

IVD Medical Device Standards: Increasing the Benefits, Reducing the Risks

Donald M Powers, Chairman, ISO/TC212

11th Conference of the GHTF

Washington, DC – Oct. 4, 2007



TC 212



About ISO/TC 212

- Organized in 1995
- Secretariat: CLSI (formerly NCCLS)
- Scope:
 - Clinical laboratory testing
 - *In vitro* diagnostic test systems
- Participating countries: 32



About ISO/TC 212

- TC 212 Working Groups
 - WG 1, Quality and competence in the medical laboratory
 - WG 2, Reference systems for *in vitro* diagnostic testing
 - WG 3, In vitro diagnostic products
 - WG 4, Antimicrobial susceptibility testing



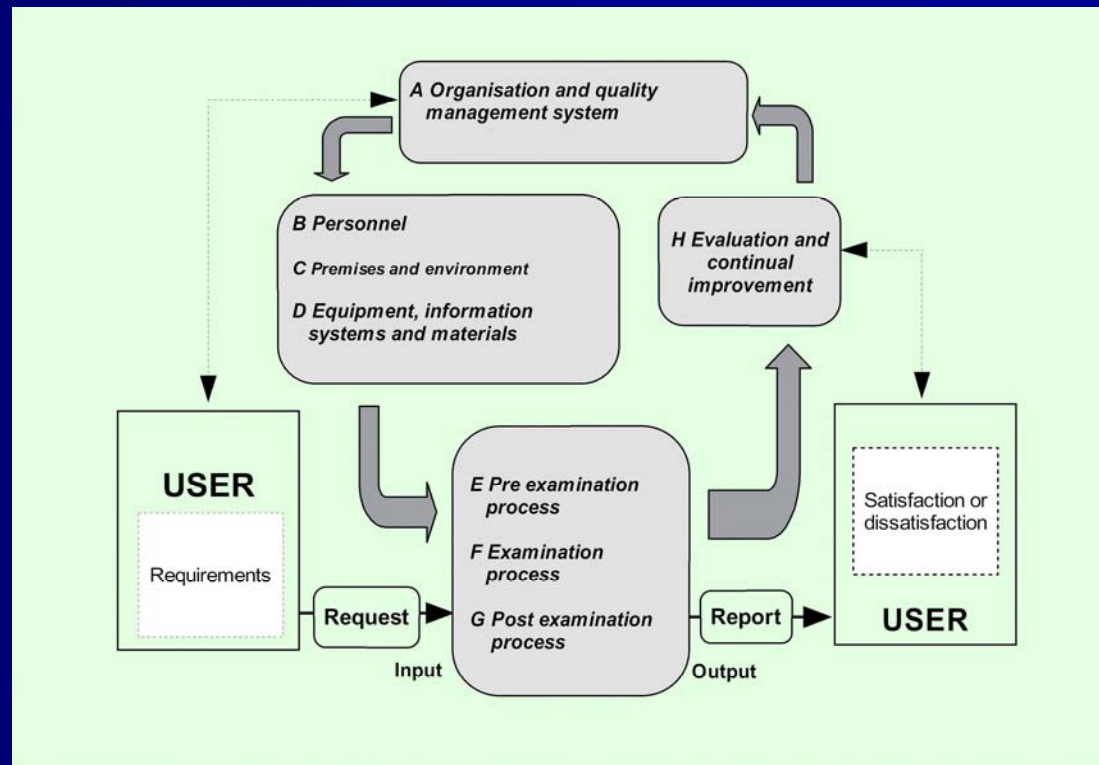
TC 212 Strategic Plan

- Areas of standardization:
 - Clinical laboratory quality management (accreditation and certification)
 - Metrological traceability and IVD reference systems
 - Self-testing devices
 - Risk management for medical laboratory testing
 - Microbiological susceptibility reference systems
 - Labelling for IVD medical devices



Clinical laboratory quality management systems (accreditation and certification)

