

HTTF

HEALTH CARE TECHNOLOGY TASK FORCE



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FINAL REPORT
WORLD STANDARDS COOPERATION
HEALTHCARE TECHNOLOGY TASK FORCE
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Executive Summary

The Healthcare Technology Task Force, formed to respond to the Recommendations of the World Standards Cooperation High Level Workshop of February 2004, has met and discussed standardization issues in the medical device and healthcare informatics technology sectors. The Task Force makes recommendations to further the development of globally relevant standards in these sectors.

Background

The Healthcare Technology Task Force (HTTF) was established by the World Standards Cooperation (WSC) in May 2005. The WSC asked the HTTF to respond to the recommendations of the WSC High Level Workshop on "International Standards for Medical Technologies", held in Geneva in February 2004. Within the Workshop Report a section titled "Results and directions for future actions" outlined several specific issues for additional discussion. The HTTF was established to deepen the discussion of these items and make recommendations to enable their accomplishment. The HTTF has developed this report for the WSC.

Scope of the Task Force

The Agenda of the WSC High Level Workshop included a wide-ranging set of discussion topics spanning the many areas of interest of the Workshop participants. However, the participants in the HTTF were not comfortable that they were technically able to address all of the issues that might be represented in this broad scope. To facilitate the discussion and to limit the discussion to the areas of competence of the HTTF members, the Scope of the HTTF is limited to discussing how to improve collaboration among Standards Developing Organizations (SDOs) and encouraging discussion of

priorities in medical devices and healthcare informatics standardization by all the materially affected interests. To enable the discussion, the HTTF adopted the globally accepted definitions for these terms.

The definitions of “Medical Devices” (MD) as promulgated by the Global Harmonization Task Force (GHTF) and “Healthcare Informatics” (HI) in widespread use and interpreted within the scope of ISO TC215 and CEN TC251 were adopted and included in the Scope of the HTTF. The definition of medical devices is meant to include *in-vitro* diagnostic devices. The adopted Scope and definitions are shown as Appendix 1 to this Report.

Invited Participants – Among the concerns expressed by the participants in and the reviewers of the Report of the WSC 2004 High Level Workshop was the apparent lack of balance in the participation - that the participants in the Workshop did not represent a cross-section of the interested and affected community. They indicated that any follow-up discussion should be open to all interested parties. The planners of the HTTF recommended that a broad spectrum of participants, including regulators, manufacturers associations, standards development organizations, and product users be invited to participate in the HTTF. Also, an effort was made to obtain geographical balance. In consultation with the WSC members, the partners of the 2004 Workshop, and the HTTF, invitations were sent to more than 60 organizations globally. These organizations represent the existing developers of globally used standards in this area, the manufacturers of MD and HI products, and regulators. However, medical professionals are important stakeholders for health technology standards, but had little representation.

Although the meetings of the HTTF were scheduled at times to make it feasible for all invitees to participate, the majority of active participants were from Western Europe and North America. Consequently the views from outside these two regions were not well represented in the HTTF discussions.

The majority of the active HTTF participants were from IEC and ISO. Therefore, the discussion time was devoted largely to MDs. “Harmonizing the HI standardization”, and “achieving product and system interoperability”, have been extremely challenging in the past. Interested medical professionals, hospital CIOs and the HI industry have formed a global organization, Integrating the Healthcare Enterprise (IHE), to address some of these issues. Any future activities should attempt to engage the IHE as an active participant. As a consequence of the lack of broad participation from the HI community, the HTTF limited its discussion to the “safety of HI technology”, including the increasing use of wireless communication by MDs and “safety of software applications”.

HTTF Procedure

e-Room Procedures – To enable the timely development of the HTTF work with frequent opportunities for discussion, the HTTF resolved to meet electronically, using teleconferencing and e-room discussion of issues. IEC was willing to provide access to their e-room software for the HTTF. This is, perhaps, the first time these techniques were used exclusively and with success on this scale in this type of a discussion.

