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# **World Standards Cooperation Workshop on International Standards for Medical Technologies**

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# Standards & Developing Countries

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- Purposes of Standards
- Standards Developers
- Modes of Participation
- Value Gained
- Application of Standards



# Twofold Purposes

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1. Describe the state of the art
  - Establishes safety guidelines and goals
  
2. Facilitate Market Access
  - For Medical Devices, regulatory clearance/approval is the gateway to the market
    - Approval often relies on compliance with voluntary standards



# Standards Developers

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- Internationally the major developers are IEC and ISO – Standards designated as IS - **nation members**
- Others – AAMI, ASTM, IEEE, NCCLS – used internationally; sometimes basis for IS – **individual and organization members**



# Membership Modes

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- ISO
  - 148 Full Members - **vote**
  - 35 Correspondent Members – no vote
  - 13 Subscriber Members – no vote
- IEC
  - 66 Full Members – must vote
  - 66 Affiliate Countries – vote on 4 TCs



# Participation Modes

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- Comments and Votes
- Attend meetings
- Send Experts to Working Groups
- Support Secretaries/Chairmen



# Participation Benefits

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- Input
  - Comments
  - Votes
  - National requirements, e.g., infrastructure
  - Votes
- Learning experience
  - How do other countries do it?
  - Develop contacts



# Value Gained

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- Your ideas in Standard
- Regulatory Compatibility
- Education
  - How system works
  - How others do it
  - “Best practices”



# Use of Standards

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International Standards

are

**Voluntary Consensus**

**Documents**

# Standards Should **Not** Be



- Used to account for *economic* differences among nations
- Used to account for *social* differences among nations
- Used to account for *political* differences among nations



# Standards Should Be

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- A means to set Contract Requirements
- A means to satisfy Regulatory Requirements
- **Voluntary**
- **Tools for knowledgeable people to use to make wise decisions**