Medical laboratories -
Particular requirements for quality and competence (ISO 15189)



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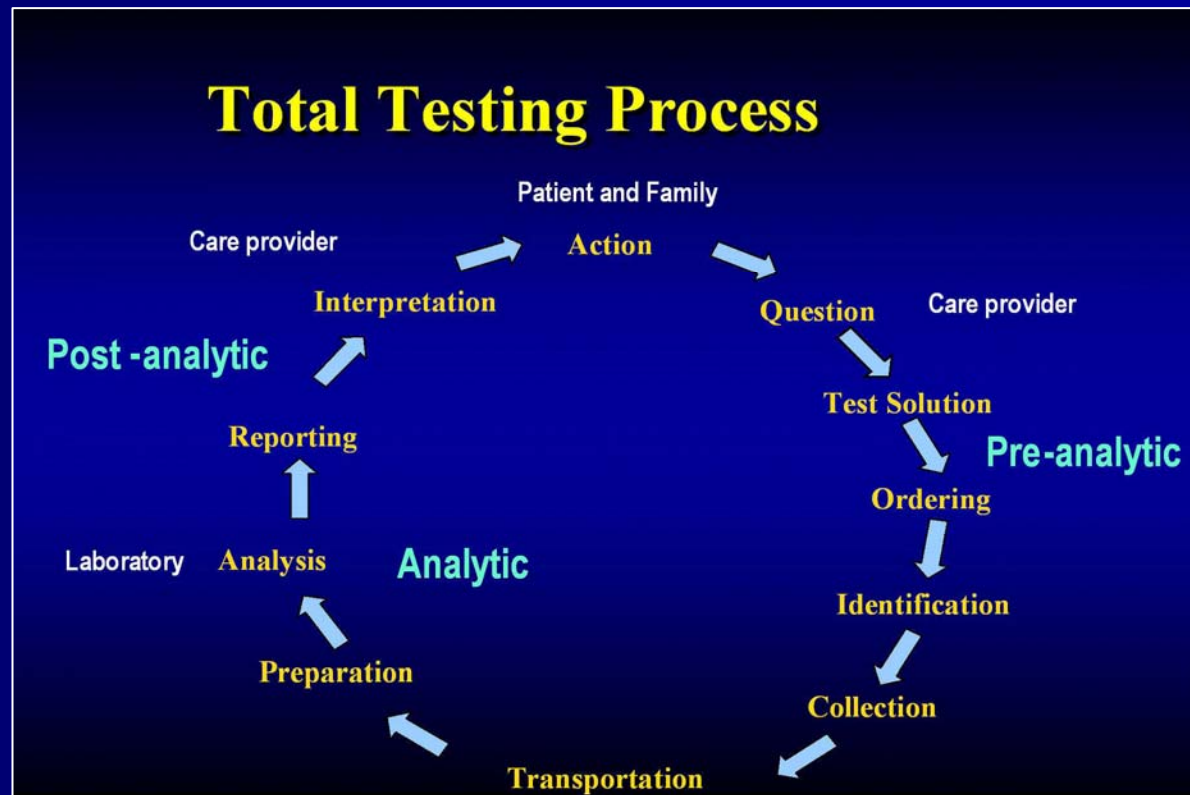


TC 212



Clinical laboratory quality management systems (accreditation and certification)

Guidance on laboratory implementation of ISO 15189 (ISO TR 22869)