Meetings – HTTF met five times over a 3-month period to evaluate the issues, make recommendations, and develop and review this report. Meetings were scheduled so that it was possible to participate from any geographic time zone. Prior to each meeting, an agenda for the planned meeting and a Meeting Summary of the recent meetings were posted on the e-room. Each meeting was planned to have a two-hour duration.

Discussion and Results

The agenda for the discussions of the HTTF and, therefore, this report are based on the five “Results and directions for future actions” contained in the Report of the WSC 2004 High Level Workshop (See Appendix 3). To supplement these discussion topics, HTTF members were repeatedly reminded to identify any additional issues that should be discussed.

1. Strengthen the dialog between ISO/IEC/ITU-T, the WHO and the GHTF. The three entities need to share strategic information aiming at:
 - a. Defining a clear and harmonized presentation of the respective standardization programs
 - b. Mapping the existing standardization programs and priorities in the medical technology field
 - c. When relevant, promoting the adoption of the GHTF *Essential Principles* as a guiding reference for the development of standards that can be used by regulators

HTTF strongly supports the need to strengthen the dialog and communications among all the members of the global standards community. This would include the members of the WSC, the partners in and the invitees to the High Level Workshop of February 2004, the participants in the HTTF, plus all developers and users of global standards in this sector. The HTTF members cited several instances and examples where improved communication in the future will be important to relevant standards development:

1. Interoperability of equipment;
2. Engagement of all global standards developers; and,
3. Functioning of joint task forces and committees

In addition to a continued need to encourage and improve the communications between the WSC members, e.g., ISO and IEC, the HTTF discussion pointed particularly to the need for effective communication between ISO and CENELEC, and IEC and CEN. This

is driven by the increased sophistication of MD and HI and the intersection of the spheres of influence and activity of these organizations.

The HTTF discussed at length the issues presented by projects that properly overlap the jurisdiction areas of several SDOs. HTTF believes that, in spite of the difficulty of integrating these interests, execution of joint projects continues to be the most viable approach to mutual development of the needed standards. The HTTF was advised that the current operational guidelines for Joint Working Groups and Technical Committees are being revised. HTTF was made aware of the recent efforts to develop the “Draft rules for the operation of joint working groups” and was provided with an early draft. The HTTF was specifically advised that the functioning of joint working groups between WSC members was often difficult at the national level. When issues had surfaced in the past that were possibly best addressed by joint committees, the organization of the mirror committees in some participating countries had proven to be an obstacle to success.

The HTTF encourages the WSC to seek ways of ensuring that the technical experts best able to address the problems and issues effectively are identified and engaged in such joint endeavours. The HTTF acknowledges that there have been recent successes in resolving the cross-WSC communication issues in the medical device area. The HTTF noted that it is somewhat easier to staff Technical Committees and Working Groups concerned with product specific or vertical issues than with cross-cutting or horizontal issues. The HTTF noted that the issue of interoperability of equipment and wireless interconnection of information streams between medical equipment and patient records brings this issue into focus for the near future. The developers of standards for products and protocols in this area should communicate their intentions for standards development regularly.

2. Foster cooperation among the globally relevant SDOs:
 - a. Exchange information on deliverables and projects covering priority items;
 - b. Encourage ISO, IEC and ITU-T technical committees to define appropriate mechanisms to favor and optimize cooperation among relevant SDOs, WSC members and WHO;
 - c. Promote benchmarking and use of best practices across the various organizations.

Healthcare technology is intended to safely support or sustain life functions in patients, as well as to be used for less critical treatment or diagnosis. “Safety” is not just a matter of ensuring safe performance, but also balancing risk with benefit. The WSC should support the autonomy of the healthcare technology community in setting standards that meet the needs of the patient populations it serves. For example,

general standards for risk management, quality systems, symbols, etc. may not meet all the needs of the healthcare technology field and should not be imposed on healthcare technology committees.

