance to the GHTF Chair on the resolution of any complaints or disputes,
- (N) in conjunction with the GHTF Chair, determining the invitees to the “open session” of Steering Committee meetings,
- (O) taking any other initiatives that contribute to achieving GHTF’s goals and objectives.

4.1.3 Meetings

The GHTF Steering Committee will meet as often as necessary to conduct GHTF work effectively, but generally not less than two (2) times every 18 months.

Meetings are at the call of the Chair and may be conducted by teleconference or video-conference if necessary or advantageous.

As a rule, the Steering Committee meetings will take place in “closed session”. However, “open sessions” may be convened, in total or in part, on the initiative of the Chair, in agreement with the Steering Committee. Open sessions may deal with, in particular:

- reports from Study Group Chairs and *Ad Hoc* Working Group Chairs,
- input for conferences,
- identification of relevant topics for training seminars,
- analysis and assessment of new strategic approaches.

Discussions on persons on, or membership of, the Steering Committee, Study Groups, or *Ad Hoc* Working Groups are always in closed session. On request of one Founding Member or one Regional Member, the GHTF Chair may close the meeting for discussion of agreed items of business.

Steering Committee members will be notified of all Steering Committee meetings with a minimum of eight weeks notice and confirmation of all attendees should be sent to the current Chair at least four weeks before each meeting. In addition, Steering Committee meeting dates will be posted on the GHTF website.

Decisions of the Steering Committee can only be taken when all Founding Members are represented and at least 50% of Regional Members. Representation may be in person, by video-conferencing, by tele-conferencing or by a proxy.

The GHTF Steering Committee will be chaired by the GHTF Chair, or the GHTF Vice Chair if the Chair cannot fulfil his/her duties.

The Steering Committee generally operates by consensus.

Within four weeks after each meeting, the Chair will circulate a meeting summary for comment. Following incorporation of necessary revisions, the document will be made publicly available on the GHTF website and archived in the official records of the GHTF. Similarly, if no comments are received within eight weeks, the open session meeting summary will be deemed accepted and posted to the GHTF website.

4.2 GHTF Chair

4.2.1 Selection and Succession

Chairmanship of the GHTF will rotate between each of the national regulatory authorities of the Founding Members in the three geographic areas namely Europe, North America (shared between the USA and Canada), and Asia (shared between Japan and Australia). The term of office will last three years.

It will be up to each individual geographic area to decide if the Chairmanship should be carried out by one individual for the entire period or divided between two individuals for half the time period each. For the purpose of clarity, the sequence of succession to the Chair position following adoption of this document is:

- (A) Asia (Australia and Japan) commencing 1 January 2010.
- (B) Europe commencing 1 January 2013.
- (C) North America (USA and Canada) commencing 1 January 2016.

The Founding Members will continue to explore mechanisms to include the Regional Members in rotation of the chairmanship of GHTF.

To help ensure continuity in leadership of the GHTF, the incoming Chair should offer assistance in the management of any outstanding Steering Committee activities.

In addition, a transition meeting should be organized between the outgoing and incoming Chairs and staff carrying out secretariat functions on or about the date of the actual transfer of Chairmanship.

4.2.2 Functions

The GHTF Chair is responsible for providing general management oversight of all work of the GHTF and the Steering Committee. This includes:

- (A) Ensuring that the Steering Committee effectively meets to execute its tasks, proposing an agenda for the Steering Committee meetings, chairing the meetings and achieving consensus,
- (B) resolving all disputes regarding GHTF decisions or actions brought forward by GHTF members or persons outside the GHTF, with the assistance of the Steering Committee as needed,
- (C) representing the GHTF in *ad hoc* consultations with external parties concerning GHTF activities,
- (D) making arrangements for regular Conferences of the GHTF and proposing the agenda for and presiding over the plenary session,
- (E) the provision of secretariat services and planning support to the GHTF for the duration of his/ her term as Chair, either via an outside contract or through assignment of one or more of his/ her

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staff. In agreement between the Steering Committee and the Chair certain tasks of the Secretariat may be delegated to one of the Founding Member or be outsourced.