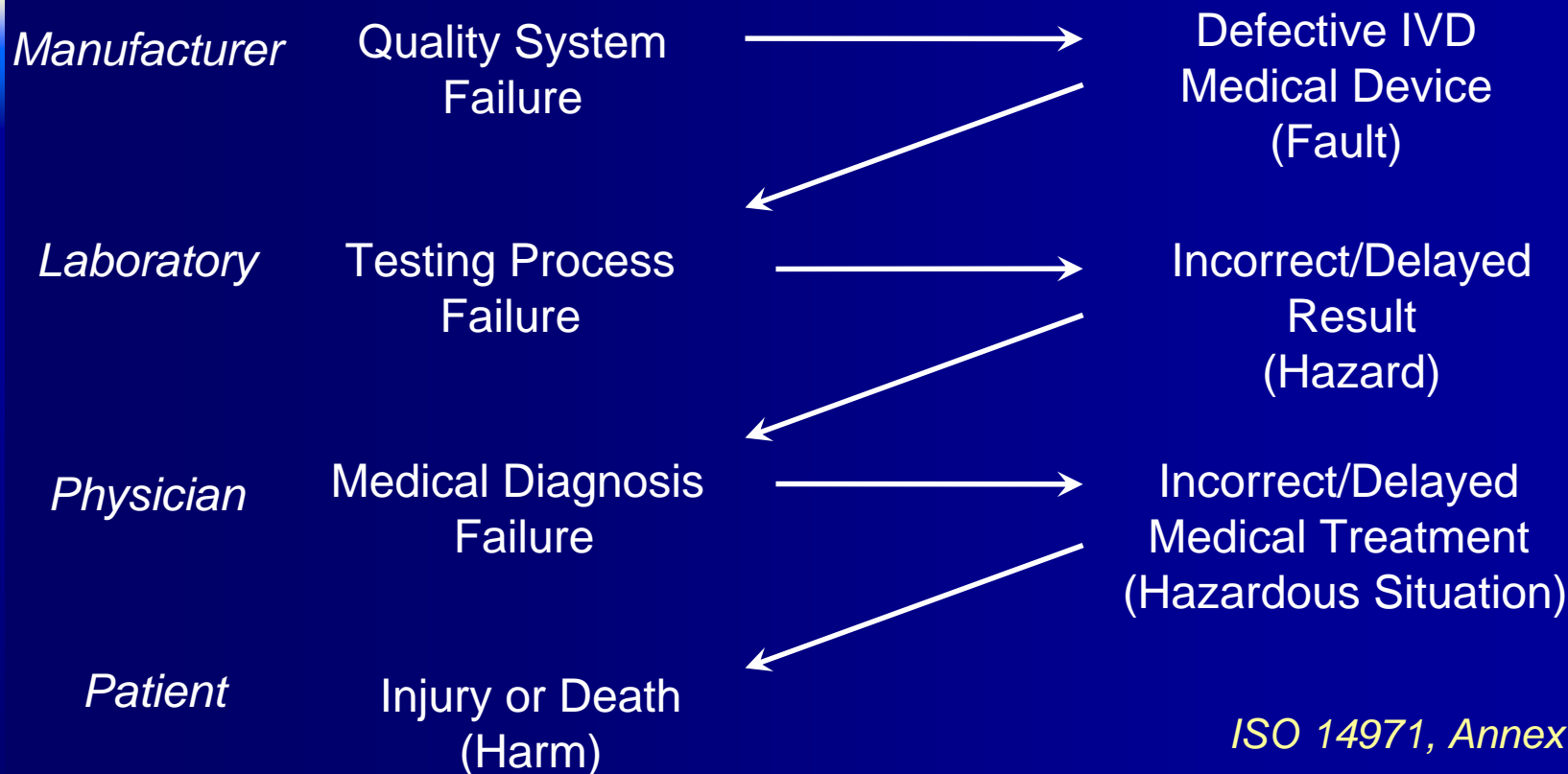
Clinical laboratory quality management systems

(accreditation and certification)

- ISO 15189:2007, Medical laboratories - Particular requirements for quality and competence (2nd Ed)
- ISO/TR 22869:2005, Medical laboratories - Guidance on laboratory implementation of ISO 15189: 2003



Risk Management for Medical Laboratory Testing



Risk Management Guidelines for IVD Medical Devices

- ISO 14971:2007 (Annex H), Guidance on risk management for IVD medical devices *
- ISO/TS 22367:2007, Medical laboratories - Reduction of error through risk management and continual improvement
- Future NWIP?: Risk management for hospital laboratories * (TC210 N141)