At the same time, there is a need for general standards that support compatibility between different technical areas (e.g., limits for electromagnetic emissions and susceptibility). For such standards, the WSC should assist the healthcare community in its negotiations with other sectors and/or generic standards-writing communities to ensure that patient safety is not compromised.

The HTTF supports a process that includes all SDOs that develop globally relevant standards. The HTTF strongly reinforced the concept that developers of globally relevant standards are those that follow the WTO Technical Barriers to Trade (TBT) Code of Practice and the TBT Annex IV – Principles for the Development of International Standards, Guides and Recommendations. The free exchange of information on projects and deliverables will partially address the need to avoid duplication of development efforts. Developers of globally recognized standards for medical device safety, medical device communications, enterprise-wide health informatics and fundamental technologies should work together where appropriate to minimize redundancy of scope of their standards and to ensure that there is as much consistency and mutual referencing as the broad spectrum of business needs and safe performance of function permit. WSC should make efforts to ensure that due diligence in searching for ongoing development projects and existing (or final) standards that could overlap a proposed new project as part of the justification of New Work Item Proposals (NWIP) is properly carried out.

HTTF notes that the WSC was established to foster cooperation and communication among all developers of global standards. Each of the individual globally relevant SDOs serves a different, but often overlapping, community. Within the MD community, experience has shown that this community has been able to resolve many issues, both at the national and regional levels, through negotiation and cooperation. Issues among developers of international standards should be resolved by the TCs/SCs/WGs/TFs involved. HTTF anticipates that similar cooperative processes will continue to evolve in the HI community, and between the MD and HI communities.

- a. To do their job efficiently, standards writers need to have access to existing standards that are relevant to the work they are pursuing. The HTTF supports a process that shares information among all SDOs that develop globally relevant standards for the MD and HI communities. The HTTF asks the SDOs to each establish a single point-of-contact to handle requests for existing standards from committees developing standards in other organizations. Also the HTTF encourages each SDO to publish on a publicly available web site the scope and a summary of the content of each existing standard, and the scope of New Work

- Items. In time, the HTTF envisions that a combined list for all participating SDOs will be on each SDO's public web site.
- b. The HTTF submits that the most important issue remaining unresolved in this context is the identification of needed standards and establishment of priorities for their development. SDOs depend on the willingness of their members to engage in each standards development effort. The priorities for standards development must be established carefully to optimize the use of these resources. HTTF discussed the role that stakeholder organizations should play in conveying their standardization needs to the SDOs. For MD, no mechanism to formally gather and assess these needs exists today. In the HI arena, major user associations (medical professionals, hospital CIOs) have founded a globally active initiative, Integrating the Healthcare Enterprise (IHE), to orchestrate the use of existing standards (or some subset of them) for achieving the most urgent interoperability needs, and to steer the priorities for further standardization work. Similar "stakeholder groups" will be implemented in Europe by the EC to give guidance to "eHealth standards".

HTTF considered recommending the development of a standard terminology in this community. The HTTF notes that terminology and nomenclature are not synonymous terms. The HTTF was unable to address this issue in detail but noted that the purpose of a terminology/nomenclature has to be clear and that, for example, GMDN, SNOMED, LOINC and ISO/IEEE 11703-10101 all have device related content for different purposes.

During these discussions, those HTTF participants with experience in the HI community noted that this community is increasingly sensitivity to the safety aspects of their work. Interoperability of equipment, particularly in a wireless environment, and transmission errors in control signals and patient information are issues that are being worked on. The role of ITU (often in co-operation with IEC and JTC 1) in establishing and maintaining the standards for the basic infrastructure while the HI community generally develops the applications layers of the system was acknowledged. HTTF believes that the WSC should encourage continued efforts to harmonize regional, and if possible global, use of the spectrum to facilitate safe use for MD and for HI applications – and that this should be integrated with wider networking considerations as necessary and feasible.