4.2.3 GHTF Secretariat

The GHTF Secretariat will have the following responsibilities:

- (A) providing direct staff support to the GHTF Chair and Steering Committee,
- (B) preparing records of all Steering Committee meetings and GHTF conferences, and arranging for their dissemination to Steering Committee and GHTF members,
- (C) maintaining a current inventory of all completed and in-process documents and acting as custodian of all GHTF historical, policy and other documents that have a bearing on GHTF operations,
- (D) serving as the primary focal point for receipt of all Study Group and other GHTF documents for distribution to the Steering Committee or the GHTF Study Groups for review and/or final endorsement,
- (E) making arrangements for the transition meeting at which the physical transfer of GHTF records to the incoming GHTF Chair will be effected, and
- (F) supervising the maintenance of the GHTF website, in addition to ensuring that all documents recommended for posting to the website conform with established formats and have received all necessary clearances.

4.3 GHTF Vice Chair

4.3.1 Appointment

To support the GHTF Chair, a GHTF Vice Chair will be designated by the industry association(s) representing the region that holds the Chair.

4.3.2 Functions

The principal duty of the Vice Chair is to support the current Chair in his/her activities and to substitute for the Chair, should he/she not be able to fulfil his/her duties.

In the event that the GHTF Chair is unable to carry out his/her full term of duty, he/she should promptly notify the Steering Committee so that the Vice Chair can act for him/her until an alternate from the national authority of the GHTF Chair can be designated to take over.

Additionally, the Vice Chair may share the responsibility of the Chair for the provision of secretariat services.

4.4 GHTF Study Groups

4.4.1 Creation/Termination/Renewal

Study Groups may be formed at any time by the Steering Committee. They may be formed for a specific work assignment.

The Steering Committee may also discharge a Study Group from further responsibility, redefine the Study Group's original terms of reference, charge the Study Group with a new task, appoint a new chair, and/or renew an existing Chair's appointment.

4.4.2 Membership

The size and overall composition of each Study Group is determined by the Study Group Chair. It is recommended that each Study Group include one or more representatives from each geographic area with Founding Member and Regional Member status and with an appropriate balance between the number of industry and regulatory experts representing different device types or regulatory classes.

Participation in Study Group meetings by Participating Members, Liaison Bodies and Observer requires prior written permission of the Study Group Chair.

In case of dispute over Study Group membership, the Study Group Chair and/or the applicant should ask the Steering Committee to arbitrate.

Study Group Chairs are encouraged to look for the following qualities when assessing nominations for Study Group membership:

- (A) expert in the subject matter of the Study Group,
- (B) ability to participate in most meetings related to Study Group activity,
- (C) ability to represent effectively the interests of the geographic area and its regulators or industry,
- (D) ability to report effectively on Study Group meetings, and
- (E) ability to call for and consolidate comments and positions of the respective geographic area on Study Group documents.

Nominations for Study Group members are made by the respective regulatory authority or industry association. They should be accompanied by a *Curriculum Vitae* allowing the Study Group Chair to evaluate whether the nominee possesses the qualities listed above. The decision will be taken by the Study Group Chair.

In exceptional cases, the Study Group Chair may authorize an individual, with appropriate knowledge and expertise, to participate in a Study Group meeting as a substitute of a Study Group member.

4.5 GHTF Study Group Chairs

4.5.1 Appointment

Study Group Chairs, normally a regulator, are appointed to a three-year term, but may have their appointment renewed by the Steering Committee based on the needs of the Study Group. Where a Study Group is established for a specific work referral, the term of the Study Group Chair concludes at the completion of the assignment.

Chairs may be supported by a Vice Chair, normally an industry representative, desirably from another geographic area. Study Groups should be supported by a secretary.