* TC 210 collaboration



TC 212



Metrological traceability and IVD reference systems

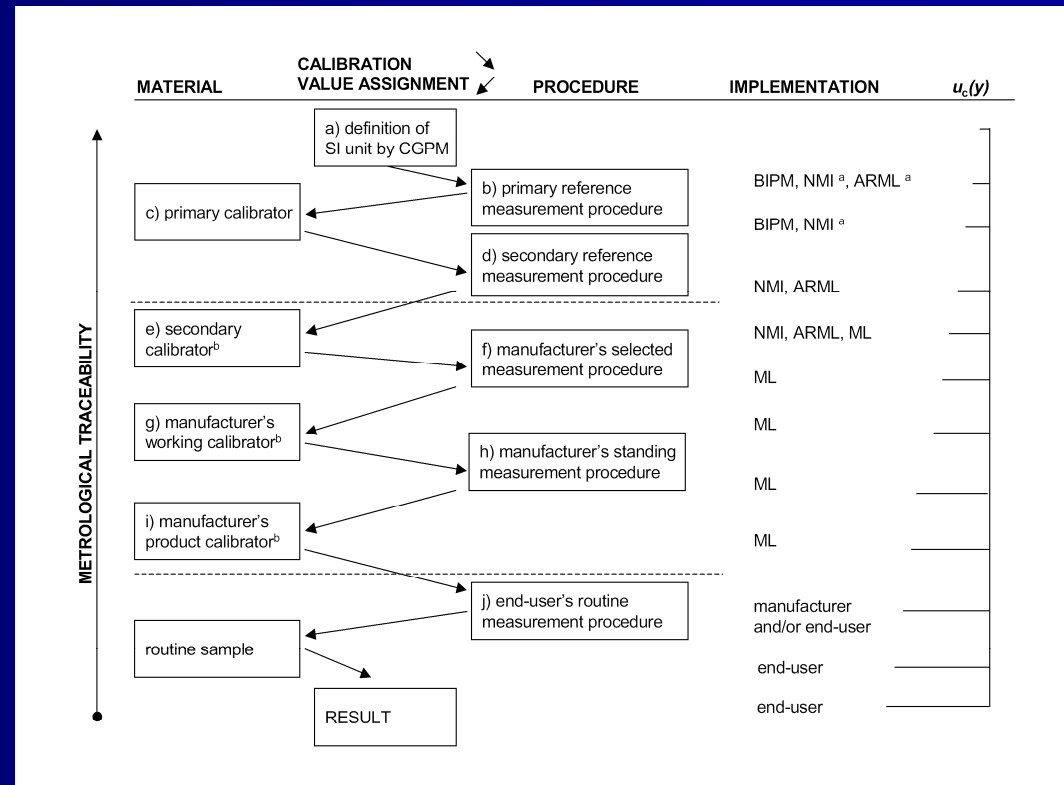
Calibrator Value Traceability

(ISO 17511/18153)

Reference methods (ISO 15193)

Reference materials (ISO 15194)

Reference laboratories (ISO 15195)



Metrological traceability and IVD reference systems

- ISO 17511:2003, Metrological traceability of values assigned to calibrators and controls
- ISO 18153:2003, Metrological traceability of catalytic concentration values assigned to calibrators and controls
- ISO 15193:2002, Reference measurement procedures*
- ISO 15194:2002, Reference materials*
- ISO 15195:2003, Reference measurement laboratories
- ISO TS 25680, Medical laboratories - Calculation and expression of measurement uncertainty**