3. Promote the visibility of achievements and existing programs, enable optimal and effective use of the international standardization system:
 - a. develop presentation materials and guides;
 - b. favor communication and dissemination of results;
 - c. highlight successful models of cooperation between developers of voluntary standards and regulators.

HTTF immediately recognized the value of sharing the activities and accomplishments of the several developers of globally used standards. However, it may not be possible to arrive at a single mechanism to accomplish this goal. Even within the narrow Scope of the HTTF, approaches to the solution of this issue may differ among the MD, HI, and in-vitro diagnostic (IVD) device communities. The communities of manufacturers, users and regulators are at quite different levels of development and mutual cooperation is sometimes not easily accomplished. Even the logic schemes and development processes for these communities seem to differ. For example, in the MD community, the development and introduction into use of the product usually precedes development of the standard. For HI, the opposite process is often the case where interoperability is the objective.

In the past the cooperation between standards developers and regulatory authorities has resulted in development of many standards in the MD sector that have had significant regulatory importance in that sector. Examples are the IEC 60601 series, ISO 13485, the ISO 10993 series, IEC 62304, and ISO 14971.

HTTF is quite certain that, at least for MD, and probably for IVD, the existence of standards and the role they play in enabling the delivery of safe products to users is generally well known to the MD manufacturers and regulators. However, some SDOs have noticed a significant unwillingness of the MD regulatory authorities and the HI corporate purchasers to commit the resources to the maintenance of the existing standards and the development of any new documents. HTTF is concerned that this has resulted in a weakening of the consensus process. Participation in and support of voluntary standards are also in the best interest of regulators since standards are among the least resource intensive regulatory tools that they have.

HTTF believes that the needs of smaller companies that are vendors on a global scale, particularly those in countries in which the industry is just developing, are important to standards development. Targeting this group of companies with as much information as possible about the development of new work items and the revision of existing standards will help ensure that the input to the standards is as wide as possible within the resource constraints of those companies.

The HTTF believes that many countries lack the resources to engage in the development and standards maintenance processes.

The HTTF learned that the GHTF is working towards expanding its influence, and perhaps its membership, beyond the current group of industrialized nations. The HTTF welcomes and supports this change in the GHTF.

Finally HTTF recommends that the WSC and other SDOs engage in a global campaign to make the public aware at every opportunity of the role that standards play in ensuring that the medical products they use are safe and effective.

4. Incorporate effectively the risk management approach in the standardization process:
 - a. Promote its application, especially in emerging technology fields;
 - b. Prepare case studies/success stories;
 - c. Undertake broader educational efforts.

Risk management is at the heart of medicine – balancing the risk of the condition being treated with the benefit of the treatment. The MD sector is well advanced in implementation of a risk management approach. The WSC should support efforts to educate the healthcare technology standards-writing community as well as the broader community of standards users about the contents of ISO 14971, how to incorporate this approach into the standards-setting process, and how ISO 14971 and other medical standards fit into a manufacturer's risk management program. Some ways of supporting these efforts may include sponsoring a seminar for healthcare technology standards developers on ISO 14971 and/or distributing articles to that community on this subject. The HTTF also discussed asking experts from ISO/TC 210 to write an article for broad distribution (e.g. via ISO and IEC newsletters, AAMI's *Biomedical Instrumentation and Technology* Journal and other appropriate vehicles) on the part each healthcare standard represents as a “piece of the total risk management package.”

HTTF strongly supports the risk management approach to the development of medical device standards. The risk management approach has been the norm in development of medical device standards for over a decade. The HTTF noted the recent efforts by an ISO Technical Management Board (TMB) task force to develop a more global risk management standard. WSC should ensure that development of a more general Risk Management Standard does not pre-empt, change, or interfere with the existing ISO 14971, *Medical devices – Application of risk management to medical devices*, standard commonly in use by the medical device community.