Appointment of a Study Group Chair should be based on the following considerations:

- (A) possession of group and project management skills,
- (B) possession of technical expertise and/or regulatory experience (of the country or integrational organization of states that he/ she represents) relevant to the task assigned to the particular Study Group,
- (C) the ability of the individual to devote adequate time and attention to the assigned task,
- (D) diversity in relation to the geographical areas represented by other Study Group Chairs, and
- (E) other considerations, e.g., the capacity of the person's employer, or other sponsor, to support such an outside activity that requires continuity.

Should a Study Group Chair be unable to fulfill his/her term, he/she should promptly notify the GHTF Chair who in turn will inform the Steering Committee. The GHTF Chair or his/her designee will then consult within the Steering Committee (using teleconference or e-mail as needed) and appoint a replacement, either on an interim or permanent basis.

4.5.2 Functions

Each Study Group Chair is responsible for the following activities:

- (A) supporting the development of the GHTF regulatory model,
- (B) ensuring an appropriate balance and breadth of membership in accordance with Section 4.4.2,
- (C) reporting to the Steering Committee on the activities of his/her Group on a regular basis, including a brief report at each face-to-face meeting of the Steering Committee, or at the request of the GHTF Chair,
- (D) organizing and chairing meetings, seeking consensus, discussing assigned tasks, and developing documents in accordance with milestones set by the Steering Committee,
- (E) ensuring efficient and timely completion of assigned tasks, including the use of teleconferences and e-mail to facilitate effective communication,

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- (F) preparing summary reports regarding the work of their Study Group for dissemination on the GHTF website,
- (G) following each Study Group meeting, circulating to his/her members, all relevant documents and an agreed-to actions list,
- (H) promoting open discussion during Study Group meetings and dissuading meeting attendees from circulating their own personal notes, and
- (I) consulting with other Study Group Chairs, to avoid duplication of effort and ensure consistency between all GHTF outputs, irrespective of originating Study Group.

4.6 Study Group Meetings

Study Groups meet as often as necessary to carry out the tasks assigned to them by the GHTF Steering Committee. Study Groups should generally give preference to electronic communication tools (e.g. e-mail, teleconferencing or videoconferencing) wherever practicable.

Meetings are at the call of the individual Study Group Chairs and should be convened in different locations on a rotational basis in order to accommodate as many Study Group members as possible.

Meeting agendas should be circulated to all Study Group members at least six weeks in advance. At each meeting, time should be reserved for a discussion of issues arising after circulation of the agenda.

Study Group Chairs may, at their discretion, permit individuals who are not members of their Study Group or of the GHTF to participate in their meetings as technical experts with observer status. Participation of representatives of GHTF Founding Member should be generally accepted.

Requests for non-member participation should be submitted in writing to the Study Group Chair at least four weeks in advance of the meeting. The request should include information on the individual's affiliation and an explanation of the individual's interest in the Study Group activities. The non-member requesting permission to participate in the meeting will be notified of the decision in writing by the Study Group Chair.

A meeting summary including action items emerging from each Study Group meeting should be prepared and forwarded to the GHTF Chair within six weeks of each meeting who will then forward it to the members of the GHTF Steering Committee. The summary will also be posted on the GHTF website.

4.7 Joint Study Group Meetings

The Steering Committee will encourage joint meetings of all Study Groups as appropriate.

4.8 GHTF *Ad Hoc* Working Groups

4.8.1 Creation/Termination/Renewal

Ad Hoc Working Groups may be formed at any time by the Steering Committee for the proper fulfillment of its tasks. *Ad Hoc* Working Groups shall be appointed by the GHTF Chair with the agreement of the Steering Committee.

Before creating an *Ad Hoc* Working Group the Steering Committee shall consider whether the proposed mandate could fit within the terms of reference of existing Study Groups.

