



**NCCLS... *global consensus
standardization for health
technology***

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NCCLS

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**

HSI-A
Vol. 22 No. 13

Replaces GP26-A
Vol. 19 No. 20

A Quality System Model for Health Care: Approved Guideline

This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality systems.
A guideline for global application developed through the NCCLS consensus process.



INTERNATIONAL
STANDARD

ISO
15189

First edition
2003-02-15

Corrected version
2003-07-15

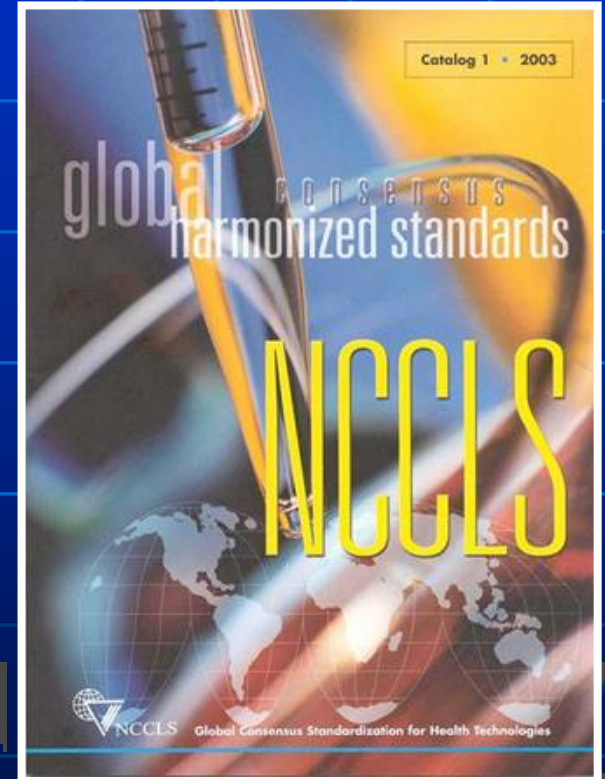
Medical laboratories — Particular
requirements for quality and competence

Laboratoires d'analyses de biologie médicale — Exigences particulières
concernant la qualité et la compétence



Reference number
ISO 15189:2003(E)

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How does NCCLS work?

- **Organization matrix**
- **Project Selection**
- **Volunteers**

NCCLS

Organizational Chart

Active and Corresponding Member Organizations

Board of Directors

Executive Committee

Chairholders Council

Area Committees

Subcommittees

Working Groups

NRSCL

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

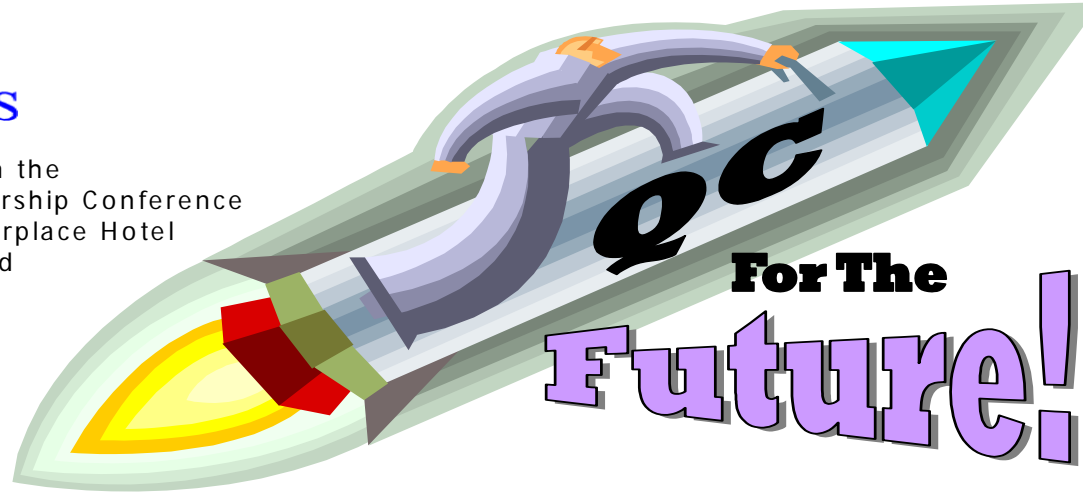
- Point-of-care testing
- Electronic technologies and connectivity
- Molecular diagnostics
- Laboratory Automation and Informatics
- Equivalent quality control Workshop on March 18, 2005

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

NCCLS/CLSI



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