The HTTF noted that technology areas such as pharmaceuticals and nanotechnology might make use of this approach to be most relevant. Other technical committees of the several WSC members perhaps need training in the application of risk management approaches. It may be valuable to make the risk management standards that exist in the medical device area, namely ISO 14971, available at no cost to other committees.

5. Join forces and achieve better synergies to support developing countries:
 - a. Improve coordination between WSC members and WHO on technical assistance and education

HTTF supports this as both a general concept and a particular focus for the MD area and noted that there has been some recent success. HTTF encourages the developers of global standards to continue their efforts to engage developing countries towards active participation in the standards process.

HTTF is sensitive to the ethical issues of equipment sophistication and access to medical care and, in particular, notes the difficulty that developing countries may have with implementation of standards that are applicable to developed countries. These may not be appropriate in developing countries, perhaps because of assumed availability of infrastructure such as power and water services, or because the state of technology or medical practice in some developing countries may not be able to sustain standards currently required by the regulatory authorities of the developed countries.

There are many examples where technology has advanced significantly and, while the older technology is no longer accepted in the developed countries, it is still in common use elsewhere. Thus the regulatory authorities of some developing countries may still want standards with the cachet or logo of the major global SDOs for this older/technically simpler equipment. The current option of national adoption of superseded and withdrawn standards resolves neither the need for the cachet, nor the question of updating technology. However, SDOs have great difficulty in mustering the resources to develop or maintain standards for equipment that is no longer manufactured in significant quantities. The HTTF suggests that SDOs continue to make available the withdrawn or historical standards when they are requested, but mark them as such.

Recommendations

The following are recommendations of the HTTF that were agreed to be helpful to achieve the goals that have been set in the summary “Results and directions for future action” of the WSC high-level workshop on International Standards for Medical Technologies, Geneva, 26-27 February 2004.

1. Strengthen the communications

- a. Ensure cooperation among healthcare sector committees and committees writing general (non sector-specific) standards:
 - i. The WSC should support the authority of the healthcare technology community to set standards that meet the needs of the user, patient and manufacturer populations it serves.
 - ii. The WSC should assist the healthcare community in its negotiations with other sectors and/or generic standards-writing communities to ensure that patient safety is not compromised.
- b. The use of electronic communication, web casts, and other technology to facilitate the development of standards by SDOs should be encouraged by WSC. This use should be designed to facilitate work and reduce overall cost to working groups, subcommittees, technical committees, and delegates to those groups as well as to the SDOs themselves.
- c. HTTF recommends the development of agreements similar to the Vienna and Dresden agreements between ISO and CENELEC, and IEC and CEN. HTTF is certainly supportive of and recognizes the success of the existing agreements. The purpose of these new agreements is to strengthen the dialog and communications among the members of the global standards community in support of the growing interoperability of and communications between MD and HI equipment.
- d. The HTTF recommends that SDOs assist the several stakeholders in the MD and HI communities in establishing a new work identification and prioritization process. The HTTF suggests that the GHTF serve as a forum within the MD area to provide a consolidated regulatory input into the devices-related work programs of SDOs. The HTTF also suggests IHE, or an analogous body with broad HI expertise, might be used to recommend where global standards are needed in HI at the enterprise level.
- e. HTTF encourages the completion of the “Draft rules for the operation of joint working groups” and urges the WSC to broaden the constituency developing the rules to include the ITU and other global SDOs.

