# International Standards for Medical Technologies

In February 2004, a high-level workshop on International Standards for Medical Technologies was organised in Geneva by the World Standards Cooperation and hosted by WHO. WSC is a consortium of the 3 majorglobal standardisation organisations, i.e. the international organisation for standardisation (ISO), the telecommunication standardization bureau (ITU) and the international electrotechnical commission (IEC). FDI had received an invitation to participate from the WHO and was represented by the FDI science manager. About 150 individuals attended the meeting, representing some 70 regulatory agencies, standardisation committees and institutions, biomedical organizations and the medical technology industry.

The speakers presented during two days a fascinating picture of the complexities associated with regulating the extremely rapid developments of new medical technologies. The view from the industry is that this moves so fast that it is hard to follow up with development of standards and there are examples where current standardisation efforts get in the way of creative processes that industry makes available. In view of a claim that industry now pays for >90% of the costs associated with standardisation work by sponsoring researchers to participate it becomes understandable that the outcome of these activities are appraised critically.

Speakers representing the regulatory “world” are fully aware that standards are not panaceas because they have limitations. Before, the standards were rather mechanistic and the agenda today is to move away from defining dimensions and design and instead address behaviour and performance. Several speakers focused on risk aspects when addressing the issues and it seems that both regulatory efforts are moving towards risk based system standards in the future. Thus one may define today the regulation of medical technologies as a risk management process with the two central questions 1. is the product safe to use; 2 is it effective, i.e. does it do what it claims to do and 3, evaluate the risk versus the benefits.

**In sum, more questions than answers were presented. E.g. although many standards are not good – how are they being evaluated? Who are the “customers” of the standards being developed? E.g. for over the counter devices, are the lay-persons represented in standards development? On the other hand, modern medical technologies are acquired by sophisticated users in contrast to products meant for the high volume markets. How much improvement is needed in order for the profession to implement a new technology? Isn’t it in the end the independent professional that undertakes the responsibility to apply the new technology into his or her own use?*

FDI needs to be aware of the changes in the regulations of medical devices that are currently ongoing on a global level, since this also affects dentistry and the daily life of dental practitioners.

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Your reference:
Votre référence:

11 February 2004

Dear Prof. Jokstad,

**WSC High-level Workshop in International Standards for Medical Technologies: confirmation of registration**

I refer to Dr Gordon-Smith's letter dated 16 January 2004, informing us of your participation in the World Standards Cooperation High-level Workshop on International Standards for Medical Technology, to be held in the Executive Board room of the World Health Organization, from 26 to 27 February 2004.

I am pleased to inform you that **your participation has been registered**.

You are invited to visit the workshop web site at http://www.iso.org/iso/en/domains/WSC-MedTech/index.html, where the latest information is posted as it develops.

Please produce this **confirmation of registration** on request to access WHO premises on arrival. A workshop security badge in your name will be issued at the venue front desk for the duration of the meeting.

I am looking forward to welcoming you at the workshop.

Sincerely yours,

Dr Tim Evans
Assistant Director-General
Evidence & Information for Policy