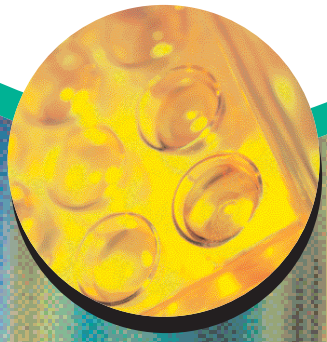
Global Consensus Standardization for Health Technologies

CATALOG 3 • 2004

NCCLS



It's Official!

NCCLS's new organizational name, effective January 2005, has been approved:

CLINICAL AND LABORATORY STANDARDS INSTITUTE

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

2004 CATALOG III

BECOME AN NCCLS MEMBER

NCCLS recognizes that member organizations provide significant support to the organization and the voluntary consensus process. NCCLS offers your organization a wide range of membership options. Membership categories have been redefined and streamlined to provide your organization with documents in electronic and printed formats.

In addition to Basic membership, there are six other membership categories. For instance, Associate Active membership is for an institution that wants a broader, more active role in the NCCLS consensus process; Healthcare Delivery Systems is designed to meet the needs of hospital/healthcare systems with networked laboratories; Corresponding Customized Membership is tailored for small institutions or departments performing specialized, discipline-specific, or a limited number or variety of medical tests.

For detailed information on all membership categories, see page 38; to join, see page 39. We encourage you to take full advantage of the reduced prices offered through NCCLS membership.

A = Approved standard or guideline

P = Proposed standard or guideline

T = Tentative standard or guideline

R = Report

TABLE OF CONTENTS

PLUS NEW DOCUMENTS

PLUS

Quality System Essentials Index

NCCLS's quality system model has characterized the necessary aspects of all organizations as "the quality system essentials" or "QSEs." The QSEs are the building blocks of any kind of organization and perhaps are best described as the "Administrator's or Manager's Handbook." Every organization, whatever its size, has established guidance for these QSEs. In small organizations, the QSEs are often unwritten. In larger organizations, functional efficiency depends on understood, written guidance and processes that address each QSE.

(continued on next page)

Quality System Essentials Index *(continued)*

NCCLS Specialty Collections

Save $ by purchasing documents in a convenient, bound collection.

The volumes of NCCLS Specialty Collections combine related standards and guidelines in key subject areas. The purchase price reflects a significant savings over the combined list price of the individual documents for both member and nonmember organizations.

Please refer to the collections below for a listing of the individual document titles, individual purchase prices, and the locations in the catalog for descriptions. We've made it easy for you to see the savings!

Evaluation Protocols (SC1-L)

This volume provides help in choosing the right instruments and analytical methods for desired procedures, which is critical to the efficient operation of clinical laboratories. Included are procedures for evaluating precision linearity, stated performance characteristics, and guidelines on clinical sensitivity and specificity. This collection contains:

EP5-A2 – Precision (page 11)
Members $85 Nonmembers $200
EP6-A – Linearity (page 11)
Members $60 Nonmembers $120
EP7-A – Interference (page 11)
Members $85 Nonmembers $200
EP9-A2 – Comparison of Methods (page 11)
Members $60 Nonmembers $120
EP10-A2 – Preliminary Evaluation (page 11)
Members $60 Nonmembers $120
EP14-A2 – Evaluation of Matrix Effects (page 11)
Members $60 Nonmembers $120
EP15-A – Demonstration of Performance (page 11)
Members $60 Nonmembers $120
GP10-A – Assessment of Tests (page 12)
Members $50 Nonmembers $100

Members $210 Nonmembers $525
SAVINGS: Mem. $310/Nonmem. $575

Specimen Collection (SC2-L)

SC2-L can be used to establish collection criteria for laboratory procedure manuals, patient care units, and phlebotomy team training manuals. This convenient reference includes standards with procedures for collection of venous, arterial, and capillary blood specimens, as well as single and timed urine specimens. The collection includes:

GP16-A2 – Routine Urinalysis (page 12)
Members $60 Nonmembers $120
H3-A5 – Venipuncture (page 12)
Members $85 Nonmembers $200
H4-A5 – Capillary (page 13)
Members $60 Nonmembers $120
H11-A4 – Arterial Collection (page 10)
Members $60 Nonmembers $120
H21-A4 – Coagulation Specimens (page 13)
Members $85 Nonmembers $200
M15-A – Parasitic Diseases (page 15)
Members $60 Nonmembers $120
M28-A – Fecal Parasitology (page 16)
Members $60 Nonmembers $120
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200

Members $280 Nonmembers $570
SAVINGS: Mem. $290/Nonmem. $630

General Hematology (SC7-L)

This collection provides guidance for the laboratorian performing routine hematology procedures. Manual methodologies for determining the erythrocyte sedimentation rate and packed cell volume are included. The collection also provides recommendations for specimen processing; immunophenotyping lymphocytes and counting reticulocytes by flow cytometry; and a reference method for automated differential counting. It contains:

H2-A4 – Erythrocyte Sedimentation Rate (ESR) (page 12)
Members $50 Nonmembers $100
H7-A3 – Microhematocrit (page 13)
Members $60 Nonmembers $120
H18-A3 – Handling and Processing (page 13)
Members $60 Nonmembers $120
H20-A – Differential Count (page 13)
Members $50 Nonmembers $100
H42-A – Flow Cytometry (page 13)
Members $50 Nonmembers $100
H44-A2 – Reticulocyte Counting (page 13)
Members $50 Nonmembers $100
H45-A – Bleeding Time Test (page 13)
Members $50 Nonmembers $100

Members $190 Nonmembers $400
SAVINGS: Mem. $180/Nonmem. $340

Laboratory Safety (SC10-L)

This is a must-have collection for all clinical laboratory settings. The guidelines included provide practical recommendations for establishing protocols to ensure a safe work environment for employees. Because of its wide application, NCCLS recommends that this specialty collection be purchased as a complement to any or all of the other collections. It includes:

GP5-A2 – Laboratory Waste (page 11)
Members $60 Nonmembers $120
GP17-A2 – Laboratory Safety (page 12)
Members $60 Nonmembers $120
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200
X3-R – Needlestick (page 28)
Members $65 Nonmembers $150
ISO 15190 – Medical laboratories – Requirements for safety (page 19)
Members $150 Nonmembers $200

Members $175 Nonmembers $400
SAVINGS: Mem. $260 Nonmem. $390

CLIA Collection (SC11-L)

The documents in this collection include a group of four NCCLS standards and guidelines selected because of their value in helping laboratorians adapt the CLIA '88 requirements to their settings. These documents include principles and definitions of internal quality control; preliminary evaluation of test methods; preparation of technical procedure manuals; and quality assurance procedures for culture media. The collection includes:

C24-A2 – Quality Control (page 9)
Members $60 Nonmembers $120
EP10-A2 – Preliminary Evaluation (page 11)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals (page 11)
Members $85 Nonmembers $200
M22-A3 – Media QC (page 15)
Members $60 Nonmembers $150

Members $150 Nonmembers $300
SAVINGS: Mem. $115/Nonmem. $290

Coagulation (SC12-L)

These documents highlight NCCLS coagulation standards. The collection features procedures for collecting, transporting, and storing blood samples for coagulation testing, and reporting of test results and precautions. The volume contains general guidelines for performing the one-stage PT, APTT, and fibrinogen assay in the clinical laboratory. Included in the collection are:

H21-A4 – Coagulation Specimens (page 13)
Members $85 Nonmembers $200
H30-A2 – Fibrinogen (page 13)
Members $60 Nonmembers $120
H47-A – One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test (page 13)
Members $50 Nonmembers $100

Members $85 Nonmembers $185
SAVINGS: Mem. $110 Nonmem. $235

Laboratory Information Systems (SC14-L)

This collection of former ASTM standards provides a wide variety of information relating to clinical laboratory computer systems. Some included documents are of general interest as reference sources; others represent specifications of primary importance to instrument manufacturers.

The collection includes:

LIS1-A – Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (page 9)
Members $65 Nonmembers $120
LIS2-A2 – Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems (page 9)
Members $65 Nonmembers $120

LIS3-A – Standard Guide for Selection of a Clinical Laboratory Information Management System (page 9)
Members $60 Nonmembers $120

LIS4-A – Standard Guide for Documentation of Clinical Laboratory Computer Systems (page 9)
Members $60 Nonmembers $120

LIS5-A – Standard Specification for Transferring Clinical Observations Between Independent Computer Systems (page 9)
Members $60 Nonmembers $120

LIS6-A – Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (page 9)
Members $60 Nonmembers $120

LIS7-A – Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory (page 9)
Members $60 Nonmembers $120

LIS8-A – Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems (page 9)
Members $60 Nonmembers $120

LIS9-A – Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures (page 9)
Members $60 Nonmembers $120

Members $250 Nonmembers $500
SAVINGS: Mem. $300/Nonmem. $580

Technical Laboratory Management (SC15-L)

This collection contains a series of NCCLS documents specifically designed to assist in technical laboratory management. These standards and guidelines include requirements for reagent grade water and methods to monitor water quality; principles and definitions of internal quality control; protocol for determining reference intervals; recommendations on writing procedure manuals; procedure for the handling and transport of specimens; and guidelines for handling and processing specimens. The collection includes:

C3-A3 – Reagent Water (page 9)
Members $60 Nonmembers $120
C24-A2 – Quality Control (page 9)
Members $60 Nonmembers $120
C28-A2 – Reference Intervals (page 9)
Members $60 Nonmembers $120
EP10-A2 – Preliminary Evaluation (page 11)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals (page 11)
Members $85 Nonmembers $200
H18-A3 – Handling and Processing (page 13)
Members $60 Nonmembers $120

Members $185 Nonmembers $410
SAVINGS: Mem. $200/Nonmem. $390

Administrative Laboratory Management (SC16-L)

This collection is designed specifically to assist laboratory managers in effective laboratory operations and training. These standards and guidelines include recommendations for inventory control systems; choosing a referral laboratory; establishing a workable cost accounting system; designing a laboratory; developing new data management systems; developing a training verification program; and implementing a quality system model. This collection includes:

GP9-A – Referral Laboratory (page 11)
Members $50 Nonmembers $100
GP11-A – Cost Accounting (page 12)
Members $60 Nonmembers $120
GP18-A – Laboratory Design (page 12)
Members $50 Nonmembers $100
GP19-A2 – Laboratory Instruments and Data Management Systems (page 9)
Members $60 Nonmembers $120
GP21-A2 – Training and Competence Assessment (page 12)
Members $50 Nonmembers $100
GP26-A3 – Laboratory Services (page 12)
Members $85 Nonmembers $200

Members $200 Nonmembers $460
SAVINGS: Mem. $155 Nonmem. $180

Point-of-Care Testing (SC17-L)

The Point-of-Care Testing collection provides guidance for laboratorians and other health professionals involved in point-of-care testing (POCT). The guidelines in this collection provide recommendations used in establishing a POCT program and procedures for point-of-care testing including quality control and calibration; skin puncture; ancillary glucose testing; and the design, preparation, and maintenance of technical procedure manuals. The collection contains:

AST2-A – *In Vitro* Diagnostic (page 17)
Members $60 Nonmembers $150
AST3-A – Wellness Testing (page 17)
Members $50 Nonmembers $100
C30-A2 – Blood Glucose Testing (page 10)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals (page 11)
Members $85 Nonmembers $200
GP16-A2 – Routine Urinalysis (page 12)
Members $60 Nonmembers $120
H4-A5 – Capillary (page 13)
Members $60 Nonmembers $120
POCT1-A – Connectivity (page 17)
Members $100 Nonmembers $150

Members $265 Nonmembers $545
SAVINGS: Mem. $210/Nonmem. $415

Body Fluid and Tissue Specimen Collection (SC18-L)

This collection provides guidelines for the collection of specimens for sweat testing, Papanicolaou smears, routine urinalysis, and fine needle aspiration biopsy (FNAB). Specimen transport requirements, container specifications, and safety are also included. The collection contains:

GP15-A2 – Papanicolaou Technique (page 12)
Members $60 Nonmembers $120
GP20-A2 – Fine-Needle Techniques (page 12)
Members $50 Nonmembers $100
GP23-A – Nongynecologic Specimens (page 12)
Members $60 Nonmembers $120
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200

Members $150 Nonmembers $280
SAVINGS: Mem. $120/Nonmem. $260

Blood Collection Centers (SC20-L)

This specialty collection brings together NCCLS documents that deal with the collection, processing, and handling of blood specimens for laboratory testing. This collection can be used to establish a blood collection and processing training manual. Specimen collection by venipuncture and skin puncture along with safety guidelines, and needlestick and sharps prevention are included. Documents included are:

H3-A5 – Venipuncture (page 12)
Members $85 Nonmembers $200
H4-A5 – Capillary (page 13)
Members $60 Nonmembers $120
H18-A3 – Handling and Processing (page 13)
Members $60 Nonmembers $120
H21-A4 – Coagulation Specimens (page 13)
Members $85 Nonmembers $200
LA4-A4 – Newborn Screening (page 15)
Members $60 Nonmembers $120
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200
X3-R – Needlestick (page 28)
Members $65 Nonmembers $150

Members $240 Nonmembers $480
SAVINGS: Mem. $275/Nonmem. $630

Susceptibility Testing (SC21-L)