An *Ad Hoc* Working Group shall have a clear and narrow mandate and specific work product as developed by the Steering Committee. The projected time to complete a mandate shall generally be short, typically 18 months maximum, but sufficient to accommodate the assigned work. The Steering Committee may also discharge an *Ad Hoc* Working Group from further responsibility, redefine the *Ad Hoc* Working Group's terms of reference, charge the *Ad Hoc* Working Group with a new task, appoint a new chair, and/or renew an existing Chair's appointment. *Ad Hoc* Working Groups shall be terminated upon completion of their mandate.

4.8.2 Membership

The chair of an *Ad Hoc* Working Group shall generally be selected from among the Steering Committee members.

Members of *Ad Hoc* Working Groups should represent GHTF Founding Members, Regional Members or Participating Members. Others, such as Liaison Members, may also be considered and be selected on the basis of their expertise in the specific subject matter and should be nominated by the members of the Steering Committee. In exceptional cases, the *Ad Hoc* Working Group Chair may authorize an individual, with appropriate knowledge and expertise, to participate in an *Ad Hoc* Working Group meeting(s) as an external observer/expert.

The size and overall composition of an *Ad Hoc* Working Group is determined by the Steering Committee. At minimum, an *Ad Hoc* Working Group should generally include a sufficient and balanced number of regulators and industry. If an *Ad Hoc* Working Group is intended to develop GHTF regulatory guidance, this Working Group shall include regulators from at least 3 different GHTF geographic regions. Membership of *Ad Hoc* Working Groups, shall generally be small in numbers, and shall provide a balance of regulators and industry and geographic regions.

To provide continuity and facilitate work, the *Ad Hoc* Working Group may appoint a Vice-Chair.

4.8.3 *Ad Hoc* Working Group Chairs

Ad Hoc Working Group Chairs should provide regular reports on the progress of the *Ad Hoc* Working Group's work to the Steering Committee.

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Should an *Ad Hoc* Working Group Chair be unable to fulfill his/her term, he/she should promptly notify the GHTF Chair who in turn will inform the Steering Committee. The GHTF Chair or his/her designee will then consult within the Steering Committee (using teleconference or e-mail as needed) and appoint a replacement, either on an interim or permanent basis.

4.8.4 *Ad Hoc* Working Group Meetings

Ad Hoc Working Groups meet as often as necessary to carry out the tasks assigned to them by the GHTF Steering Committee. *Ad Hoc* Working Groups shall generally give preference to electronic communication tools (e.g. E-mail, teleconferencing or videoconferencing). If in-person meetings are considered necessary the meetings should generally take place in connection with scheduled meetings of the GHTF Steering Committee or other GHTF meetings. Meetings are at the call of the individual *Ad Hoc* Working Group Chair. Meeting agendas should be circulated to all *Ad Hoc* Working Group members, with a copy to the GHTF Secretariat, at least four weeks in advance.

An activity report is to be prepared and forwarded to the GHTF Chair at least six weeks before the next meeting of the Steering Committee who will then forward it to the members of the GHTF Steering Committee.

4.8.5 Management of documents

In general the process by which guidance documents developed by *Ad Hoc* Working Groups are reviewed and adopted shall be that of the GHTF Operating Procedures GHTF/SC/N3R9:2005. Since some of the work of *Ad Hoc* Working Groups will not result in a general guidance documents, the further disposition of such *Ad Hoc* Working Group documents shall be decided by the Steering Committee, in accordance with the original mandate.

4.8.6 Scheme - Lifecycle of *Ad Hoc* Working Groups

see attached Annex B

5.0 Conferences

5.1 GHTF Global Conference

To promote the progress on GHTF activities, the GHTF will meet in a Conference, in principle, once every eighteen months. Responsibility for planning and organizing GHTF Conferences resides chiefly with the GHTF Chair and Steering Committee, who may solicit the assistance and support, if necessary, from other members of the GHTF. The Chair may be assisted by an organizing committee.

In proposing the GHTF Global Conference programme to the GHTF Steering Committee for review and approval, the Chair will take into account that the programme should foresee the possibility for :

- (A) meeting of the Steering Committee,
- (B) meetings of individual Study Groups, as well as a joint Study Group meeting, as appropriate,
- (C) a Plenary Session,

(D) Special Topic Sessions, as described below, and

(E) Area Meetings, at which members from specific geographic areas may meet to discuss issues pertinent to them.