* 2nd edition at DIS stage

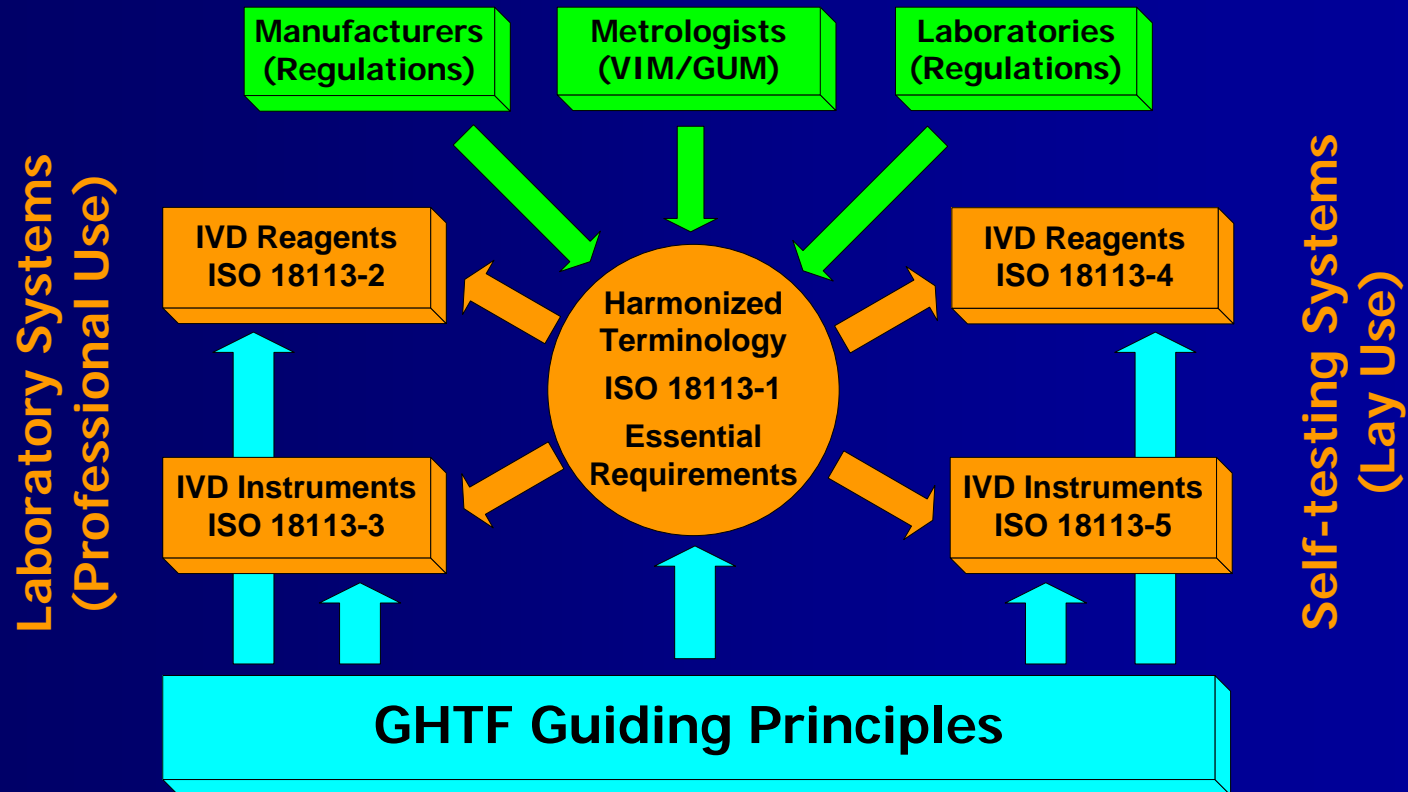
** In development



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Labelling for IVD medical devices



Labelling for IVD medical devices

- ISO/DIS 18113: IVD medical devices – information supplied by the manufacturer (labelling)
 - Part 1 – Terms, definitions and general requirements
 - Part 2 – IVD reagents for professional use
 - Part 3 – IVD instruments for professional use
 - Part 4 – IVD reagents for self-testing
 - Part 5 – IVD instruments for self-testing
 - Part 6 – IVD reagents for staining in biology (ISO 19001:2002)
- ISO/TR 18112:2006, IVD medical devices for professional use – Summary of regulatory requirements for information supplied by the manufacturer (Report)