This group of documents allows the microbiology laboratory to access in one volume all NCCLS consensus documents relating to susceptibility testing. The collection addresses disk, dilution, and bactericidal testing procedures, including interpretive tables for antimicrobial, antifungal, and veterinary susceptibility tests. The collection includes:

M2-A8 – Disk Susceptibility Tests (page 15)
Members $150 Nonmembers $275
M7-A6 – Aerobic Susceptibility Testing (page 15)
Members $150 Nonmembers $275
M11-A6 – Anaerobic Susceptibility Testing (page 15)
Members $85 Nonmembers $200
M21-A – Serum Bactericidal (page 15)
Members $60 Nonmembers $120
M23-A2 – Test Development (page 15)
Members $150 Nonmembers $250
M26-A – Bactericidal Activity (page 15)
Members $60 Nonmembers $120
M27-A2 – Antifungal Reference Method (page 15)
Members $60 Nonmembers $120
M31-A2 – Veterinary Antimicrobial (page 16)
Members $60 Nonmembers $120
M38-A – Filamentous Fungi (page 16)
Members $60 Nonmembers $120
M39-A – Analysis and Presentation (page 16)
Members $60 Nonmembers $120
M100-S15 – Susceptibility Testing Supplement (page 16)
Members $85 Nonmembers $200

Members $465 Nonmembers $880
SAVINGS: Mem. $515/Nonmem. $1040

General Microbiology (SC22-L)

This new collection provides guidance for the microbiologist performing aerobic or anaerobic antimicrobial susceptibility testing and routine quality assurance of commercially prepared culture media. Guidance is included for protection from infectious diseases transmitted by blood, body fluids, and tissue and instrument biohazards. The collection includes:

M2-A8 – Disk Susceptibility Tests (page 15)
Members $150 Nonmembers $275
M7-A6 – Aerobic Susceptibility Testing (page 15)
Members $150 Nonmembers $275
M11-A6 – Anaerobic Susceptibility Testing (page 15)
Members $85 Nonmembers $200
M15-A – Parasitic Diseases (page 15)
Members $60 Nonmembers $120
M22-A3 – Media QC (page 15)
Members $60 Nonmembers $150
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200
M35-A – Rapid Identification (page 16)
Members $60 Nonmembers $120
M100-S15 – Susceptibility Testing Supplement (page 16)
Members $85 Nonmembers $200

Members $375 Nonmembers $725
SAVINGS: Mem. $375/Nonmem. $815

Flow Cytometry (SC23-L)
This collection contains a series of NCCLS documents specifically designed to guide laboratorians in flow cytometric analyses. These documents include recommendations for the performance of immunophenotyping leukemias and lymphomas and performance of reticulocyte counting by flow cytometry. Guidelines for establishing quality assurance procedures for immunophenotyping lymphocytes by flow cytometry are also included in this collection. The collection includes:
H42-A – Flow Cytometry (page 13)
Members $50 Nonmembers $100
H43-A – Leukemia Immunophenotyping (page 13)
Members $50 Nonmembers $100
H44-A2 – Reticulocyte Counting (page 13)
Members $50 Nonmembers $100
H52-A – Fetal Red Cell Detection (page 14)
Members $60 Nonmembers $120
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200

Members $160 Nonmembers $330
SAVINGS: Mem. $150/Nonmem. $290

Quality Series (SC24-L)
This collection contains a series of documents intended for healthcare managers who wish to improve their programs through quality management activities. Guidelines are for statistical quality control, training verification, continuous quality improvement, a quality system model, and using proficiency testing. The collection includes:
ISO 15189 – Medical laboratories – Particular requirements for quality and competence (page 19)
Members $150 Nonmembers $200
GP2-A4 – Procedure Manuals (page 11)
Members $85 Nonmembers $200
GP21-A2 – Training and Competence Assessment (page 12)
Members $50 Nonmembers $100
GP22-A2 – Continuous Quality Improvement (page 12)
Members $85 Nonmembers $200
GP26-A3 – Laboratory Services (page 12)
Members $85 Nonmembers $200
HS1-A2 – A Quality Management System Model for Health Care (page 8)
Members $85 Nonmembers $200
HS4-A – Respiratory Services (page 8)
Members $50 Nonmembers $100
HS5-A – Medical Imaging Services (page 8)
Members $50 Nonmembers $100

Members $320 Nonmembers $630
SAVINGS: Mem. $320/Nonmem. $670

Molecular Methods (SC25-L)
The documents in this collection provide guidance on the detection of genetic diseases, the conducting of tests for immunoglobulin and T-cell receptor gene rearrangement, the review of methods for infectious diseases, and recommendations for the performance of immunocytochemistry (immunohistochemistry) assays. The collection includes:
MM1-A – Molecular Genetics (page 17)
Members $60 Nonmembers $120
MM2-A2 – Molecular Hematology (page 17)
Members $60 Nonmembers $120
MM3-A – Molecular Microbiology (page 17)
Members $60 Nonmembers $120
MM4-A – Immunocytochemistry (page 15)
Members $60 Nonmembers $120
MM5-A – PCR-Based Assays (page 17)
Members $60 Nonmembers $120
MM6-A – Infectious Diseases (page 17)
Members $60 Nonmembers $120
MM7-A – FISH Methods for Medical Genetics (page 17)
Members $60 Nonmembers $120

Members $210 Nonmembers $445
SAVINGS: Mem. $210/Nonmem. $445

Veterinary Microbiology (SC26-L)
This collection provides guidance for the veterinary professional on quality assurance procedures for culture media; protection from infectious diseases transmitted by blood, body fluids, and tissue; veterinary susceptibility tests; and detection of antibodies that cause Lyme disease. The collection includes:
M22-A3 – Media QC (page 15)
Members $60 Nonmembers $150
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200
M31-A2 – Veterinary Antimicrobial Susceptibility Tests (page 16)
Members $60 Nonmembers $120
M34-A – Lyme Disease (page 16)
Members $60 Nonmembers $120
M37-A2 – Veterinary Test Development (page 16)
Members $60 Nonmembers $120
M42-R – Fish AST (page 16)
Members $60 Nonmembers $120

Members $230 Nonmembers $450
SAVINGS: Mem. $170/Nonmem. $380

Includes CD ROM

Laboratory Automation (SC27-L)
This collection of interrelated automation standards is developed to allow customers (laboratories) and vendors to enjoy products that function together (with Plug-N-Play capabilities), and buyers and suppliers to agree on a format for laboratory automation systems. This collection contains:
AUTO1-A – Specimen Container/Specimen Carrier (page 8)
Members $50 Nonmembers $100
AUTO2-A – Specimen Identification (page 8)
Members $50 Nonmembers $100
AUTO3-A – Systems Communications (page 8)
Members $50 Nonmembers $100
AUTO4-A – Systems Status (page 8)
Members $50 Nonmembers $100
AUTO5-A – Electromechanical Interfaces (page 8)
Members $50 Nonmembers $100
GP18-A – Laboratory Design (page 12)
Members $50 Nonmembers $100
GP19-A2 – Laboratory Instruments and Data Management Systems (page 9)
Members $60 Nonmembers $120
POCT1-A – Connectivity (page 17)
Members $100 Nonmembers $150

Members $350 Nonmembers $650
SAVINGS: Mem. $110/Nonmem. $220

Patient Assessment and Requisition (SC28-L)
This specialty collection is designed to provide information for respiratory service professionals and other healthcare practitioners responsible for the collection of samples for arterial blood gas and pH determination and related measurements. The documents in this collection focus on preanalyzed variables related to these measurements.
C31-A2 – Ionized Calcium (page 10)
Members $60 Nonmembers $120
C46-A – Blood Gas and pH Analysis (page 10)
Members $60 Nonmembers $120
GP15-A2 – Papanicolaou Technique (page 12)
Members $60 Nonmembers $120
H11-A4 – Arterial Collection (page 10)
Members $60 Nonmembers $120
LA4-A4 – Newborn Screening (page 15)
Members $60 Nonmembers $120

Member $150 Nonmember $320
SAVINGS: Mem. $150/Nonmem. $280

Quality Basics (SC30-L)
This collection provides medical laboratories with specific tactics for implementing quality guidelines.
ISO 15189 – Medical laboratories – Particular requirements for quality and competence (page 19)
Members $150 Nonmembers $200
GP26-A3 – Laboratory Services (page 12)
Members $85 Nonmembers $200
HS1-A2 – A Quality Management System Model for Health Care (page 8)
Members $85 Nonmembers $200
GP22-A2 – Continuous Quality Improvement (page 12)
Members $85 Nonmembers $200

Members $190 Nonmembers $350
SAVINGS: Mem. $215/Nonmem. $450

Regulatory Compliance (SC31-L)
This collection contains a series of documents that will help laboratories comply with regulatory requirements.
C24-A2 – Quality Control (page 9)
Members $60 Nonmembers $120
C28-A2 – Reference Intervals (page 9)
Members $60 Nonmembers $120
GP2-A4 – Procedure Manuals (page 11)
Members $85 Nonmembers $200
GP26-A3 – Laboratory Services (page 12)
Members $85 Nonmembers $200
GP22-A2 – Continuous Quality Improvement (page 12)
Members $85 Nonmembers $200
GP27-A – Proficiency Testing (page 12)
Members $50 Nonmembers $100
H3-A5 – Venipuncture (page 12)
Members $85 Nonmembers $200
H21-A4 – Specimens Coagulation (page 13)
Members $85 Nonmembers $200
H47-A – One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test (page 13)
Members $50 Nonmembers $100
M22-A3 – Media QC (page 15)
Members $60 Nonmembers $150
M29-A2 – Protection of Laboratory Workers (page 16)
Members $100 Nonmembers $200

Members $375 Nonmembers $850
SAVINGS: Mem. $430/Nonmem. $940

Standards and Guidelines

A = Approved standard or guideline

P = Proposed standard or guideline

T = Tentative standard or guideline

R = Report

FDA = The U.S. Food and Drug Administration (FDA) has evaluated and recognized these approved-level NCCLS consensus standards for use in satisfying a regulatory requirement.

= A document for national application.

** American National Standards have been approved by the American National Standards Institute (ANSI). NCCLS submits selected standards as candidate American National Standards when such status will enhance their national or international usefulness.*

HEALTHCARE SERVICES

A A Quality Management System Model for Health Care; Approved Guideline – Second Edition (2004)

NEW

This document provides a model for healthcare service providers that will assist with implementation and maintenance of effective quality systems. (See related publications HS4-A, HS5-A, HS10-A, and GP26-A2.) **(HS1-A2)**

Members $85 Nonmembers $200

Chairholder: Lucia M. Berte, M.A., M.T. (ASCP), SBB, DLM; CQA (ASQ)
Quality System Consultant

A Provider-Performed Microscopy Testing; Approved Guideline (2003)

This guideline provides recommendations for provider-performed microscopy (PPM) procedures in settings outside the traditional clinical laboratory, such as physicians' offices, outpatient clinics, public health clinics, health maintenance organizations, and medical training programs. These consensus recommendations focus on producing accurate diagnostic information from microscopy procedures as an adjunct to clinical laboratory testing. **(HS2-A)**

Members $50 Nonmembers $100

Chairholder: Mina L. Harkins, M.T.(ASCP)
Columbia Medical Plan, Inc.

A Pulse Oximetry; Approved Guideline (2005)

AVAILABLE 2005

Pulse oximetry is a widely used clinical technique for assessment of arterial oxygenation and pulse rate. The clinical applications, quality assessment, and limitations are discussed in this guideline. **(HS3-A)**

Members $50 Nonmembers $100

Chairholder: Judy Dye, M.A.
University of Arizona Medical Center

A Application of a Quality System Model for Respiratory Services; Approved Guideline (2002)

This document provides a model for providers of respiratory services that will assist with implementation and maintenance of an effective quality system. **(HS4-A)**

Members $50 Nonmembers $100

Chairholder: Susan Blonshine, RRT, RPFT, FAARC
Tech Ed
This document is intended for use with HS1 when developing a quality system for the clinical laboratory.

A Application of a Quality System Model for Medical Imaging Services; Approved Guideline (2002)

This guideline provides the necessary background information and infrastructure to develop a quality system that defines a structure for a comprehensive, systematic approach to build quality into the imaging services processes, assess its performance, and implement quality improvements. Individual service areas, such as diagnostic radiology, CT, ultrasound, interventional radiology, magnetic resonance imaging (MRI), mammography, and nuclear medicine, will benefit from applying this model to their respective operations. To provide a practical example of how a quality system is developed and implemented, suggestions for diagnostic radiology are included. **(HS5-A)**

Members $50 Nonmembers $100

Chairholder: Judy Dye, M.A.
University of Arizona Medical Center
This document is intended for use with HS1when developing a quality system for the clinical laboratory.

A Studies to Evaluate Patient Outcomes; Approved Guideline (2004)

NEW

This guideline describes the essential issues in planning outcomes research including resources needed, formulating a research question, validity and sources of error, feasibility, and ethical issues; addresses the design and implementation of a patient outcomes research plan including study design, study subjects, measurements, interventions, and analysis; summarizes recommendations for reporting patient outcomes research; and includes definitions, references, and resources for those interested in planning, conducting, and using patient outcomes research. **(HS6-A)**

Members $50 Nonmembers $100

Chairholder: D. Joe Boone, Ph.D.
Centers for Disease Control and Prevention

A Application of a Quality System Model for Inpatient Medication Use; Approved Guideline (2004)

NEW

This document describes the path of workflow for inpatient medication use, which is defined as the sequential processes in preservice, service, and postservice activities that transform a physician's medication order into an administered medication. Pharmacy-specific information and examples for the path of workflow and quality system essentials are provided. **(HS10-A)**

Members $50 Nonmembers $100

Chairholder: Steven P. Gray, M.S., DAHCE, FAAHC
Superior Consultant Company

This document is intended for use with HS1 when developing a quality system for the clinical laboratory.