All GHTF members are to be notified of the date(s) of the next GHTF Conference by the Chair, in principle no later than twelve months prior to the event.

5.1.1 Plenary Sessions

The purpose of the Plenary Session at a GHTF Conference is to provide information on ongoing GHTF activities and initiatives. In addition, the Plenary Session may serve as a forum for members to discuss pertinent issues or present material that may be of interest to regulators or industry representatives, and also to non-member countries or representatives of international organizations.

The Plenary Session is open to all registered participants.

The Plenary Session agenda must be reviewed and approved by the GHTF Steering Committee, and will include the following:

- (A) a report, prepared by the current GHTF Chair on behalf of the Steering Committee, outlining accomplishments since the previous Conference including new strategic initiatives and proposed or effected changes to existing GHTF procedures, a summary of work assignments, and other actions taken by the Steering Committee,
- (B) reports, prepared by each Study Group Chair, outlining the status of the Group's work, its current standing and future direction(s),
- (C) presentations from Area Meetings, as appropriate,
- (D) special presentations, by any participant, on a topic relevant to the Conference agenda (see Section 5.1.2),
- (E) reports highlighting significant new regulatory initiatives from each Founding Member and Regional Member, including the implementation of GHTF guidance documents,
- (F) an open session during which any participant may nominate a topic for discussion.

A summary of the proceedings of each GHTF Conference will be prepared by the Chair and circulated to the GHTF Steering Committee for comment in a timely manner.

Following incorporation of necessary revisions, if any, the document will be made publicly available on the GHTF website and archived in the official records of the GHTF.

5.1.2 Special Topic Sessions

Special workshops, symposia, technical and single topic sessions may be convened during a GHTF Conference. Requests to have such meetings as part of the Conference programme should be directed to

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the GHTF Chair, who will then forward them to members of the GHTF Steering Committee for discussion and approval.

Prior to each Conference, the GHTF Chair will invite members to suggest topics for inclusion in the Conference programme.

5.1.3 Registration Fee

In order to defray the administrative and other costs associated with planning and hosting GHTF Conferences, and at the discretion of the host, a reasonable registration fee may be charged to all Conference attendees. Differential registration fees may be applied.

5.2 Regional Conferences

Without prejudice to the GHTF Global Conferences GHTF may organize Regional Conferences in order to promote its activities and guidance in specific geographic areas.

Such conferences may offer GHTF training and /or training on GHTF guidance documents.

The organization of Regional Conferences takes place on proposal of the Chair and in agreement with the Steering Committee.

Such Conferences may be organized in conjunction with other regional events, such as for example APEC, AHWP, WHO or MERCOSUR or similar organizations and cooperation arrangement events.

