NCCLS… *global consensus standardization for health technology*

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What is NCCLS?

- An American National Standards Institute accredited consensus standards organization
- A not-for-profit corporation
- An educational organization
- An association of organizations
- A volunteer organization
- A global organization
NCCLS Principles

- Open to all organizations in health care;
- **Multi-constituency (Government, Industry, Professions)** addressing issues impacting many different groups;
- Structured to give consideration to all views and preclude conflicts of interest;
- Voluntary in development and implementation;
- Practical, in addressing healthcare issues;
- Timely, to keep pace with technological change and effectively meet current needs.

- Balanced by representatives from industry, government, and professions
NCCLS Responsibilities and Activities

- NCCLS Standards and Guidelines
- American National Standards
- ISO TC 212 Standards
- Consensus Development is the Core Competence of NCCLS
This document provides a model for providers of healthcare services that will assist with implementation and measurement of effective quality systems.

A guideline for global adoption developed through the NCCLS consensus process.
How does NCCLS work?

- Organization matrix
- Project Selection
- Volunteers
Process for Project Selection

- **Idea generation**
  - Volunteer & Member Questionnaires
  - Area Committee and Subcommittee Strategic Planning
  - Website input and project proposal invitation

- Comprehensive proposal required

- Internal idea assessment completed

- External (qualitative) interest assessment

- External (quantitative) market assessment

- Subcommittee membership

- Business plan

- Authorization
Process for Document Development

- Subcommittee Formation Complete by Project Authorization Time
- Subcommittee usually has nine months to draft Proposed-level Document
- Proposed-level Document circulated widely for review and comment
- Subcommittee revises document and submits to Area Committee for Consensus Vote
- Board of Directors votes to publish
- Total time target from proposal authorization to publication of approved-level document is twenty-two months
Process for Evaluation of the Utility and Use of a Standard, Guideline, or Report

- **Document Sales are monitored and analyzed by the Chairholders Council and Board of Directors**

- **Review of the Annual Questionnaires of Volunteers, Members, and Customers**

- **Comments received on each document are reviewed by subcommittee or workgroup at next document revision activity**

- **FDA List of Recognized Standards for use in device submissions**
NCCLS Documents are Used Worldwide

- Obtained in bulk to distribute to stakeholders
- Utilized in professional practice guidelines
- Translated into other languages
- Referenced in government regulations and international standards
NCCLS Documents are Used By Industry Scientists

- **Evaluation Protocol Documents**
  - No need to develop new material
  - Speeds up product development
  - Standardizes results across the field
  - Helps customers compare performance

- **FDA Recognizes Standards for use by Industry in Product submissions**
  - Currently 82 NCCLS Approved Standards are recognized by FDA
Recent NCCLS Publications

42 new documents scheduled for publication this year
- 26 already published
- All others on track

Examples:
- Free Thyroid Hormones; Bone Markers; Immunoassay Systems; Fluorescence Calibration; Maternal Serum Screening; Evaluation of Precision; Limits of Detection; Media Quality Control; and Point of Care Hemostasis and Coagulation Testing
What’s new?
Important Developments for NCCLS

Technical
- Point-of-care testing
- Electronic technologies and connectivity
- Molecular diagnostics
- Laboratory Automation and Informatics
- Equivalent quality control Workshop on March 18, 2005

Process
- Increased speed and responsiveness to need for documents
- A new name for NCCLS
In conjunction with the 2005 NCCLS Leadership Conference
Renaissance Harborplace Hotel
Baltimore, Maryland
16-19 March 2005

EQUIVALENT QUALITY CONTROL WORKSHOP
18 March 2005

🌟 Learn about the current and future technology of QC.
🌟 Experience contributing to the future of QC.
🌟 Network with colleagues
   (NCCLS President’s Reception, 17 March at 7:00 p.m.)
🌟 Participate in discussion and breakout groups.
🌟 Available following the meeting: a meeting report,
   NCCLS consensus guidelines with QC mechanisms
   and a plan for future QC.

Presented by recognized experts, this one-day workshop is intended for technical
and management laboratory personnel, IVD industry representatives and
government staff.

Organizers: AACC, ASCLS, AdvaMed, CDC, CMS, FDA, NCCLS

Come be a part of the Future!

For more information, visit http://www.nccls.org/
NCCLS

...Coming January 1, 2005...

CLSI

Providing NCCLS Standards and Guidelines, ISO/TC 212 Standards, and ISO/TC 76 Standards