AUTOMATION AND INFORMATICS

A Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard (2000)

This document provides standards for the design and manufacture of specimen containers and carriers used for collecting and processing liquid samples, such as blood and urine, for clinical testing in laboratory automation systems. **(AUTO1-A)**

Members $50 Nonmembers $100

FDA

Chairholder: Paul J. Orsulak, Ph.D.
North Texas Health Care System

A Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard (2000)

This document provides specifications for use of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems. **(AUTO2-A)**

Members $50 Nonmembers $100

FDA

Chairholder: David Chou, M.D.
University of Washington Medical Center

A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard (2000)

This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements. *AUTO3 has adapted and incorporated HL7 triggers, messages, and segments, with permission from Health Level Seven (HL7).* **(AUTO3-A)**

Members $50 Nonmembers $100

FDA

Chairholder: Charles D. Hawker, Ph.D.
ARUP Laboratories

A Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard (2001)

This document describes operational requirements, characteristics, and required information elements of clinical laboratory automation systems. This information is used to determine the status of a clinical specimen within the clinical laboratory automation system, as well as the status of the actual components of the clinical laboratory automation system. **(AUTO4-A)**

Members $50 Nonmembers $100

FDA

Chairholder: Russell H. Tomar, M.D.
University of Wisconsin

A Laboratory Automation: Electromechanical Interfaces; Approved Standard (2001)

This document provides standards for the development of an electromechanical interface between instruments and specimen processing and handling devices used in automated laboratory testing procedures. **(AUTO5-A)**

Members $50 Nonmembers $100

FDA

Chairholder: Richard A. McPherson, M.D.
Medical College of Virginia Hospital

A Laboratory Automation: Data Content for Specimen Identification; Approved Standard (2004)

This document provides specifications for the content of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems. **(AUTO7-A)**

Members $150 Nonmembers $250

Chairholder: Randy R. Davis
Dade Behring Inc.

A Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline – Second Edition (2003)

This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software. **(GP19-A2)**

Members: $60 Nonmembers: $120

Chairholder: Andrzej J. Knafel, Ph.D.
Roche Instrument Center AG

A Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems (2003)

This specification describes the electronic transmission of digital information between the clinical laboratory instruments (those that measure one or more parameters from one or multiple samples) and computer systems (those that are configured to accept instrument results for further processing, storage, reporting, or manipulation). **(LIS1-A)**

Members: $65 Nonmembers: $120

A Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard – Second Edition (2004)

This specification covers the two-way digital transmission of remote requests and results between clinical instruments and computer systems. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standard and interpretable form. **(LIS2-A2)**

Members $65 Nonmembers $120

Chairholders: Rodney S. Markin, M.D., Ph.D.
University of Nebraska Medical Center, and
Andrzej J. Knafel, Ph.D.
Roche Instrument Center AG

A Standard Guide for Selection of a Clinical Laboratory Information Management System (2003)

This guide covers the selection, purchase, use, enhancement, and updating of computer technology supplied by a vendor as a complete system in the clinical laboratory. The purpose of the guide is to assist hospitals, clinics, and independent laboratories through the entire automation project in order to minimize the risks and maximize the benefits. It also includes checklists of items and design aids to be considered at each stage of planning to assist in carrying out the project. **(LIS3-A)**

Members: $60 Nonmembers: $120

A Standard Guide for Documentation of Clinical Laboratory Computer Systems (2003)

This guide covers documentation (defined as the information needed to install, use, maintain, or modify the system) for a computer system operating in a clinical laboratory. **(LIS4-A)**

Members: $60 Nonmembers: $120

A Standard Specification for Transferring Clinical Observations Between Independent Computer Systems (2003)

This specification details how clinical observations can be transferred between independent computer systems. **(LIS5-A)**

Members: $60 Nonmembers: $120

A Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems (2003)

This practice describes a system for collecting data, maintaining records, and reporting on the reliability of operating clinical laboratory computer systems. The reliability measure will be achieved by documenting the number, severity, cause, impact, and duration of the failures that a system experiences. This practice can be implemented with paper forms or computer records. **(LIS6-A)**

Members: $60 Nonmembers: $120

A Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory (2003)

This specification identifies the way bar-coded sample identification labels are applied to clinical specimen containers. It documents the form, placement, and content of bar-code labels on specimen tubes that are used on clinical laboratory analyzers. It enables Laboratory Information System vendors to produce reliable bar-coded symbols that are readable by any complying clinical laboratory analyzer vendor. **(LIS7-A)**

Members: $60 Nonmembers: $120

A Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems (2003)

This guide covers the capabilities needed for a Clinical Laboratory Information Management System (CLIMS). It was written so that both vendors/developers of CLIMS and laboratory managers would have a common understanding of the requirements and logical structure of a laboratory data system. This guide will also provide more uniformity in the way that requirements are expressed from one laboratory to another. **(LIS8-A)**

Members: $60 Nonmembers: $120

A Standard Guide for Coordination of Clinical Laboratory Services Within the Electronic Health Record Environment and Networked Architectures (2003)

This guide covers the process of defining and documenting the capabilities, sources, and pathways of data exchange within a given network architecture of a Health Information Network (HIN) serving a set of constituents. **(LIS9-A)**

Members: $60 Nonmembers: $120

Currently, the newly adopted LIS documents are not part of the member benefit package. As documents are revised through the NCCLS consensus process, they will be distributed to members according to membership category.

CLINICAL CHEMISTRY AND TOXICOLOGY

A Blood Glucose Testing in Settings Without Laboratory Support; Approved Guideline (1999)

This document provides recommendations for personnel performing blood glucose testing at sites outside the traditional clinical laboratory. The guideline addresses test performance, quality control, personnel training, and administrative responsibility. **(AST4-A)**

Members: $60 Nonmembers: $120

Chairholder: Judith T. Barr, Sc.D.
Northeastern University, Boston, MA

A Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline – Third Edition (1997)

This document provides guidance on water purified for clinical laboratory use; methods for monitoring water quality and testing for specific contaminants; and water system design considerations. **(C3-A3)**

Members: $60 Nonmembers: $120

Chairholder: Daniel A. Nealon, Ph.D.
Ortho-Clinical Diagnostics

A Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline – Second Edition (1999)

This guideline provides definitions of analytical intervals; plans for quality control procedures; and guidance for quality control applications. **(C24-A2)**

Members: $60 Nonmembers: $120

Chairholder: James O. Westgard, Ph.D.
University of Wisconsin

A How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition (2000)

This document provides guidance for determining reference values and reference intervals for quantitative clinical laboratory tests. **(C28-A2)**

Members: $60 Nonmembers: $120

Chairholder: Edward A. Sasse, Ph.D.
Medical College of Wisconsin

A Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard – Second Edition (2000)

This standard contains recommendations for the expression of results of ion-selective electrode measurement of sodium and potassium ion activities in undiluted serum, plasma, or whole blood in clinical practice. **(C29-A2)**

Members: $60 Nonmembers: $120

Chairholder: Paul D'Orazio, Ph.D.
Instrumentation Laboratory

A Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Second Edition (2002)

This document provides guidance for performing point-of-care blood glucose tests, with an emphasis on quality control, training, and administrative responsibility. **(C30-A2)**

Members: $60 Nonmembers: $120

Chairholder: David B. Sacks, M.D.
Brigham and Women's Hospital and Harvard Medical School

A Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline – Second Edition (2001)

This document addresses preanalytical considerations – such as patient condition, specimen choice, collection, and handling – that can influence accuracy and clinical utility of ionized calcium measurements. **(C31-A2)**

Members: $60 Nonmembers: $120

Chairholder: Paul D'Orazio, Ph.D.
Instrumentation Laboratory

A Sweat Testing: Sample Collection and Quantitative Analysis; Approved Guideline – Second Edition (2000)

This guideline describes sweat stimulation, collection, and the quantitative analysis of sweat chloride and sodium with an emphasis on avoiding evaporation and contamination. Quality control issues and possible sources of error associated with sweat testing are discussed. **(C34-A2)**

Members: $60 Nonmembers: $120

Chairholder: Vicky LeGrys, Dr.A., M.T.(ASCP)
University of North Carolina School of Medicine

A Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline (1999)

This guideline details procedures for the manufacture and evaluation of human serum pools for cholesterol measurement. **(C37-A)**

Members: $60 Nonmembers: $120

Chairholder: Gary L. Myers, Ph.D.
Centers for Disease Control and Prevention

A Control of Preanalytical Variation in Trace Element Determinations; Approved Guideline (1997)

This document contains guidelines for patient preparation, specimen collection, transport, and processing for the measurement of trace elements in a variety of biological matrices. **(C38-A)**

Members: $60 Nonmembers: $120

Chairholder: Gillian Lockitch, M.B.Ch.B., M.D., FRCPC
British Columbia's Children's Hospital

A A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard (2000)

This document describes a designated comparison method to standardize the ionized calcium measurements made by ion-selective electrode (ISE) potentiometry. This system can be used to assign ionized calcium concentrations to a commercially available, serum-based material to improve the traceability and transferability of results for ionized calcium measurements in the clinical laboratory. **(C39-A)**

Members: $60 Nonmembers: $120

Co-Chairholders: Paul D'Orazio, Ph.D., Instrumentation Laboratory, and Gary A. Graham, Ph.D., Ortho-Clinical Diagnostics

A Analytical Procedures for the Determination of Lead in Blood and Urine; Approved Guideline (2001)

This document offers guidance for the measurement of lead in blood and urine, including specimen collection, measurement by GFAAS and ASV, quality assurance, and quality control. **(C40-A)**

Members: $60 Nonmembers: $120

Chairholder: Patrick J. Parsons, Ph.D., C.Chem., FRSC
Wadsworth Center New York State Department of Health/State University of New York at Albany

A Erythrocyte Protoporphyrin Testing; Approved Guideline (1996)

This document contains recommended guidelines for the measurement, reporting, and interpretation of erythrocyte protoporphyrin using hematofluorometric and extraction measurement methods. **(C42-A)**

Members $50 Nonmembers $100

Chairholder: Noel V. Stanton, M.S.
Wisconsin State Laboratory of Hygiene

A Gas Chromatography/Mass Spectrometry (GC/MS) Confirmation of Drugs; Approved Guideline (2002)

This document provides guidance for establishing uniform practices necessary for producing quality data for quantitation and identification of a drug or drug metabolite using the GC/MS method; specific quality assurance criteria for maintaining and documenting optimal instrument performance are also presented. **(C43-A)**

Members: $60 Nonmembers: $120

Chairholder: Larry D. Bowers, Ph.D.
Indiana University of Medicine Center

A Harmonization of Glycohemoglobin Measurements; Approved Guideline (2002)

This document describes an established program to harmonize glycohemoglobin (GHB) testing results among laboratories to a common, outcomes-based reference system and includes recommendations for the clinical application of harmonized GHB testing results. **(C44-A)**

Members: $60 Nonmembers: $120

Chairholder: David E. Goldstein, M.D.
University of Missouri School of Medicine

A Measurement of Free Thyroid Hormones; Approved Guideline (2004)

This document addresses analytical and clinical validation of free (nonprotein-bound) thyroid hormone (FTH) measurement procedures. An NCCLS-IFCC joint project. **(C45-A)**

Members $60 Nonmembers $120

Chairholder: Linda Thienpont, Ph.D.
University of Ghent

A Blood Gas and pH Analysis and Related Measurements; Approved Guideline (2001)

*American National Standard.** This document provides clear definitions of the several quantities in current use, and provides a single source of information on appropriate specimen collection, preanalytical variables, calibration, and quality control for blood pH and gas analysis and related measurements. **(C46-A)**

Members: $60 Nonmembers: $120

Chairholder: W. Gregory Miller, Ph.D.
Virginia Commonwealth University

A Application of Biochemical Markers of Bone Turnover in the Assessment and Monitoring of Bone Diseases; Approved Guideline (2004)

Biochemical markers of bone turnover are increasingly used in clinical chemistry. This guideline provides information on how bone markers can be applied to facilitate and harmonize data interpretation and to help answer clinical questions in the area of bone diseases. An NCCLS-IFCC joint project. **(C48-A)**

Members $60 Nonmembers $120

Chairholder: Hubert Vesper, Ph.D.
Centers for Disease Control and Prevention

A Procedures for the Collection of Arterial Blood Specimens; Approved Standard – Fourth Edition (2004)

*American National Standard.** This standard describes principles for collecting, handling, and transporting arterial blood specimens. The document is aimed at reducing collection hazards and ensuring integrity of the arterial specimen. **(H11-A4)**

Members $60 Nonmembers $120

Chairholder: Susan Blonshine, BS, RRT, RPFT
Tech Ed/AARC

A Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation; Approved Standard (1998)

This document provides methods for determining serum iron and total iron-binding capacity; and describes the measurement of serum iron concentration as well as the determination of the percent saturation of transferrin with iron. **(H17-A)**