- f. A single, freely available, web-based file or database that contains the title, scope and status of all globally used standards in the Medical Devices, Healthcare Informatics and In-vitro Diagnostic areas should be compiled, published, kept current, and actively promoted. HTTF was informed that the basis of such a file for ISO and IEC standards is under development and that a structured collection of HI standards already exists on the web:
http://www.who.int/ehscg/resources/en/ehscg_standards_list.pdf,
 - i. HTTF strongly encourages the sponsors of this file to negotiate with the other global standards developers to make the file complete and develop the means to keep it current.
 - ii. HTTF recommends that all the SDOs whose standards are shown in the compilation should link to the combined list.
 - iii. HTTF recommends that the GHTF create the link to this file from the GHTF web site.
- g. For the HI sector, WSC should encourage the development of an Essential Principles document similar to ISO TR 16142 as they relate to that sector.
- h. For each healthcare standard being developed or revised, WSC should encourage the development of an informative annex that maps the requirements of the standard to the Essential Principles in ISO TR 16142-1999, when applicable. WSC members should facilitate this development by:
 - i. Providing a standard format/template for this annex.
 - ii. Amending their procedures to make production of this annex an administrative process to avoid prolonged debates over adequacy of coverage.
 - iii. Providing public access to this annex once the standard is published.
- i. ISO 210, working with the responsible stakeholders including the GHTF and ISO TC 215, should examine the practicality of extending the Essential Principles in ISO 16142 to encompass the Medical Device related aspects of Healthcare Informatics.

2. Foster cooperation among globally relevant SDOs

- a. The HTTF supports a process that shares information among all Standards Development Organizations (SDOs) that develop globally relevant standards and fosters the best possible means to accomplish the development of the needed standards.
- b. Jurisdictional issues and differences of technical requirements for similar standards should be resolved by the SDOs involved.

WSC should not establish any additional processes to address these issues. Nevertheless, it is important to resolve duplication and conflicts before Work Items are adopted. For that reason there should be active public notification by the respective SDOs of all Preliminary work and NWIPs.

- c. To enable the work of the technical committees, all SDOs should make available to the officers of the Technical Committees, Subcommittee, and Working Groups (as appropriate) of all SDOs in the healthcare sector secure access to all the standards relevant to this sector. (NOTE: To enable optimal harmonization, this may include non-health areas). HTTF recommends that each SDO establish a single point-of-contact from whom requests for copies of existing standards might be requested and delivered in a timely way.
- d. HTTF believes that the WSC should work towards obtaining dedicated and globally harmonized frequencies for signals between medical devices.

3. Promote the visibility of achievements and existing programs, enable optimal and effective use of the international standardization system

- a. The SDOs, particularly ISO and IEC, should establish a long-term goal to make easily available through their Websites information about which standards apply to healthcare. To enable the understanding and use of standards, the title, scope and status of standards should be compiled and published by each SDO and made available independent of the standard itself. HTTF recommends that all the SDOs whose standards are shown in the compilation should link to the combined list. HTTF recommends that the GHTF create a link to this file also. Additionally, as work in the area progresses, they should provide similar information regarding Healthcare Informatics.
- b. The HTTF recommends that providing links to the Essential Principles mapping in standards through the web-based system recommended previously (See Recommendation 1.h.) showing how standards enable conformity to the Essential principles would materially improve global use of standards.
- c. HTTF recommends that the WSC and other SDOs engage in a global campaign to make the public aware at every opportunity of the role that standards play in ensuring that the medical products they use are safe and effective.
- d. HTTF proposes that the WSC and other global SDOs engage the regulatory authorities, possibly through the GHTF, to enable the participation by government technical experts in standards development.

4. Incorporate effectively the risk management approach in the standardization process

- a. WSC should ensure that development of other, including more generally applicable, Risk Management Standards does not preempt, change or interfere with the further development and use of the existing ISO 14971, *Medical devices – Application of risk management to medical devices* standard commonly in use by the medical device community.
- b. HTTF noted that the need to include the “benefit” argument in the risk/benefit management discussion should be strengthened, i.e., the total argument needs to be a Risk Management/Benefit discussion
- c. The WSC should support efforts to educate the healthcare technology standards-writing community as well as the broader community of standards users about the contents of ISO 14971, how to incorporate this approach into the standards-setting process, and how ISO 14971 and other medical device related standards fit into a manufacturer's risk management program. Some ways of supporting these efforts may include
 - i. sponsoring a seminar for healthcare technology standards developers on ISO 14971, and/or
 - ii. distributing articles to the healthcare community on this subject

5. Join forces and achieve better synergies to support developing countries

- a. HTTF recommends that SDOs continue to make their historical and withdrawn standards available upon request. HTTF recommends that these standards be marked as having been superseded or replaced when they are so distributed.
- b. HTTF noted the value of involving the smaller companies on a global scale, particularly those in countries in which the industry is just developing. Involving this group of companies will help ensure that the input to the standards is as wide as possible.