Requirements for self-testing devices

- ISO 15197:2003, Blood-glucose monitoring systems for self-testing in managing diabetes mellitus
- ISO 17593:2007, In vitro monitoring systems for self-testing of oral anticoagulant therapy

Microbiological susceptibility reference systems

- ISO 20776, Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices
 - Part 1 (2006) Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases
 - Part 2 (2007) Evaluation of performance of antimicrobial susceptibility test devices
- ISO XXXXX, Reference method for susceptibility testing of fungi (NWIP approved 2007-09-21)

TC 212 Strategic Plan

- Potential new project areas:
 - Genetic testing laboratories
 - Proficiency testing
 - Reference intervals
 - IVD reagent stability (EN 13640: 2002*)
 - Harmonized terminology

*Vienna Agreement



Stakeholder Survey for TC 212 Strategic Plan (March 2007)

- Relationships and communications with external organisations are essential to further TC 212's strategic goals

(49 positive, 3 negative responses)



Cooperative Relationships

■ External organisations

- BIPM*
- CLSI**
- EC4*
- EDMA*
- ELM*
- EUROM*
- IFBLS*
- IFCC*
- ILAC*
- IUPAC*
- OECD*
- WASPALM*
- WHO*

* Formal liaison

** Secretariat



TC 212



Cooperative Relationships

■ Standards committees

- ISO/TC 48*
- ISO/TC 69
- ISO/TC 76*
- ISO/TC 176*
- ISO/TC 210*
- ISO/TC 215*
- ISO/CASCO
- ISO/REMCO*
- IEC/TC 66*
- CEN/TC 140**

* Formal liaison

** Vienna agreement



TC 212



TC 212 Strategic Plan

- Maintain key stakeholder balance on the WGs (laboratorians, manufacturers, physicians, regulators/accreditors)
- Continue cooperative development of IVD standards with CEN / TC 140
- Partner with other ISO/TCs to provide IVD expertise and obtain their expertise
- Increase cooperation with global partners, including GHTF



ISO 212 Standards: Increasing the Benefits, Reducing the Risks

Thank you !



TC 212



WG 1, Quality and competence in the medical laboratory

- ISO 15189:2007, Medical laboratories - Particular requirements for quality and competence (2nd Ed)
- ISO/TR 22869:2005, Medical laboratories - Guidance on laboratory implementation of ISO 15189: 2003
- ISO 15190:2003, Medical laboratories - Requirements for safety
- ISO 22870:2006, Point-of-care testing (POCT) - Requirements for quality and competence
- ISO/TS 22367:2007, Medical laboratories - Reduction of error through risk management and continual improvement

WG 2, Reference systems for laboratory medicine

- ISO 17511:2003, Metrological traceability of values assigned to calibrators and controls
- ISO 18153:2003, Metrological traceability of catalytic concentration values assigned to calibrators and controls
- ISO 15193:2002, Reference measurement procedures*
- ISO 15194:2002, Reference materials*
- ISO 15195:2003, Reference measurement laboratories
- ISO TS 25680, Medical laboratories - Calculation and expression of measurement uncertainty**

* 2nd edition at DIS stage

** In development



TC 212



WG 3, *In vitro* diagnostic products

- ISO 15197:2003, Blood-glucose monitoring systems for self-testing in managing diabetes mellitus
- ISO 17593:2007, In vitro monitoring systems for self-testing of oral anticoagulant therapy
- ISO 15198:2004, Validation of user quality control procedures by IVD manufacturers
- ISO 14971:2007 (Annex H), Guidance on risk management for IVD medical devices *

* TC 210 collaboration



TC 212



WG 3, *In vitro* diagnostic products

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WG 4, Antimicrobial susceptibility testing

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