Members: $60 Nonmembers: $120

Chairholder: Onno W. van Assendelft, M.D., Ph.D.
Centers for Disease Control and Prevention

A Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997)

This document provides technical and administrative guidance on laboratory procedures related to blood alcohol testing, including specimen collection, methods of analysis, quality assurance, and reporting of results. **(T/DM6-A)**

Members $50 Nonmembers $100

Chairholder: Kurt M. Dubowski, Ph.D.
University of Oklahoma

A Urine Drug Testing in the Clinical Laboratory; Approved Guideline (1999)

This guideline addresses the development of procedures for urine analysis to determine the presence of certain controlled substances. Specimen collection and processing, methods of analysis, quality assurance, and reporting of results are also described. **(T/DM8-A)**

Members $50 Nonmembers $100

Chairholder: M. Jeffery Shoemaker, Ph.D.
Pennsylvania Department of Health

EVALUATION PROTOCOLS

A Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline – Second Edition (2004)

This document provides guidance for designing an experiment to evaluate the precision performance of clinical chemistry devices; recommendations for comparing the resulting precision estimates with manufacturer's precision performance claims and determining when such comparisons are valid; as well as manufacturer's guidelines for establishing claims. **(EP5-A2)**

Members $85 Nonmembers $200

Chairholder: John W. Kennedy
Medstat Consultants

A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003)

This document provides guidance for characterizing the linearity of a method during a method evaluation; for checking linearity as part of routine quality assurance; and for determining and stating a manufacturer's claim for linear range. **(EP6-A)**

Members: $60 Nonmembers: $120

Chairholder: Dan Tholen, M.S.
Dan Tholen Statistical Services

A Interference Testing in Clinical Chemistry; Approved Guideline (2002)

This guideline provides background information, guidance, and experimental procedures for investigating, identifying, and characterizing the effects of interfering substances on clinical chemistry test results. **(EP7-A)**

Members $85 Nonmembers $200

Chairholder: Donald M. Powers, Ph.D.
Powers Consulting Services

A Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition (2002)

This document addresses procedures for determining the bias between two clinical methods or devices, and for the design of a method comparison experiment using split patient samples and data analysis. **(EP9-A2)**

Members: $60 Nonmembers: $120

Chairholder: John W. Kennedy
Medstat Consultants

A Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline – Second Edition (2002)

This guideline addresses experimental design and data analysis for preliminary evaluation of the performance of an analytical method or device. (See related publication GP10-A in General Laboratory Practices section.) **(EP10-A2)**

Members: $60 Nonmembers: $120

Chairholder: Jan S. Krouwer, Ph.D.
Krouwer Consulting

A User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline (2002)

This document contains a protocol that optimizes the experimental design for the evaluation of qualitative tests, to better measure performance and provide a structured data analysis. **(EP12-A)**

Members: $60 Nonmembers: $120

Chairholder: Larry W. Clark, M.S.
Bayer Corp.

R Laboratory Statistics – Standard Deviation; A Report (1995)

This report provides correct methods for calculating standard deviation and the means to test related software. **(EP13-R)**

Members $60 Nonmembers $120

Chairholder: Allan Louderback, Ph.D.
Clinical Chemistry Consultants

A Evaluation of Matrix Effects; Approved Guideline – Second Edition (2004)

This document provides guidance for evaluating the error or bias in analyte measurements that is due to the sample matrix (physiological or artificial) when two analytical methods are compared. **(EP14-A2)**

Members: $60 Nonmembers: $120

Chairholder: Fred D. Lasky, Ph.D.
Ortho-Clinical Diagnostics

A User Demonstration of Performance for Precision and Accuracy; Approved Guideline (2001)

This guideline demonstrates method precision and accuracy for laboratory analyte determinations, utilizing a protocol designed to be completed within five or fewer working days. **(EP15-A)**

Members: $60 Nonmembers: $120

Chairholder: R. Neill Carey, Ph.D.
Peninsula Regional Medical Center

A Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline (2004)

This guideline provides protocols for determining the lower limit of detection of clinical laboratory methods, for verifying claimed limits, and for the proper use and interpretation of these limits. This document also provides guidance for determining lower limits of quantitation based on a laboratory's goals for performance at low levels. This applies to all quantitative procedures, even if the reported result is qualitative. An NCCLS-IFCC joint project. **(EP17-A)**

Members $60 Nonmembers $120

Chairholder: Dan Tholen, M.S.
Dan Tholen Statistical Services

A Quality Management for Unit-Use Testing; Approved Guideline (2002)

This guideline recommends a quality management system for unit-use devices that will aid in the identification, understanding, and management of sources of error and help to ensure correct results. It is targeted for those involved in the supervision of laboratory-testing quality management, and it addresses issues related to specimen collection through reporting of test results. **(EP18-A)**

Members: $60 Nonmembers: $120

Chairholder: David L. Phillips
Roche Diagnostics

R A Framework for NCCLS Evaluation Protocols; A Report (2002)

This document describes the different types of performance studies that are conducted to evaluate clinical assays. **(EP19-R)**

Members: $60 Nonmembers: $120

Chairholder: Jan S. Krouwer, Ph.D.
Krouwer Consulting

A Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline (2003)

This document provides manufacturers and end users with a means to estimate total analytical error for an assay. A data collection protocol and an analysis method which can be used to judge the clinical acceptability of new methods using patient specimens are included. These tools can also monitor an assay's total analytical error by using quality control samples. **(EP21-A)**

Members: $60 Nonmembers: $120

Chairholder: Jan S. Krouwer, Ph.D.
Krouwer Consulting

GENERAL LABORATORY PRACTICES

A Clinical Laboratory Technical Procedure Manuals; Approved Guideline – Fourth Edition (2002)

This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community. (See related publication GP21-A2.) **(GP2-A4)**

Members $85 Nonmembers $200

Chairholder: Lucia M. Berte, MA, MT(ASCP) SBB, DLM; CQA (ASQ) CQMgr.
Quality Systems Consultant, Denver, Colorado

A Clinical Laboratory Waste Management; Approved Guideline – Second Edition (2002)

Based on U.S. regulations, this document provides guidance on safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory. **(GP5-A2)**

Members $60 Nonmembers $120

Chairholder: Peter A. Reinhardt, M.A.
University of North Carolina

A Selecting and Evaluating a Referral Laboratory; Approved Guideline (1998)

This guideline provides an outline of reasons and criteria for choosing a referral laboratory. A checklist for evaluating potential referral laboratories is included to assist in the decision process. **(GP9-A)**

Members $50 Nonmembers $100

Chairholder: Robert R. Rickert, M.D.
St. Barnabas Medical Center

A Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline (1995)

This document describes the design of a study to evaluate clinical accuracy of laboratory tests and contains procedures for preparing ROC curves; glossary of terms; and information on computer software programs. (See related publication EP10-A2 in the Evaluation Protocols section.) **(GP10-A)**

Members $50 Nonmembers $100

Chairholder: Mark H. Zweig, M.D.
National Institutes of Health

A Basic Cost Accounting for Clinical Services; Approved Guideline (1998)

This document provides principles and techniques to help laboratory managers establish a workable cost-accounting system. **(GP11-A)**

Members $60 Nonmembers $120

Chairholder: Eleanor M. Travers, M.D., MHA
Department of Veterans Affairs, Office of Patient Care Services

A Papanicolaou Technique; Approved Guideline – Second Edition (2001)

This guideline addresses procedures for cervical specimen collection, as well as the preparation, fixation, staining, and storage of Papanicolaou slides. (See related publications GP20-A2 and GP23-A.) **(GP15-A2)**

Members: $60 Nonmembers: $120

Chairholder: Nina Dhurandhar, M.D.
Tulane University Medical Center

A Routine Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline – Second Edition (2001)

This guideline describes routine urinalysis test procedures that address materials and equipment, macroscopic examinations, clinical analyses, and microscopic evaluations. **(GP16-A2)**

Members: $60 Nonmembers: $120

Chairholder: Albert Rabinovitch, M.D., Ph.D.
Specialty Laboratories

A Clinical Laboratory Safety; Approved Guideline – Second Edition (2004)

*American National Standard.** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory. An NCCLS-CAP joint project. **(GP17-A2)**

Members $60 Nonmembers $120

Chairholder: Sheila M. Woodcock, A.R.T., M.B.A.
QSE Consulting

A Laboratory Design; Approved Guideline (1998)

This guideline provides a foundation of information about laboratory design elements that can be used to help define the issues being considered when designing a laboratory. **(GP18-A)**

Members $50 Nonmembers $100

Chairholder: Pennell C. Painter, Ph.D., F.A.C.B.
University of Tennessee Medical Center

A Fine-Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline – Second Edition (2003)

This document contains recommended procedures for performing fine-needle aspiration biopsies of superficial (palpable) and deep-seated (nonpalpable) lesions, from patient preparation through staining the smear. (See related publications GP15-A2 and GP23-A.) **(GP20-A2)**

Members $50 Nonmembers $100

Chairholder: Nina Dhurandhar, M.D.
Tulane University Medical Center

A Training and Competence Assessment; Approved Guideline – Second Edition (2004)

This document provides background and recommended processes for the development of training and competence assessment programs that meet quality regulatory objectives. **(GP21-A2)**

Members $50 Nonmembers $100

Chairholder: Sheila M. Woodcock, A.R.T., M.B.A.
QSE Consulting

A Continuous Quality Improvement: Essential Management Approaches; Approved Guideline – Second Edition (2004)

This guideline considers continuous quality improvement (CQI) as a system of managerial programs addressing team actualization, customer needs anticipation, and quality assessment and improvement. **(GP22-A2)**

Members $85 Nonmembers $200

Chairholder: Gary B. Clark, M.D., M.P.A.
Wellness for Life

A Nongynecologic Cytologic Specimens: Collection and Cytopreparatory Techniques; Approved Guideline (1999)

This document provides recommended procedures for the collection, handling, transport, and processing of cytologic specimens from nongynecologic sources. (See related publications GP15-A2 and GP20-A2.) **(GP23-A)**

Members: $60 Nonmembers: $120

Chairholder: Kenneth D. McClatchey, M.D., D.D.S.
Loyola University Medical Center

A Application of a Quality Management System Model for Laboratory Services; Approved Guideline – Third Edition (2004)

This guideline describes the clinical laboratory's path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements. **(GP26-A3)**

Members $85 Nonmembers $200

Chairholder: Lucia M. Berte, M.A., M.T. (ASCP), SBB, DLM; CQA (ASQ) CQMgr.
Quality System Consultant

This document is intended for use with HS1 when developing a quality system for the clinical laboratory.

A Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline (1999)

This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool. **(GP27-A)**

Members $50 Nonmembers $100

Co-chairholders: Gary B. Clark, M.D., M.P.A., Quality Laboratory Management Associates Inc., and Stephen J. Sarewitz, M.D., Valley Medical Center

P Microwave Device Use in the Clinical Laboratory; Proposed Guideline (2004)

This document provides recommendations for reproducible performance of microwave-accelerated procedures for preparation of biological specimens in the clinical histopathology laboratory. **(GP28-P)**

Members $60 Nonmembers $120

Chairholder: Gary R. Login, D.M.D., D.M.Sc.
Harvard School of Dental Medicine

A Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guideline (2002)

This guideline will suggest workable alternatives for evaluating the accuracy of an assay when standard interlaboratory comparison programs are unavailable. **(GP29-A)**

Members: $60 Nonmembers: $120

Chairholder: Stephen J. Sarewitz, M.D.
Valley Medical Center

HEMATOLOGY

A Tubes and Additives for Venous Blood Specimen Collection; Approved Standard – Fifth Edition (2003)

*American National Standard.** This standard contains requirements for blood collection tubes and additives including heparin, EDTA, and sodium citrate. **(H1-A5)**

Members $50 Nonmembers $100

Chairholder: Charles F. Arkin, M.D.
Lahey Clinic

A Reference and Selected Procedure for the Erythrocyte Sedimentation Rate (ESR) Test; Approved Standard – Fourth Edition (2000)

*American National Standard.** This document provides a description of the principle, materials, and procedure for reference and standardized ESR methods, as well as a procedure to evaluate routine methods, and an outline of quality control programs for the ESR test. **(H2-A4)**

Members $50 Nonmembers $100

Co-chairholders: John A. Koepke, M.D., Duke University Medical Center, and Onno W. van Assendelft, M.D., Ph.D., Centers for Disease Control and Prevention

A Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Fifth Edition (2003)

This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children. It also includes recommendations on order of draw. **(H3-A5)**

Members $85 Nonmembers $200

Chairholder: Charles F. Arkin, M.D.
Lahey Clinic

See related publication X3-R on page 28.

A Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard – Fifth Edition (2004)

This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic capillary blood specimens are also included. **(H4-A5)**

Members $60 Nonmembers $120

Chairholder: Dennis J. Ernst, M.T.(ASCP)
Center for Phlebotomy Education

See videotape section for H4-A3-V information.
See related publication X3-R on page 28.

A Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third Edition (2000)

*American National Standard.** This standard describes the standard microhematocrit method for determining packed-cell volume. It also addresses recommended materials and potential sources of error. **(H7-A3)**

Members $60 Nonmembers $120

Chairholder: Onno W. van Assendelft, M.D., Ph.D.
Centers for Disease Control and Prevention

A Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard – Third Edition (2000)

*American National Standard.** This document describes the principle, materials, and procedure for reference and standardized hemoglobin determinations. It includes specifications for secondary hemiglobincyanide (HiCN) standards. **(H15-A3)**

Members $50 Nonmembers $100

Chairholder: Onno W. van Assendelft, M.D., Ph.D.
Centers for Disease Control and Prevention

A Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – Third Edition (2004)

This guideline addresses multiple factors associated with handling and processing specimens, as well as factors that can introduce imprecision or systematic bias into results. **(H18-A3)**

Members $60 Nonmembers $120

Chairholder: Roger R. Calam, Ph.D.
St. John Hospital

A Reference Leukocyte Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard (1992)

This standard describes automated differential counters and establishes a reference method based on the visual (or manual) differential count for leukocyte differential counting, to which an automated or manual test method can be compared. **(H20-A)**

Members $50 Nonmembers $100

Chairholder: John A. Koepke, M.D.
Duke University Medical Center

A Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline – Fourth Edition (2003)

This guideline contains procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and provides general recommendations for performing the tests. **(H21-A4)**

Members $85 Nonmembers $200

Chairholder: Charles F. Arkin, M.D.
Lahey Clinic

A Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard (1996)

This standard contains recommended performance goals for analytical accuracy and precision based on mathematical models for the following measurements: hemoglobin concentration, erythrocyte count, leukocyte count, platelet count, and mean corpuscular volume. (See related publications H7-A3, H15-A3, and H20-A in this section.) **(H26-A)**

Members $50 Nonmembers $100

Chairholder: A. Richardson Jones, M.D.
Coulter Corporation

A Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline – Second Edition (2001)

This document provides general guidelines for performing the fibrinogen assay in the clinical laboratory. It also includes reporting of results and *in vivo* and *in vitro* conditions that may alter results. (See related publication H21-A4 in this section.) **(H30-A2)**

Members: $60 Nonmembers: $120

Chairholder: Richard Marlar, Ph.D.
Denver VA Medical Center

P Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard (1999)

This document addresses calibration and quality control strategies for multichannel hematology analyzers; assignment of values to calibrator materials; calibration using stabilized blood controls; internal quality control; pair difference analysis; and use of the weighted moving average (x–B) method. An NCCLS–ICSH joint project. **(H38-P)**

Members $50 Nonmembers $100

Co-Chairholders: John A. Koepke, M.D.,
Durham, North Carolina, and Onno W. van Assendelft, M.D., Ph.D., Centers for Disease Control and Prevention

A Clinical Applications of Flow Cytometry: Quality Assurance and Immunophenotyping of Lymphocytes; Approved Guideline (1998)

This document contains guidance for the immunophenotypic analysis of non-neoplastic lymphocytes by immunofluorescence-based flow cytometry; guidelines for sample and instrument quality control; and precautions for data acquisition from lymphocytes. **(H42-A)**

Members $50 Nonmembers $100

Chairholder: Michael Borowitz, M.D., Ph.D.
The Johns Hopkins University

A Clinical Applications of Flow Cytometry: Immunophenotyping of Leukemic Cells; Approved Guideline (1998)

This document provides performance guidelines for the immunophenotypic analysis of leukemic and lymphoma cells using immunofluorescence-based flow cytometry; guidelines for sample and instrument quality control; and precautions for data acquisition from leukemic cells. **(H43-A)**

Members $50 Nonmembers $100

Chairholder: Michael Borowitz, M.D., Ph.D.
The Johns Hopkins University

A Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline – Second Edition (2004)

This document provides guidance for the performance of reticulocyte counting by flow cytometry. It includes methods for determining the accuracy and precision of the reticulocyte flow cytometry instrument and a recommended reference procedure. An NCCLS–ICSH joint project. **(H44-A2)**

Members $50 Nonmembers $100

Chairholder: Bruce H. Davis, M.D.
Maine Medical Center Research Institute

A Performance of the Bleeding Time Test; Approved Guideline (1998)

This document contains guidelines for performing the template bleeding time test. A descriptive list of variables that can affect test results is also included. **(H45-A)**

Members $50 Nonmembers $100

Chairholder: Charles F. Arkin, M.D.
Boston University Medical Center

A One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline (1996)

This document provides guidelines for performing the PT and APTT tests in the clinical laboratory, for reporting results, and for identifying sources of error. **(H47-A)**

Members $50 Nonmembers $100

Chairholder: Charles F. Arkin, M.D.
Boston University Medical Center

A Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline (2004)

This guideline provides guidance to users and manufacturers of point-of-care coagulation devices for monitoring of heparin and warfarin anticoagulant therapy and to ensure reliable results comparable to those obtained by routine clinical laboratory testing. **(H49-A)**

Members $50 Nonmembers $100

Chairholder: Jack E. Ansell, M.D.
Boston University Medical Center

A Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline (2002)

This guideline describes appropriate test specimens, reagents and materials, methods of platelet agglutination and ELISA, preparation of reference curves, determination of reference intervals, quality control procedures, result interpretation, and sources of error for assays of von Willebrand factor antigen and ristocetin cofactor activity. A brief description of von Willebrand disease and its various subtypes is included, as well as a list of references to more comprehensive reviews of this commonly inherited and rarely acquired bleeding disorder. **(H51-A)**

Members $60 Nonmembers $120 FDA

Chairholder: Richard Marlar, Ph.D.
Denver VA Medical Center

A Fetal Red Cell Detection; Approved Guideline (2001)

This document provides guidance for the quantitation of fetal red blood cells in blood and other biologic fluids. The performance characteristics of various flow cytometric and microscopic assays are reviewed, recommendations are made for control usage, and principles for distinction of F cells and fetal red cells are discussed. **(H52-A)**

Members $60 Nonmembers $120

Chairholder: Bruce H. Davis, M.D.
William Beaumont Hospital

P Procedures for Validation of INR and Local Calibration of PT/INR Systems; Proposed Guideline (2004)

NEW

This document reviews limitations of the INR system that may occur when a manufacturer-determined ISI is used without local validation or calibration and provides a rationale for performing local ISI validation with recommendations as to when PT calibration may be indicated. **(H54-P)**

Members $50 Nonmembers $100

Chairholder: Dorothy M. Adcock, M.D.
Esoterix Coagulation

IMMUNOLOGY AND LIGAND ASSAY

A Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials; Approved Guideline – Second Edition (1993)

This guideline provides a description of and procedures for evaluating the performance of materials used in immunoprecipitin analyses. It also includes a discussion of specificity. **(DI2-A2)**

Members $50 Nonmembers $100 FDA

Chairholder: Robert M. Nakamura, M.D.
Scripps Clinic and Research Foundation

A Agglutination Analyses: Antibody Characteristics, Methodology, Limitations,and Clinical Validation; Approved Guideline (1993)

This guideline describes the specificity of antibodies and antigens for agglutination techniques; labeling information; and characteristics and limitations of agglutination methods. **(DI3-A)**

Members $50 Nonmembers $100

Chairholder: Robert M. Nakamura, M.D.
Scripps Clinic and Research Foundation

A Quality Assurance for the Indirect Immunofluorescence Test for Autoantibodies to Nuclear Antigen (IF-ANA); Approved Guideline (1996)

This document offers guidelines for the development of reference sera of defined antibody specificity to ANA and standardization of the immunofluorescent test for ANA. **(I/LA2-A)**

Members $50 Nonmembers $100 FDA

Chairholder: Robert M. Nakamura, M.D.
Scripps Clinic and Research Foundation

A Apolipoprotein Immunoassays: Development and Recommended Performance Characteristics; Approved Guideline (1997)

This guideline describes the characterization and preparation of immunogens, antibodies, samples, and methods, and provides guidance for immunochemical testing of apolipoproteins. **(I/LA15-A)**

Members $50 Nonmembers $100

Chairholder: Robert F. Ritchie, M.D.
Foundation for Blood Research

A Specifications for Immunological Testing for Infectious Diseases; Approved Guideline – Second Edition (2001)

This guideline outlines specimen requirements; performance criteria; algorithms for the potential use of sequential or duplicate testing; recommendations for intermethod comparisons of immunological test kits for detecting infectious diseases; and specifications for development of reference materials. **(I/LA18-A2)**

Members $50 Nonmembers $100

Chairholder: W. Harry Hannon, Ph.D.
Centers for Disease Control and Prevention

A Evaluation Methods and Analytical Performance Characteristics of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies of Defined Allergen Specificities; Approved Guideline (1997)

This document provides guidance for the design, analytical performance, standardization, and quality assurance of laboratory assays used in the measurement of total serum IgE and IgE antibodies of defined allergen specificity. **(I/LA20-A)**

Members $50 Nonmembers $100 FDA

Chairholder: Per N.J. Matsson, Ph.D.
Pharmacia & Upjohn

A Clinical Evaluation of Immunoassays; Approved Guideline (2002)

This guideline provides recommendations on designing trials that are appropriate for evaluating both the safety and effectiveness of immunoassays. It is a valuable resource in determining the necessary steps in designing an evaluation for new methods, new applications for existing methods, or variations on existing methods. **(I/LA21-A)** FDA

Members $50 Nonmembers $100

Chairholder: Linda Ivor, Gen-Probe International

A Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline (2004)

NEW

This guideline addresses components for harmonizing and assessing the quality of immunoassay systems for several commonly used dose-response indicator categories, e.g., radioisotopes, enzymes, fluorescence, luminescence, reagents, and experimental components criteria essential to characterizing an immunoassay. **(I/LA23-A)**

Members $50 Nonmembers $100

Chairholder: W. Harry Hannon, Ph.D.
Centers for Disease Control and Prevention

A Fluorescence Calibration and Quantitative Measurement of Fluorescence Intensity; Approved Guideline (2004)

NEW

This guideline describes the basic principles, the reference materials, and the laboratory procedures upon which quantitative fluorescence calibration is based. **(I/LA24-A)**

Members $50 Nonmembers $100

Co-Chairholders: Gerald E. Marti, M.D., Ph.D., FDA Ctr. for Biologics Evaluation/Research, and Robert F. Vogt. Jr., Ph.D., Centers for Disease Control and Prevention

A Maternal Serum Screening; Approved Standard (2004)

AVAILABLE DECEMBER

This document addresses the steps required to provide reliable screening and reporting using examples of serum markers currently in common use (AFP, hCG, uE3, DIA). Outcome evaluation, information management, and calculation of risk are also emphasized in this standard. **(I/LA25-A)**

Members $50 Nonmembers $100

Chairholder: Sanda Clejan, Ph.D.
Tulane University School of Medicine

A Performance of Single Cell Immune Response Assays; Approved Guideline (2004)

NEW

This document contains methods of intracellular cytokine evaluation, major histo-compatibility complex (MHC) tetramer quantitation, and enzyme-linked immunospot (ELISPOT) technology. This document provides basic aspects of specimen collection, transport, and preparation, in addition to quality assurance and test validation approaches. An NCCLS-IFCC joint project. **(I/LA26-A)**

Members $50 Nonmembers $100

Chairholder: Alan L. Landay, Ph.D.
Rush Presbyterian-St. Luke's Medical Center

A Assessing the Quality of Radioimmunoassay Systems; Approved Guideline – Second Edition (1994)

This guideline contains definitions and procedures for properly assessing radioimmunoassay systems. (See related publication I/LA9-T in this section.) **(LA1-A2)**

Members $50 Nonmembers $100 FDA

Chairholder: Robert M. Nakamura, M.D.
Scripps Clinic and Research Foundation

A Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard – Fourth Edition (2003)

This document addresses the issues associated with specimen collection, the filter paper collection device, and the transfer of blood onto filter paper, and provides uniform techniques for collecting the best possible specimen for use in newborn screening programs. **(LA4-A4)**

Members $60 Nonmembers $120

Chairholder: W. Harry Hannon, Ph.D.
Centers for Disease Control and Prevention

See videotape section for LA4-A3-V information.

A Quality Assurance for Immunocytochemistry; Approved Guideline (1999)

This document provides recommendations for the performance of immunocytochemical assays on cytologic and surgical pathology specimens. It is intended to promote a better understanding of the requirements, capabilities, and limitations of these diagnostic methods; to improve their intra- and inter-laboratory reproducibility; and to improve their positive and negative predictive values in the diagnosis of disease. **(MM4-A)**

Members $60 Nonmembers $120

Chairholder: Timothy J. O'Leary, M.D., Ph.D.
Armed Forces Institute of Pathology

MICROBIOLOGY

A Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard – Eighth Edition (2003)

*American National Standard.** This standard contains updated recommended techniques, interpretive criteria, and quality control parameters for disk susceptibility testing. **THIS DOCUMENT IS COMPLETE WITH DISK SUSCEPTIBILITY TESTING TABLES UPDATED FOR 2004 (M100-S15).**
(See related publication M7-A6.) **(M2-A8)**

Members $150 Nonmembers $275 FDA

Chairholder: Mary Jane Ferraro, Ph.D., M.P.H.
Massachusetts General Hospital
Vice-Chairholder: Matthew A. Wikler, M.D., M.B.A.
ViroPharma, Incorporated

See videotape section for M2-A5-V information.

MICROBIOLOGY: Susceptibility Testing

M2-A8 Antimicrobial Disk Testing
M7-A6 Dilution Testing (Aerobes)

*** The prices for any one of the M2-A8 or M7-A6 documents plus the M100-S15 tables are listed below:**

	Members	Nonmembers
1 document & tables	$150	$275
2 documents & tables	$250	$375

M2 Quality Control Flowcharts

NCCLS is offering a laminated 8 1/2 x 11 flowchart that will provide an easy to use, easy to understand, and readily available resource of critical NCCLS-recommended protocols for the establishment of a quality control system to be used with disk antimicrobial susceptibility test methods.