Appendices

Appendix 1 - Scope of the HTTF

Appendix 2 - Participants in the HTTF

Appendix 3 - Recommendations of the WSC High Level Workshop

Appendix 1

WSC Healthcare Technology Task Force

Scope

The Healthcare Technology Task Force (HTTF) was established by the World Standards Cooperation (WSC) following the WSC high level workshop on “International Standards for Medical Technologies” held in Geneva in February 2004. Within the report of that Workshop a section titled “Results and directions for future actions” outlined several specific issues for additional discussion. The HTTF is established to further the discussion of these items. To enable the HTTF to reach consensus for this work program, the breadth of the discussion is limited to medical devices (including *in-vitro* diagnostic products) and healthcare informatics (see the globally used definitions for these terms below). The HTTF will develop a HTTF Report for the WSC that makes recommendations on-going WSC actions and/or structures to address the Workshop recommendations, including:

- Recommend follow-through mechanisms and/or WSC organizational changes
- Recommend sustainable WSC actions/activities
- Recommend possible partition the HTTF areas into smaller, more natural sub-topics

Definitions

- Medical Device (from GHTF)

‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or

metabolic means, but which may be assisted in its intended function by such means.

Note 1: The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some *in-vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations.

Note 2: Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices (see Note 3),
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

Note 3: Accessories intended specifically by manufacturers to be used together with a 'parent' medical device to enable that medical device to achieve its intended purpose should be subject to the same GHTF procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification than the 'parent' device.

Note 4: Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a 'medical device'.

- Healthcare Informatics (van Bommel et al.: Handbook of Medical Informatics, modified in the discussion of HTTF)

Healthcare Informatics is the science that studies the use and processing of data, information, and knowledge applied to medicine, health care and public health.

Scope of standardization TCs:

"Standardization in the field of information for health, and Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems. Also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancies." (ISO TC 215)

"Standardization in the field of Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems and to enable modularity. This includes requirements on health information structure to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality." (CEN TC251)

Appendix 2

Participants in the Healthcare Technology Task Force

The following Members have been nominated by their organizations to the HTTF.

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Appendix 3

Recommendations WSC High Level Workshop International Standards for Medical Technologies Geneva February 2004

1. Strengthen the dialog between ISO/IEC/ITU-T, the WHO and the GHTF. The three entities need to share strategic information aiming at:
 - Defining a clear and harmonized presentation of the respective standardization programs
 - Mapping the existing standardization programs and priorities in the medical technology field
 - When relevant, promoting the adoption of the GHTF essential principles as a guiding reference for the development of standards that can be used by regulators
2. Foster cooperation among the globally relevant SDOs
 - Exchange information on deliverables and projects covering priority items
 - Encourage ISO, IEC and ITU-T technical committees to define appropriate mechanisms to favor and optimize cooperation among relevant SDOs, WSC members and WHO
 - Promote benchmarking and use of best practices across the various organizations
3. Promote the visibility of achievements and existing programs, enable optimal and effective use of the international standardization system
 - develop presentation materials and guides
 - favor communication and dissemination of results
 - highlight successful models of cooperation between developers of voluntary standards and regulators
4. Incorporate effectively the risk management approach in the standardization process
 - Promote its application, especially in emerging technology fields
 - Prepare case studies/success stories
 - Undertake broader educational efforts
5. Join forces and achieve better synergies to support developing countries
 - Improve coordination between WSC members and WHO on technical assistance and education