

Converging and Emerging Technologies

- From the experience of those involved in nanotechnology, we learned that coordination, cooperation and communication are key to harmonization within converging technology areas
- While Nanotechnology is a specific example, many of the experiences can be generalized
- Coordination is important at all levels, between and among
 - ISO/TMB and IEC/SMB
 - ISO and IEC TCs and SCs
- And coordination is critical between and among
 - US/TAGs to ISO and IEC committees
- ISO and IEC standards development models will work if participants understand and utilize processes and tools available

Patents, Copyright and IPR

- ISO, IEC and ITU have a joint patent policy
- We are all well served when participants understand how patents, copyright and IPR issues are properly addressed during the standards development process
- ISO/TMB is considering implementation of a policy requiring attendees to sign a declaration related to copyright and IPR
- We have great concern with the proposed ISO “Assignment of Copyrights” form and these concerns will be addressed with the ISO/TMB
 - Important to understand the difference between “Assigning” and “Licensing” rights

Establishing and Maintaining International Alliances

- International Alliances at all levels
 - Are key to corporate strategic decision making
 - Can influence product development to meet specific regional needs
 - Help companies understand technology needs in emerging markets
 - Drives open innovation
 - Leverages resources
 - Demonstrate value
 - Standards are critical – why companies drive, lead and participate in global standards development

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Establishing and Maintaining International Alliances

- Alliances related to standards development
 - Encourage international technical cooperation, discussion and exchange,
 - Create cooperative bonds between countries that can be beneficial during standards development
 - Promote joint development of standards,
 - Increase international representation and participation
 - Establish industry or committee specific protocols that can expedite the standards development process

Application of IT in Standards Development

- IT solutions for accessing/archiving documents, publishing standards, balloting and collaboration continue to evolve and are becoming integrated more and more into the standards development process.
- IT solutions need to be well thought out – planning is essential, and ongoing maintenance should not be overlooked
- Collaborative tools, especially asynchronous collaborative tools, provide cost-effective solutions – and represent the wave of the future for standards development
- Flexibility needed, no one tool serves all

Using and Referencing ISO and IEC Standards for Technical Regulation

- ISO and IEC strategic objectives include consideration for promoting ISO and IEC international standards in support of regulations
- In June 2007 ISO and IEC will approve a draft special publication on the subject
- Intended to support public policy objectives related to
 - Eliminating technical barriers to trade
 - Sustainable development
 - Public safety and security policies
 - Good regulatory practice
- Where appropriate, regulators (such as FDA) may choose to use voluntary consensus standards, including international standards
 - FDA supports the ISO and IEC guidance document
- Some issues that may occur with standards referenced in regulation:
 - Pressure to develop the international standard to meet national requirements
 - Reluctance to make changes after regulatory adoption
 - Changes made after regulatory adoption can impact manufacturers
- Standards and regulations important to consumers
 - Key issues are safety, efficacy and labeling