Sold in sets of 5
Members $35 Nonmembers $60

A Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard (1996)

This standard contains procedures for evaluating production lots of Mueller-Hinton agar, and for the development and application of reference media. **(M6-A)**

Members $50 Nonmembers $100 FDA

Chairholder: George L. Evans, Ph.D.
Becton Dickinson Microbiology Systems, Retired

A Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard – Sixth Edition (2003)

*American National Standard.** This newly revised standard provides updated reference methods for the determination of minimal inhibitory concentrations (MICs) for aerobic bacteria by broth macrodilution, broth microdilution, and agar dilution. **THIS DOCUMENT CONTAINS MIC INTERPRETIVE CRITERIA AND QUALITY CONTROL PARAMETERS TABLES UPDATED FOR 2004 (M100-S15).** (See related publication M11-A6 in this section.) **(M7-A6)**

Members $150 Nonmembers $275 FDA

Chairholder: Mary Jane Ferraro, Ph.D., M.P.H.
Massachusetts General Hospital
Vice-Chairholder: Matthew A. Wikler, M.D., M.B.A.
ViroPharma, Incorporated

M7 Quality Control Flowcharts

NCCLS is offering a laminated 8 1/2 x 11 flowchart that will provide an easy to use, easy to understand, and readily available resource of critical NCCLS-recommended protocols for the establishment of a quality control system to be used with MIC test methods.

Sold in sets of 5
Members $35 Nonmembers $60

A Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard – Sixth Edition (2004)

NEW

*American National Standard.** This standard provides reference methods for the determination of minimal inhibitory concentrations (MICs) of anaerobic bacteria by broth macrodilution, broth dilution, and agar dilution. **THIS DOCUMENT IS COMPLETE WITH TABLES FOR AST OF ANAEROBIC BACTERIA UPDATED FOR 2004. (M11-A6)**

Members $85 Nonmembers $200 FDA

Chairholder: Matthew A. Wikler, M.D., M.B.A.
Peninsula Pharmaceuticals, Inc.

A Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline (2000)

This document contains guidelines for specimen collection, blood film preparation, and staining procedures. Recommendations for optimum timing of specimen collection to assist laboratories in detecting, identifying, and reporting certain parasites are also included. **(M15-A)**

Members $60 Nonmembers $120 FDA

Chairholder: Lynne S. Garcia, M.S., F(AAM)
Diagnostic Medical Parasitology

A Methodology for the Serum Bactericidal Test; Approved Guideline (1999)

This guideline describes a direct method of antimicrobial susceptibility testing using a patient's serum to measure the activity of serum against bacterial pathogen isolated from the patient. (See related publication M26-A in this section.) **(M21-A)**

Members $60 Nonmembers $120

Chairholder: James H. Jorgensen, Ph.D.
University of Texas Health Science Center

A Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – Third Edition (2004)

NEW

This standard contains quality assurance procedures for manufacturers and users of prepared, ready-to-use microbiological culture media. **(M22-A3)**

Members $60 Nonmembers $150

Chairholder: Karen Krisher, Ph.D., D(ABMM)
Oregon Public Health

A Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline – Second Edition (2001)

This document addresses the required and recommended data needed for the selection of appropriate interpretive standards and quality control guidelines for antimicrobial agents. **(M23-A2)**

Members $150 Nonmembers $250 FDA

Chairholder: Mary Jane Ferraro, Ph.D., M.P.H.
Massachusetts General Hospital

A Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard (2003)

This standard provides protocols and related quality control parameters and interpretive criteria for the susceptibility testing of mycobacteria, Nocardia spp., and other aerobic actinomycetes. **(M24-A)**

Members $60 Nonmembers $120

Chairholder: Gail L. Woods, M.D.
Merck & Company, Inc.

A Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline (1999)

This guideline contains procedures for determining the lethal activity of antimicrobial agents. (See related publication M21-A in this section.) **(M26-A)**

Members $60 Nonmembers $120

Chairholder: James H. Jorgensen, Ph.D.
University of Texas Health Science Center

A Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard – Second Edition (2002)

This standard addresses the selection and preparation of antifungal agents; implementation and interpretation of test procedures; and quality control requirements for susceptibility testing of yeasts that cause invasive fungal infections. **(M27-A2)**

Members $60 Nonmembers $120

Chairholder: Michael A. Pfaller, M.D.
University of Iowa College of Medicine

Quality Control MIC Limits for Broth Microdilution; Informational Supplement (2004)

NEW

This supplemental table, which includes two new drugs, provides quality control limits for broth microdilution susceptibility tests of ten antifungal agents. It is available as an 8.5" X 11" laminated chart for easy posting in the laboratory. **(M27-S1)**

Members $15 Nonmembers $35

A Procedures for the Recovery and Identification of Parasites from the Intestinal Tract; Approved Guideline (1997)

This guideline addresses the collection, processing, and examination of intestinal tract specimens for the identification of parasites. **(M28-A)**

Members $60 Nonmembers $120

Chairholder: Lynne S. Garcia, M.S., F(AAM)
UCLA Medical Center

A Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Second Edition (2004)

This document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure. **(M29-A2)**

Members $100 Nonmembers $200

Chairholder: David L. Sewell, Ph.D.
Veteran Affairs Medical Center
See videotape section for M29-A2 information.
See related publication X3-R on page 28.

A Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Approved Standard – Second Edition (2002)

This document provides the currently recommended techniques for antimicrobial agent disk and dilution susceptibility testing, criteria for quality control testing, and interpretive criteria for veterinary use. **(M31-A2)**

Members $60 Nonmembers $120

Chairholder: Thomas R. Shryock, Ph.D.
Lilly Research Laboratories

Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals; Informational Supplement (2004)

NEW

This document provides updated tables for the NCCLS antimicrobial susceptibility testing standard M31-A2. **(M31-S1)**

Members $35 Nonmembers $60

Chairholder: Thomas R. Shryock, Ph.D
Lilly Research Laboratories

P Evaluation of Lots of Mueller-Hinton Broth for Antimicrobial Susceptibility Testing; Proposed Guideline (2001)

This document describes methods for evaluation of production lots of Mueller-Hinton broth by manufacturers of the dehydrated product. Performance of production lots is determined by testing defined organism/antimicrobial combinations. The results of testing must conform to defined quality control limit ranges for each combination of antimicrobial and ATCC quality control strain. Guidelines are provided for ranges of specific ion contents (cations and anions) that will provide results within the defined quality control limit ranges. **(M32-P)**

Members $60 Nonmembers $120

Chairholder: Robert P. Rennie, Ph.D.
University of Alberta Hospital

A Antiviral Susceptibility Testing: Herpes Simplex Virus by Plaque Reduction Assay; Approved Standard (2004)

NEW

This document provides a protocol for the performance of the plaque reduction assay for phenotypic antiviral susceptibility testing of herpes simplex virus. **(M33-A)**

Members $60 Nonmembers $120

Co-Chairholders: Richard L. Hodinka, Ph.D., Children's Hospital of Philadelphia, and Ella M. Swierkosz, Ph.D., St. Louis University

A Western Blot Assay for Antibodies to *Borrelia burgdorferi*; Approved Guideline (2000)

This document addresses technical and interpretive considerations for use of Western blot assays that detect antibodies to *Borrelia burgdorferi* and other Borrelia species that cause Lyme Disease. **(M34-A)**

Members $60 Nonmembers $120

Chairholder: Alan G. Barbour, M.D.
University of California Irvine College of Medicine

A Abbreviated Identification of Bacteria and Yeast; Approved Guideline (2002)

This document provides a series of microbial identification protocols that are designed to minimize the use of expensive, time-consuming laboratory tests, allowing timely reporting of accurate organism identification. **(M35-A)**

Members $60 Nonmembers $120

Chairholder: Ellen Jo Baron, Ph.D.
Stanford University Medical School

A Clinical Use and Interpretation of Serologic Tests for *Toxoplasma gondii*; Approved Guideline (2004)

NEW

This guideline provides the user with information about the biology of *Toxoplasma gondii*, the methods available for use in the laboratory diagnosis of human toxoplasmosis, techniques that should be performed for specific clinical situations, and how to interpret laboratory results. **(M36-A)**

Members $60 Nonmembers $120

Chairholder: Lynne S. Garcia, M.S., F(AAM)
LSG Associates

A Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline – Second Edition (2002)

This document addresses the required and recommended data needed for selection of appropriate interpretative standards and quality-control guidance for veterinary antimicrobial agents. **(M37-A2)**

Members $60 Nonmembers $120

Chairholder: Thomas R. Shryock, Ph.D.
Lilly Research Laboratories

A Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard (2002)

This document addresses the selection of antifungal agents; preparation of antifungal stock solutions and dilutions for testing; implementation and interpretation of test procedures; and quality control requirements for susceptibility testing of filamentous fungi (moulds) that cause invasive fungal infections. **(M38-A)**

Members $60 Nonmembers $120

Chairholder: Michael A. Pfaller, M.D.
University of Iowa College of Medicine

A Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline (2002)

This document describes methods for the recording and analysis of antimicrobial susceptibility test data, consisting of cumulative and ongoing summaries of susceptibility patterns of epidemiologically significant microorganisms. **(M39-A)**

Members $60 Nonmembers $120

Chairholder: Mary Jane Ferraro, Ph.D., M.P.H.
Massachusetts General Hospital

A Quality Control of Microbiological Transport Systems; Approved Standard (2003)

This standard provides criteria to manufacturers and end-users of transport devices to assist with provision of dependable products for the transport of microbiological clinical specimens. Quality control considerations are presented, as well as techniques, control organisms, and acceptability criteria. This document provides a consistent protocol for initial testing or microbiological transport devices by manufacturers and a method by which laboratories can validate manufacturer claims and compare devices. An NCCLS–DIN pilot project. **(M40-A)**

Members $60 Nonmembers $120

Co-Chairholders: Judy C. Arbique, A.R.T., C.L.S., Queen Elizabeth II Health Sciences Center, and Barbara Ann Body, Ph.D., D(ABMM), LabCorp

R Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated from Aquatic Animals; A Report (2003)

This document provides the most up-to-date techniques for disk diffusion susceptibility testing of aquatic species isolates and criteria for quality control testing. **(M42-R)**

Members $60 Nonmembers $120

Co-Chairholders: John P. Hawke, Ph.D., Louisiana State University, and Renate Reimschuessel, Ph.D., V.M.D., Center for Veterinary Medicine, FDA

A Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline (2004)

NEW

This guideline provides newly established methodology for disk diffusion testing of Candida spp., zone interpretive criteria, and recommended quality control ranges. **(M44-A)**

Members $85 Nonmembers $200

Chairholder: Daniel J. Sheehan, Ph.D
Pfizer Inc

Performance Standards for Antimicrobial Susceptibility Testing:

AVAILABLE DECEMBER

Fifteenth Informational Supplement (January 2005)

This document provides updated tables for the NCCLS antimicrobial susceptibility testing standards for Disk (M2-A8) and MIC (M7-A6). **(M100-S15)**

Members $85 Nonmembers $200

Chairholder: Matthew A. Wikler, M.D., M.B.A.
Peninsula Pharmaceuticals, Inc.

Wallchart — Glossary of Antimicrobial Terms and Abbreviations Wallchart: Fifteenth Informational Supplement

AVAILABLE DECEMBER

This wallchart features important terminology (drug classes, subclasses, and dosage forms) for all antimicrobial agents featured in NCCLS document M100. This format serves as a handy reference for laboratorians in "speaking the language" when transmitting important clinical susceptibility information to the clinician. The chart also features a comprehensive listing of abbreviations used around the world to identify antimicrobials in *in vitro* diagnostic products such as automated susceptibility test systems and antimicrobial agent disks. **(M100-S15)**

Members $35 Nonmembers $60

MOLECULAR METHODS

A Molecular Diagnostic Methods for Genetic Diseases; Approved Guideline (2000)

This document provides guidance for the use of molecular biologic techniques for clinical detection of heritable mutations associated with genetic disease. **(MM1-A)**

Members $60 Nonmembers $120

FDA

Chairholder: Dale H. Altmiller, Ph.D.
University of Oklahoma Health Sciences Center

A Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline – Second Edition (2002)

This document provides guidance on the performance of gene rearrangement assays, including indication; specimen collection, transport, and processing; assessment of specimen adequacy; and quality control. **(MM2-A2)**

Members $60 Nonmembers $120

Co-Chairholders: Russel K. Enns, Ph.D.
Vysis, Inc.
Dale H. Altmiller, Ph.D.
Edmond, Oklahoma

A Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline (1995)

This document contains guidelines for use of nucleic acid probes and nucleic acid amplification techniques for detection of target sequences specific to particular microorganisms. Limitations, quality assurance, proficiency testing, and interpretation of results are also described. **(MM3-A)**

Members $60 Nonmembers $120

FDA

Chairholder: Russel K. Enns, Ph.D.
Vysis, Inc.

A Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline (2003)

This document addresses guidelines for a variety of amplification-based laboratory tests, including polymerase chain reaction (PCR), transcription-based amplification system (TAS), strand displacement amplification (SDA), ligase chain reaction (LCR), and other methods now widely used in diagnostic hematopathology. This guideline provides a basis for laboratory implementation and quality assurance in this important area of diagnostic molecular medicine. **(MM5-A)**

Members $60 Nonmembers $120

FDA

Chairholder: Timothy J. O'Leary, M.D., Ph.D.
Armed Forces Institute of Pathology

A Quantitative Molecular Methods for Infectious Diseases; Approved Guideline (2003)

This document provides guidance for the development and use of quantitative molecular methods, such as nucleic acid probes and nucleic acid amplification techniques of the target sequences specific to particular microorganisms. It also presents recommendations for quality assurance, proficiency testing, and interpretation of results. **(MM6-A)**

Members $60 Nonmembers $120

Chairholder: Roberta M. Madej, M.S., M.T.
Roche Molecular Systems, Inc.

A Fluorescence *In Situ* Hybridization (FISH) Methods for Medical Genetics; Approved Guideline (2004)

NEW

This document addresses FISH methods for medical genetic determinations, identification of chromosomal abnormalities, and gene amplification. Topics addressed include probe and assay development, qualification, and validation; instrument requirements; quality assurance; and recommendations for evaluation of results. Guidance for assay development includes detailed recommendations on specimen selection, handling and treatment, hybridization conditions/efficiency, and test limitations, precautions, and warnings. **(MM7-A)**

Members $60 Nonmembers $120

Chairholder: Russel K. Enns, Ph.D.
Vysis, Inc.

A Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline (2004)

AVAILABLE DECEMBER

This document addresses automated, PCR-based, dideoxyterminator and primer extension sequencing done on gel or capillary based sequencers. Topics covered include: specimen collection and handling; isolation of nucleic acid; amplification and sequencing of nucleic acids; interpretation and reporting results; and quality control/assessment considerations as appropriate. **(MM9-A)**

Members $60 Nonmembers $120

Chairholder: Michael A. Zoccoli, Ph.D.
Celera Diagnostics

P Proficiency Testing for Molecular Methods; Proposed Guideline (2004)

NEW

This document provides guidelines for a quality proficiency testing program including reliable databases; design control in the choice of materials and analytes; good manufacturing processes; documentation procedures; complaint handling; corrective and preventive action plans; and responsive timing of reports. **(MM14-P)**

Members $60 Nonmembers $120

Chairholder: Roberta M. Madej, M.S., M.T.
Roche Molecular Systems, Inc.

POINT-OF-CARE TESTING

A Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline (1999)

This document contains guidelines for users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory to produce reliable results comparable to those obtained in the clinical laboratory. **(AST2-A)**

Members $60 Nonmembers $150

Chairholder: Barbara M. Goldsmith, Ph.D.
St. Christopher's Hospital for Children

A Wellness Testing Using IVD Devices; Approved Guideline (1999)

This document provides procedures and recommendations for implementing a quality wellness-testing program. **(AST3-A)**

Members $50 Nonmembers $100

Chairholder: Nina Peled, Ph.D.
Cygnus, Inc.

A Point-of-Care Connectivity; Approved Standard (2001)

This document provides the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data concentrators, and laboratory information systems from a variety of vendors. An NCCLS, IFCC, CIC joint publication. **(POCT1-A)**

Members: $100 Nonmembers: $150

FDA

Chairholder: Jeffrey A. DuBois, Ph.D.
Nova Biomedical Corporation
Note: Distributed on CD-ROM

NATIONAL REFERENCE SYSTEM FOR THE CLINICAL LABORATORY

A The Reference System for the Clinical Laboratory: Criteria for Development and Credentialing of Methods and Materials for Harmonization of Results; Approved Guideline (2000)

*American National Standard.** This document contains procedures for developing and evaluating definitive methods, reference methods, designated comparison methods, and reference materials to provide a harmonized clinical measurement system. (See related publications ISO 15193 and 15194 on page 19). **(NRSCL13-A)**

Members $50 Nonmembers $100

Chairholder: F. Alan Andersen, Ph.D.
Cosmetic Ingredient Review

METHODS AND MATERIALS CREDENTIALED BY THE COUNCIL OF THE NATIONAL REFERENCE SYSTEM FOR THE CLINICAL LABORATORY

Using the NCCLS consensus process, the NRSCL Council has established guidelines describing the attributes of definitive methods, reference methods, and reference materials. Brief summaries of the methods and materials for individual analytes credentialed by the NRSCL Council are available AT NO CHARGE.

A Glucose; Approved Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS1-A)**

A Aspartate Aminotransferase (AST); Approved Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS2-A)**

A Cholesterol; Approved Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS3-A)**

A Alanine Aminotransferase (ALT); Approved Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS4-A)**

A Total Protein; Second Edition Approved Summary of Methods and Materials Credentialed by the NRSCL Council (1993) **(RS5-A)**

A Bilirubin; Approved Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS6-A)**

P Sodium; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS7-P)**

P Potassium; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS8-P)**

P Calcium; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1989) **(RS9-P)**

P Chloride; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS10-P)**

P Urea Nitrogen; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1988) **(RS11-P)**

P Creatine Kinase; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1993) **(RS14-P)**

P Antimicrobial Susceptibility Testing; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1993) **(RS16-P)**

P γ-Glutamyltransferase; Proposed Summary of Methods and Materials Credentialed by the NRSCL Council (1993) **(RS17-P)**

Electronic Archived Documents

These documents are no longer being reviewed as part of the NCCLS consensus process. However, because of their usefulness to a limited segment of the healthcare community, NCCLS is continuing to make the documents available for their informational content. These are available in electronic format only.

Assessing the Quality of Radioimmunoassay Systems – Second Edition; Approved Guideline (1994) **(LA1-A2)**
Members: $25 Nonmembers: $75

A Candidate Reference Method for Serum Digoxin: A Model for Radioimmunoassay Reference Methods; Tentative Guideline (1996) **(I/LA9-T)**
Members: $15 Nonmembers: $25

Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (1997) **(I/LA19-A)**
Members: $25 Nonmembers: $75

Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline (1997) **(I/LA6-A)**
Members: $25 Nonmembers: $75

Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials—Second Edition; Approved Guideline (1993) **(DI2-A2)**
Members: $25 Nonmembers: $75

Agglutination Analyses: Antibody Characteristics, Methodology, Limitations, and Clinical Validation; Approved Guideline (1993) **(DI3-A)**
Members: $25 Nonmembers: $75

Temperature Calibration of Water Baths, Instruments, and Temperature Sensors—Second Edition; Approved Standard (1990) **(I2-A2)**
Members: $25 Nonmembers: $75

Standard for Relating Spectrophotometer Performance Characteristics to Analytical Goals (1980) **(I3-A)**
Members: $15 Nonmembers: $25

Service of Clinical Laboratory Instruments (1984) **(I6-A)**
Members: $15 Nonmember: $25

Determining Performance of Volumetric Equipment (1984) **(I8-P)**
Members: $15 Nonmembers: $25

Temperature Monitoring and Recording in Blood Banks (1986) **(I16-T)**
Members: $15 Nonmembers: $25

Labeling of Laboratory Prepared Materials (1984) **(GP4-P)**
Members: $15 Nonmembers: $25

Inventory Control Systems for Laboratory Supplies; Approved Guideline (1994) **(GP6-A)**
Members: $50 Nonmembers: $100

Labeling for Home-Use *In Vitro* Testing Products; Approved Guideline (1996) **(GP14-A)**
Members: $35 Nonmembers: $85

Histochemical Method for Leukocyte Alkaline Phosphatase; Proposed Standard (1984) **(H22-P)**
Members: $25 Nonmembers: $75

Labeling of Laboratory Prepared Materials (1984) **(GP4-P)**
Members: $15 Nonmembers: $25

Sourcebook of Reference Methods, Materials, and Related Information for the Clinical Laboratory; Proposed Guideline (1994) **(NRSCL12-P)**
Members: $50 Nonmembers: $100

International Organization for Standardization (ISO) Documents

The International Organization for Standardization Technical Committee (ISO/TC) 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, was formed in 1995 based on a proposal by NCCLS. ISO granted the Secretariat to the American National Standards Institute (ANSI), who in turn delegated the Secretariat responsibility to NCCLS. As manager of ISO's standards-development process in this field, NCCLS's role is a global one carried out on behalf of the patient-testing community throughout the world. ISO/TC 212 is not an NCCLS-sponsored activity and officially, ANSI, as the U.S. member of ISO, is listed as the Secretariat of ISO/TC 212.

As a separate, distinct national responsibility, NCCLS also manages the U.S. TAG for ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, and the U.S. TAG for ISO/TC 76, *Transfusion, infusion, and injection equipment for medical and pharmaceutical use*, on behalf of ANSI. ISO/TC 76 is particularly concerned with development of standards for glass containers for blood transfusions, plastic containers for blood collection and transfusion, and blood specimen containers for hematology and biochemistry.

Through an agreement with ANSI, NCCLS is able to offer ISO/TC 212 and ISO/TC 76 approved and draft standards. To purchase ISO/TC 76 approved and draft standards, visit Shop NCCLS at www.nccls.org.

Customers from outside the United States may order these ISO standards from their national standards bodies.

LEGEND

prEN	proposed European Norm
AWI	approved work item
TR	Technical Report
NWI	new work item
WD	working draft
CD	committee draft
DIS	draft international standard
FDIS	final draft international standard
DAmd	Draft Amendment

ISO/TC 212 STANDARDS

ISO 15189
Medical laboratories – Particular requirements for quality and competence (2003)
(formerly Quality management in the medical laboratory)
This International Standard specifies requirements for quality management of a medical laboratory.
Members $150 Nonmembers $200

ISO 15190
Medical laboratories – Requirements for safety (2003) *(formerly Safety management for medical laboratories)*
This International Standard specifies requirements for quality management of a medical laboratory.
Members $150 Nonmembers $200

ISO 15193
***In vitro* diagnostic systems – Measurement of quantities in samples of biological origin – Presentation of reference measurement procedures (2002)**
This International Standard specifies requirements for the drafting of a reference measurement procedure.
Members $65 Nonmembers $75

ISO 15194
***In vitro* diagnostic medical devices – Measurement of quantities in samples of biological origin – Description of reference materials (2002)**
This International Standard specifies requirements and formats for the description of reference materials.
Members $60 Nonmembers $70

ISO 15195
Laboratory medicine – Requirements for reference measurement laboratories (2003)
(formerly Requirements for laboratories performing reference procedures)
This International Standard describes the specific requirements for reference measurement laboratories in laboratory medicine.
Members $55 Nonmembers $65

ISO 15197
Requirements for *in vitro* blood glucose monitoring systems for self-testing in managing diabetes mellitus (2003)
This International Standard specifies procedures for the determination of performance criteria for quantitative *in vitro* blood glucose monitoring systems for management of diabetes mellitus.
Members $100 Nonmembers $110

ISO 15198
Clinical laboratory medicine – *In vitro* diagnostic medical devices – Validation of manufacturer's recommendations for user quality control *(formerly Procedures by the manufacturer)*
This International Standard specifies procedures for manufacturers of *in vitro* diagnostic devices for validating the recommendations provided in the device labeling for user quality control which assures adequate performance.
Members $55 Nonmembers $65

ISO 17511
***In vitro* diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials (2003)**
This International Standard specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement.
Members $80 Nonmembers $90

ISO/CD 17593
Clinical laboratory testing and *in vitro* diagnostic test systems- Requirements for *in vitro* monitoring systems for self-testing of oral anticoagulant therapy
This draft International Standard specifies requirements for *in vitro* monitoring systems for vitamin-K antagonist therapy, including performance, quality assurance and user training, and procedures for the verification and the validation of performance by the intended users under actual and simulated conditions of use.
Members $25 Nonmembers $35

ISO 18153
***In vitro* diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of assigned values for catalytic concentration of enzymes assigned to calibrators and control materials (2003)**
This International Standard specifies how to assure the traceability of assigned values to calibrators and control materials intended to establish or verify trueness of measurement of the catalytic concentration of enzymes. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, *in vitro* diagnostic medical devices.
Members $50 Nonmembers $60

ISO 19001
***In vitro* diagnostic medical devices - Information supplied by the manufacturer with *in vitro* diagnostic reagents for staining in biology (2002)**
This International Standard specifies requirements for information supplied with reagents used in staining in biology.
Members $65 Nonmembers $75

ISO/CD 22869
Technical Report: Medical laboratories – Guidance on laboratory implementation of ISO 15189
This draft Technical Report provides guidance to laboratories on how to meet the requirements contained in ISO 15189: 2003 for competence and quality that are particular to medical laboratories.
Members $25 Nonmembers $35

ISO/DIS 22870
Point-of-care testing (POCT)
This draft annex for ISO 15189 specifies quality management point-of-care testing.
Members $25 Nonmembers $35

ISO/DTR 22367
Medical laboratories – Reduction of error through risk management and continual improvement
Members $25 Nonmembers $35

NCCLS Projects in Development

NOTE:

These NCCLS projects are in development; they are not available for purchase at this time.

