Traceability in Laboratory Medicine

The Role of International/Global Standards in Traceability

Donna M. Meyer, Ph.D., NCCLS

June 10, 2002, Sevres
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
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
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
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
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."
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)
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
### ISO/TC 212 Membership

<table>
<thead>
<tr>
<th>Participating members (31)</th>
<th>Observer members (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argentina</td>
<td>Italy</td>
</tr>
<tr>
<td>Australia</td>
<td>Japan</td>
</tr>
<tr>
<td>Austria</td>
<td>Korea</td>
</tr>
<tr>
<td>Belgium</td>
<td>Mexico</td>
</tr>
<tr>
<td>Brazil</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>Canada</td>
<td>New Zealand</td>
</tr>
<tr>
<td>Chile</td>
<td>Norway</td>
</tr>
<tr>
<td>China</td>
<td>Portugal</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Singapore</td>
</tr>
<tr>
<td>Denmark</td>
<td>Spain</td>
</tr>
<tr>
<td>Finland</td>
<td>Sweden</td>
</tr>
<tr>
<td>France</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Germany</td>
<td>Turkey</td>
</tr>
<tr>
<td>Iran</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Ireland</td>
<td>United States</td>
</tr>
<tr>
<td>Israel</td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Malaysia</td>
</tr>
<tr>
<td>Cuba</td>
<td>Malta</td>
</tr>
<tr>
<td>Egypt</td>
<td>Mongolia</td>
</tr>
<tr>
<td>Estonia</td>
<td>Saudi Arabia</td>
</tr>
<tr>
<td>Hungary</td>
<td>Thailand</td>
</tr>
<tr>
<td>India</td>
<td>Zimbabwe</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Committee Liaisons (16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC4</td>
</tr>
<tr>
<td>ECLM</td>
</tr>
<tr>
<td>EDMA</td>
</tr>
<tr>
<td>EUROM II</td>
</tr>
<tr>
<td>IAMLT</td>
</tr>
<tr>
<td>ICSH</td>
</tr>
<tr>
<td>IEC/TC 66</td>
</tr>
<tr>
<td>IFCC</td>
</tr>
</tbody>
</table>
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).
ISO
- is recognized by WTO
- the documents usually outline general requirements

NCCLS
- 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
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.
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
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
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
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
Thank you