Appendices

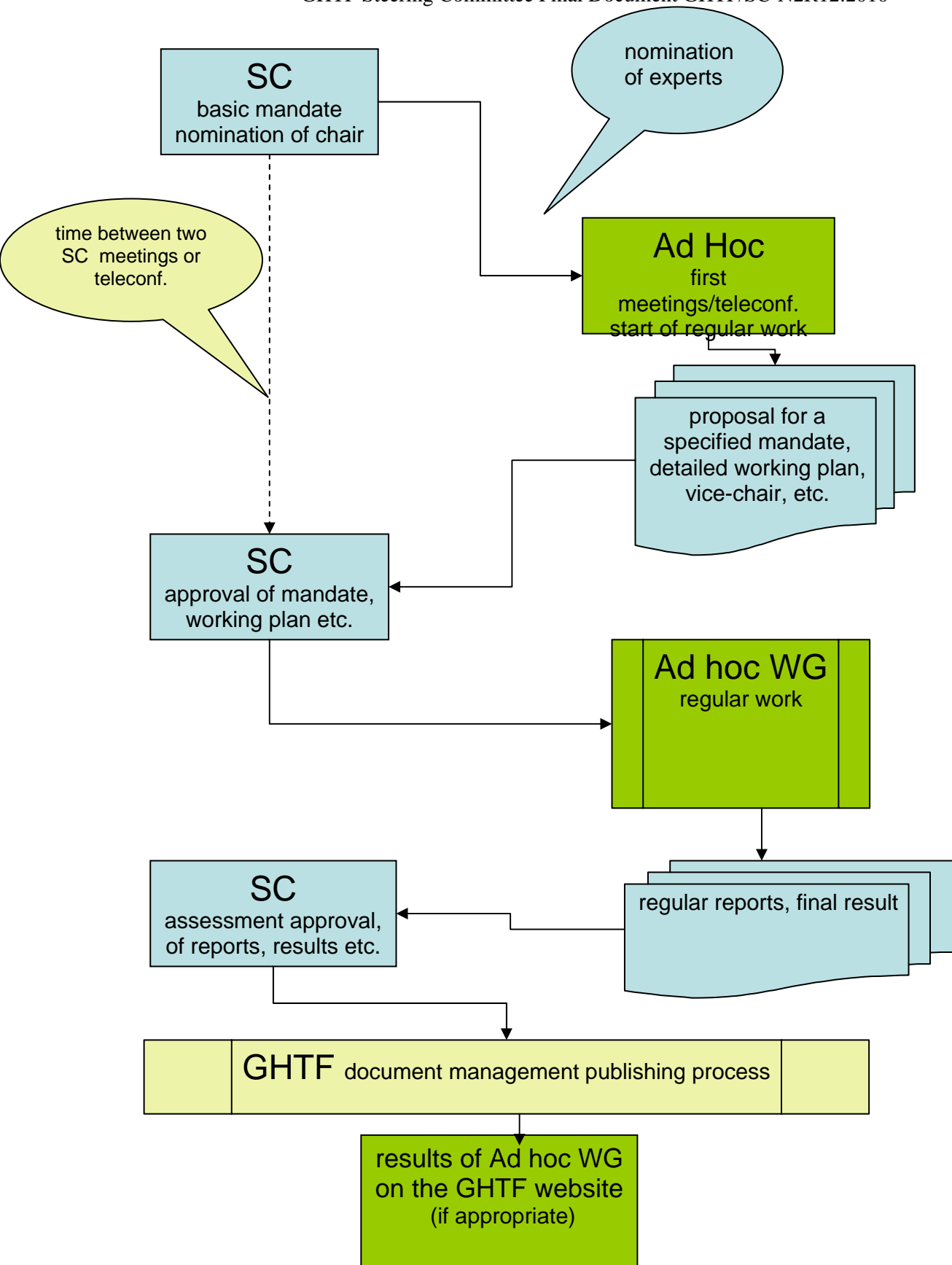
ANNEX A:

	Steering Committee Closed Session	Steering Committee Open Session	Study Groups	Other meetings, such as Plenary Sessions, Regional Conferences, Training etc.
Founding Members	Yes	Yes	Yes	Yes
Regional Members	Yes	Yes	Yes	Yes
Participating Members	No	Yes, on invitation of Chair	Yes, can propose members	Yes
Liaison Bodies	No	Yes, on invitation of Chair	Can propose observers	Yes
Observers from Founding Members	Yes, on meeting-by-meeting basis and agreement by Chair	Yes, on meeting-by-meeting basis and agreement by Chair	Yes, on meeting-by-meeting basis and agreement by Study Group Chair	Yes
Observers from Regional Members	Yes, on meeting-by-meeting basis and agreement by Chair	Yes, on meeting-by-meeting basis and agreement by Chair	Yes, on meeting-by-meeting basis and agreement by Chair	Yes
Observers from Participating Members and Liaison Bodies	No	No	Yes, on meeting-by-meeting basis and agreement by Study Group Chair	-

ANNEX B:

See chart on following page

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