Traceability in Laboratory Medicine

The Role of International/Global Standards in Traceability

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The Role of Standards
(and Guidelines)

- describe
  - quality requirements of products and processes
  - best practices
- help industry, government and users
- facilitate world trade
- harmonize the level of service to the patients at a high level
- are the basis of conformity assessment of products

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Metrological Traceability

- is an "Essential Requirement" of the European Directive 98/79/EC
- will lead to better comparability of patient results over time and space
- sets out requirements on reference measurement procedures, reference materials and laboratories

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Forces Prompting International/Global Standardization and Harmonization

- Development of a global economy
- Mobility of individuals
- Development of the World Trade Organization
- Cooperation of Governments
- Technology transfer of professional methods
- Electronic Communication

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The Impact on Healthcare and Laboratory Medicine

- Technological and medical development advances on a global scale
- Patients (and samples) move across borders
- Requirement of similar (identical) levels of quality
- Harmonization of legal requirements (GHTF)
- Most manufacturers are global suppliers

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International Standardization

ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*

Scope: "Standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems, and quality assurance."

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ISO/TC 212 Management

Chairman: Dr. Klaus Stinshoff (Switzerland)

Secretariat: NCCLS, on behalf of ISO and ANSI

Conveners:

- **Working Group 1, Quality management in the clinical laboratory - Prof. N.K. Shinton (UK)**
- **Working Group 2, Reference systems - Dr. Rene Dybkaer (Denmark)**
- **Working Group 3, In vitro diagnostic products - Dr. Don Powers (USA)**

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ISO/TC 212 - Working Group 2 Reference Systems

- ISO 15193 - Measurement of quantities in samples of biological origin – Requirements of reference procedures
- ISO 15194 – Measurement of quantities in samples of biological origin – Description of reference materials
- ISO 15195 – Requirements for reference measurement laboratories
- ISO 17511 – Metrological traceability of values assigned to calibrators and control materials
- ISO 18153 – Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials

These standards are developed jointly with CEN/TC 140 under the Vienna Agreement

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ISO/TC 212 Membership

Participating members (31)

- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- Chile
- China
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Iran
- Ireland
- Israel
- Italy
- Japan
- Korea
- Mexico
- The Netherlands
- New Zealand
- Norway
- Portugal
- Singapore
- Spain
- Sweden
- Switzerland
- Turkey
- United Kingdom
- United States

Observer members (12)

- Bulgaria
- Cuba
- Egypt
- Estonia
- Hungary
- India
- Malaysia
- Malta
- Mongolia
- Saudi Arabia
- Thailand
- Zimbabwe

Committee Liaisons (16)

- EC4
- ECLM
- EDMA
- EUROM II
- IAMLT
- ICSH
- IEC/TC 66
- IFCC
- ISO/REMCO
- ISO/TC 48/SC 1.4
- ISO/TC 76
- ISO/TC 176
- ISO/TC 210
- IUPAC
- WASP
- WHO

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What Is NCCLS?

(In addition to ISO Secretariat)

NCCLS is an accredited developer of voluntary consensus standards and guidelines for global application.

Global is Not Synonymous with International

International = Each Country gets one vote (ISO process).

Global = Participation is open to all interested experts (NCCLS).

NCCLS Develops Complementary Documents

ISO

- -is recognized by WTO
- -the documents usually outline general requirements

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- -develops user friendly documents
- -easy to understand and interpret
- -with a strong educational component
- -used worldwide

NCCLS – Global and National (if needed)

- Global participation and cooperation make NCCLS a forum for addressing global needs
- NCCLS balances this global approach with the ability to develop documents that are national in scope and application whenever there is such a need

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NCCLS as a Global Organization

- NCCLS documents serve the worldwide needs of industry, government, and the professions in enhancing the value of medical testing and healthcare services
- 34% of active members,
  - 20% of corresponding members, and
  - 20% of NCCLS volunteers
  - are from outside the United States

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NCCLS Documents are Used Worldwide

- Referenced in government regulations and international standards
- Utilized in professional practice guidelines
- Translated into other languages
- Obtained in bulk to distribute to stakeholders

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NCCLS Principles

- Practical, in addressing healthcare issues
- Timely, to keep pace with technological change and effectively meet current needs
- Voluntary in development and implementation
- Seeks participation from around the globe
- Multi-constituency in addressing issues impacting on different groups
- Balanced by representatives from industry, government, and professionals
- Fairness to give consideration to all views and precludes conflicts of interest

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NCCLS Service

- **NCCLS offers neutral consensus process**
- **Member organizations provide technical expertise**

NCCLS Products

Documents which include:

- **Standards**
- **Guidelines**
- **Reports**
- **Reference method systems (NRSCL)**

ISO Participation

ISO/TC 212 will develop international reference traceability documents

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NCCLS' Support

- NCCLS will support the traceability concept and align its activities with JCTLM decisions
- NCCLS will develop compatible, global companion documents for the users
- NCCLS Board is willing to consider broader role in support of JCTLM

Gracias

Obrigado

Merci

Arigato

Danke

Thank you

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