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International Organization for Standardization  
Международная Организация по Стандартизации



Your ref.  
Our ref. ISO/GHTF

Date 2006-04-05

Ms. Georgette Lalis  
GHTF Chair  
Directorate  
Consumer Products  
Directorate-General Enterprise and Industry  
European Commission BREY 10/258  
BE - 1049 BRUXELLES

**ISO and GHTF Cooperation**

Dear Ms Lalis,

Many thanks for your letter of 14 February and the invitation papers for the Lübeck Conference and open session. I apologize for the delay in replying. We continue to discuss next steps and interest from certain ISO Technical Committees, in support of operational participation in the GHTF and its Study Groups.

I wish to confirm ISO's continued interest to liaise actively with the GHTF. This is certainly evidenced by our existing Memoranda of Understanding (MoU) with GHTF concerning the work of ISO/TC 194, *Biological evaluation of medical devices* and ISO/TC 210, *Quality management and corresponding general aspects for medical devices* as well as the 2004 World Standards Cooperation (WSC) Workshop on Health Technologies, of which the GHTF was an important partner.

As requested, and as reference for the GHTF Steering Committee in the formal process of ISO becoming a liaison member, I attach copies of the aforementioned MoUs as well as the existing Business Plans for ISO/TC 210 (the ISO/TC 194 is currently under revision). I also attach the results of the WSC workshop, the recommendations of which are currently being pursued. Finally, of a general nature, I provide a copy of ISO's Strategic Plan 2005-2010 as well as an overview of ISO in the publication entitled "ISO in Figures".

In terms of liaison, we would envisage ISO having on-going collaboration with the GHTF at two levels. The first would be through ISO Central Secretariat on matters dealing with the GHTF Steering Committee or with GHTF as an organization. For these issues, your ISO Central Secretariat contact point is Mr. Tim Hancox (hancox@iso.org). For the GHTF Study Groups (SGs), we are currently investigating whether representatives from our related Committees may participate as ISO's observers to these SGs. Once determined, Mr. Hancox will inform you of their names and contact details.

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I myself am planning to attend the Steering Committee Open Session on 27 June. We are considering if up to two other participants from ISO Technical Committees (e.g., ISO/TC 194 and ISO/TC 210) could also attend to complement our interaction with GHTF during this session. Please let us know if this is appropriate. I also understand that this Steering Committee Open Session is quite separate from the Lübeck Conference which is open to all on a fee basis. I will not attend the Conference the following days but, should our Committee representatives be able to participate at the Steering Committee Open Session, must they pay a fee to stay on for the Conference? Again, please let us know.

With regard to promotion of the GHTF Conference, I am pleased to indicate that we are placing a notice in the May edition of our periodical "ISO Focus" to give publicity to the Lübeck conference.

Finally, I wish to indicate that the contact details of the GHTF Secretariat were provided a number of months ago to the ISO Technical Management Board (TMB) Project Leader responsible for the development of a new Guide on the use of International Standards to support technical regulations. I understand that elements of GHTF information have been considered in the initial drafting. I would encourage that GHTF make contact with the TMB Project Leader, Mr. Trevor Vyze at BSI, UK (Trevor.Vyze@BSI- GLOBAL.COM) to indicate your continued interest and to provide the latest information.

I look forward to your reply on the above matters and to our continued collaboration.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Kevin McKinley". The signature is fluid and cursive, with a large initial "K" and "M".

Kevin McKinley  
Deputy Secretary-General

Enclosures