Automation and Informatics

Protocol to Validate Laboratory Information Systems

The laboratory industry is quickly moving into the era of electronic reports and transmission of information via the Internet. Guidelines are needed to provide consistency in the industry. This project will address the validation of LIS systems for end users, to ensure accurate and reliable test results from patient accessioning to transmittal of patient results. The document will address computer system facilities, system programs, data, quality assurance standards/CQI, and validation methods. (AUTO8)

Chairholder: Sandy Pearson, M.T.(ASCP)
Center for Medicare and Medicaid Service

Remote Access to Clinical Laboratory Diagnostic Devices via the Internet

This project will lead to the development of a standard communication protocol that will allow remote connections to laboratory devices. It will establish a means to leverage the existing infrastructure provided by the hospital's Local Area Network (LAN) and the Internet to achieve the remote connectivity. These remote connections would be used to monitor the instrument sub systems to determine proper operation; collect diagnostic data for remote system troubleshooting; and collect data that would allow for electronic inventory management. (AUTO9)

Chairholder: Randy R. Davis
Dade Behring, Inc.

Clinical Chemistry and Toxicology

Analysis of Body Fluids in Clinical Chemistry

This proposed project will lead to the development of guidelines for the application of widely available analytic methods for testing body fluids and for reporting and interpreting those results. Emphasis will be placed on defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method validation for abnormal body fluids; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers. (C49) An NCCLS-IFCC joint project

Chairholder: Richard A. McPherson, M.D.
Virginia Commonwealth University

Mass Spectrometry in the Clinical Laboratory

This guideline will provide a series of guideposts, references, standards, and quality assurance markers to ensure ease of implementation and correct operation of a NMS system for the many applications in the clinical laboratory. This document will also include information regarding optimization of the analysis including maintaining optimum performance, approaches to ensuring accurate and precise mass measurement, quality control of assays and trouble shooting instrument problems versus sample preparation problems, limitations of the technology, interpretation of results, the use of relative concentrations ratios of compounds, and qualitative diagnostic profiling including protein profiling versus quantitative analysis for therapeutic monitoring. (C50)

Chairholder: Donald H. Chace, Ph.D.
Pediatrix Screening

Expression of Uncertainty of Measurement in Clinical Laboratory Medicine

This guideline is intended for diagnostic test manufacturers, clinical laboratories, and regulatory agencies. It will describe, in clear terms understood by these three groups, the principles required for estimating measurement uncertainty as stated in the GUM. It also will discuss the limitations of the concepts of uncertainty. This document will also provide advice on how to estimate measurement uncertainty in the healthcare field in an objective, economic manner and present techniques for validating uncertainty estimates gained from simulations by experimental investigations. (C51)

Chairholder: Richard R. Miller, Jr.
Dade Behring Inc.

General Laboratory Practices

Human Tissue Procurement

The scope of this guideline will cover all healthcare institutions or clinics that may collect human tissue for research purposes, by providing recommendations for the collection in accordance with the practice of ethical, legislative, and legal concerns. It will also help to ensure that human tissue procurement and use for medical research can be differentiated from that involving cloning, stem cell, and organ development/replacement research. The separation is important to prevent broad actions brought against all "genetic research" involving humans from disabling diagnostic and pharmaceutical research involving human tissue and molecular genetics. (GP30)

Co-Chairholders: Sofia Gitis
Zoion, and
Kathleen M. Smith, Ph.D.
DNAX Research Inc.

Laboratory Instrument Evaluation, Verification, and Maintenance

This guideline will provide the basic information required to make appropriate decisions concerning instrument selection, verification, and maintenance in the clinical laboratory. It will suggest reasonable and workable guidelines for laboratory personnel for fostering quality laboratory services, meeting the requirements of regulatory bodies, and using resources economically. (GP31)
An NCCLS-CAP joint project.

Co-Chairholders: William J. Castellani, M.D.
Truman Medical Center and
Keith Kaplan, M.D.
Walter Reed Army Medical Center

Hematology

Body Fluid Analysis for Cellular Composition

Accurate clinical data from body fluid analysis is essential for the correct diagnosis of disease and treatment of a patient. Many variables contribute to the results that are reported. Because these variables are loosely defined, inconsistency from one institution to another may exist. This guideline will provide users with recommendations for collection and transport of body fluids, numeration and identification of cellular components, and guidelines for qualitative and quantitative assessment of body fluid. (H56) An NCCLS–IFCC joint project.

Chairholder: Diane I. Szamosi, M.A., M.T.(ASCP)SH
Greiner Bio-One VACUETTE

Microbiology

Viral Culture

The new NCCLS project on viral culture will provide guidance on the culturing of viruses isolated from patients. Identification techniques will also be addressed. The resulting document will cover the total patient-testing process, starting in the preanalytical phase with an outline of optimal methods for collection, preservation, and transport of clinical specimens. The viral culture document will provide details on the analytic portion of the process, featuring cell culture methodology in terms of selection and maintenance of appropriate cell lines and quality control of viral culture media. Protocols for cell culture inoculation, incubation, and quality control will be included, as well as in-depth procedures for culture reading and isolate identification and suggestions for patient reporting. (M41)

Chairholder: Lorraine M. Clarke, Ph.D.
New York State Department of Health

Methods for Antimicrobial Susceptibility Testing of Human Mycoplasmas

This project will lead to a consensus guideline for methods and interpretation of *in vitro* antimicrobial susceptibilities for mycoplasmas of human origin. The protocols will be limited to methodology and interpretive criteria for *Mycoplasma pneumoniae*, *Mycoplasma hominis*, and *Ureaplasma urealyticum/parvum*. (Although other mycoplasmas may occur in human infections, disease associations and cultivation conditions are not so well established and, therefore, these organisms are not practical to study in a project of this nature.) (M43) An NCCLS–IFCC joint project.

Chairholder: Ken B. Waites, M.D.
University of Alabama at Birmingham

Susceptibility Testing of Fastidious or Infrequently Isolated Bacteria

This guideline would provide methods, quality control criteria, and interpretive breakpoints for fastidious or infrequently encountered bacteria that are not included in the current M2 and M7 susceptibility testing standards. These include several fastidious gram-negative bacteria, and miscellaneous gram-positive bacteria that lack any NCCLS interpretive criteria. These tend to be less frequently isolated organisms that may cause serious infections (e.g., infective endocarditis), or infections associated with trauma and environmental contamination (e.g., Bacillus spp.), or device associated infections in immunocompromised or post-surgical patients (e.g., intravascular catheters, implanted devices, CNS shunts). The fastidious gram-negative bacilli include members of the HACEK group (i.e., Haemophilus, Actinobacillus, Cardiobacterium, Eikenella, and Kingella). In addition to Bacillus species (not B. anthracis), the key

gram-positive organisms include Corynebacterium spp., Micrococcus spp., Aerococcus spp., Abiotrophia spp., and perhaps other less common genera. (M45)

Chairholder: James H. Jorgensen, Ph.D.
University of Texas Health Science Center

Diagnostic Microbiology for Limited Resources Laboratories

This document describes the performance of these tasks within the realm of the limited resources laboratory, e.g. those that have minimal means with which to perform microbiological analyses. Addressed in this document are the environment in which such diagnostic methods can be employed, minimal materials necessary for diagnostic microbiology, the education and training of personnel performing this testing, and the procedures for the production of clinically relevant patient test results within these constraints. To assist the limited resources laboratory, this document will include minimal standards of adherence necessary for good microbiology laboratory practices. (M46)

Chairholder: Susan Sharp, Ph.D.
Kaiser Permanente – NW

Principles and Procedures for Blood Cultures

This guideline is intended to provide guidance to clinical microbiologist for the recovery of pathogens from blood specimens taken from patients who are suspected of having bacteremia or fungemia. Specific recommendations will be offered for the collection, transport, and processing of blood cultures. (M47)

Chairholder: Michael L. Wilson, M.D.
Denver Health Medical Center

Laboratory Diagnosis of Mycobacterial Infections

This guideline is intended to provide guidance to laboratories on the total testing process for patients with suspected mycobacterial infections. Recommendations will be offered for the collection, preservation and transport of clinical specimens. Procedures for the direct detection of mycobacteria by microscopy and amplification techniques, the optimal recovery of mycobacteria from clinical specimens, and the identification of mycobacterial species by traditional (phenotypic) and alternative (phenotypic and genotypic) laboratory methods will be addressed. (M48)

Chairholder: Betty A. Forbes, Ph.D.
Medical College of Virginia

Methods for Dilution Antimicrobial Susceptibility Testing of Bacteria Isolated from Aquatic Animals

This report will provide the most up-to-date techniques for broth and agar dilution susceptibility testing of aquatic species isolates, and criteria for quality control testing. (M49)
Co-Chairholders: John P. Hawke, Ph.D., Louisiana State University, and Renate Reimschuessel, Ph.D., V.M.D., Center for Veterinary Medicine, FDA

Molecular Methods

Genotyping for Infectious Diseases: Identification and Characterization

Genotyping for infectious agents has become the standard of care in a variety of clinical settings. Applications include: (1) detection of drug resistance for selection and/or monitoring of drug therapy (HIV, HBV, M. *tuberculosis*, and CMV); (2) disease management (viral typing of HCV to determine the duration of therapy); and (3) diagnostic algorithms (HPV typing to determine risk of malignancy). These assays are widely used in clinical laboratories. This guideline will provide recommendations regarding quality control, quality assurance, proficiency testing, control material, and interpretation. (MM10)

Chairholder: Stephen P. Day, Ph.D.
Third Wave Molecular Diagnostics
Vice-Chairholder: Max Arens, Ph.D.
Washington University School of Medicine

Molecular Methods for Bacterial Strain Typing

As infectious agents disseminate throughout the world, epidemiologic questions will continually be raised about modes of transmission. This guideline will describe procedures and interpretive criteria for the most commonly used typing methods to aid in standardizing the interpretation of results and, thus, strengthen epidemiologic studies of infectious diseases. This will assist both microbiologists and epidemiologists involved in outbreak investigations by reducing the variability of interpretations from field stations. (MM11)

Chairholder: Robert D. Arbeit, M.D.
Cubist Pharmaceuticals, Inc.

Molecular Methods for Microarrays

The use of microarrays in gene expression analysis represents an emerging technology that will soon be widely used in healthcare testing. To address this technology in a proactive manner, the Area Committee on Molecular Methods will establish guidelines for analytical and clinical verification, *in vitro* diagnostic product validation, and quality management, based on the quality system approach. Preanalytical, analytical, and postanalytical considerations will be addressed. (MM12)
An NCCLS–IFCC joint project.

Chairholder: Joseph L. Hackett, Ph.D.
FDA, CDRH

Sample Collection and Handling for Molecular Test Methods

Biological specimens sent to molecular diagnostic testing laboratories include body fluids such as blood or urine, aspirates containing fluid and cells, and tissue samples of every variety. Currently, there are no standard methods for collecting, transporting, or storing specimens to be used for molecular test methods. This document will provide guidelines for handling specimens of various types and will address the stability and integrity of specimens as they pertain to standard molecular analytical methods. (MM13)
An NCCLS–IFCC joint project.

Chairholder: Lynne Raimen, Ph.D.
BD Vacutainer Systems

Determining Clinical Utility of Genetic Tests

Several government advisory committees have recently advocated that genetic testing not be performed unless "clinical utility" has been clearly demonstrated. However, this concept does not yet have a defined form in law, regulation, or guideline. The proposed project will focus on the benefits and challenges of genetic knowledge and genetic testing. The consensus guideline will provide means by which users (i.e., regulatory agencies, laboratorians, clinicians) can evaluate potential clinical utility in all phases of genetic testing. (MM15) An NCCLS–IFCC joint project.

Chairholder: Timothy J. O'Leary, M.D., Ph.D.
Armed Forces Institute of Pathology

Reports

Metrological Traceability and Its Implementation

This document, being developed as a report, will provide guidance to manufacturers of IVD devices and associated materials (e.g., calibrators), on compliance with ISO 17511 and ISO 18153. It will explain traceability and where it fits in the clinical enterprise, and will include information regarding validation of comparisons, commutability, and uncertainty.
Chairholder: Marc L. Salit, Ph.D.
NIST

ISO/TC 212

ISO 18113

Clinical laboratory testing and *in vitro* diagnostic test systems – *In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling)

Part 1: General requirements
This International Standard will specify general requirements for information supplied by the manufacturer of *in vitro* diagnostic test systems.

Part 2: *In vitro* diagnostic reagents for professional use
This International Standard will specify requirements for information supplied by the manufacturer of *in vitro* diagnostic reagents, for professional use. This Standard will also apply to information supplied by the manufacturer with calibrators, control materials and accessories intended for use with *in vitro* diagnostic reagents for professional use.

Part 3: *In vitro* diagnostic instruments for professional use
This International Standard will specify the requirements for the contents of instructions for use for *in vitro* diagnostic instruments including apparatus, equipment, calibrators and control materials for professional use.

Part 4: *In vitro* diagnostic reagents for self-testing
This International Standard will specify requirements for information supplied by the manufacturer of *in vitro* diagnostic reagents, for self-testing. This Standard will also apply to information supplied by the manufacturer with calibrators, control materials and accessories intended for use with *in vitro* diagnostic reagents for self-testing.

Part 5: *In vitro* diagnostic instruments for self-testing
This International Standard specifies the requirements for the contents of instructions for use for *in vitro* diagnostic instruments including apparatus, equipment, calibrators and control materials for self-testing.

ISO/AWI 20776

Antimicrobial Susceptibility Testing

This project will be composed of two parts which are linked: 1) Standardization of reference method(s) for *in vitro* testing of the susceptibility of bacteria with importance in human infections against antimicrobial agents and; 2) Standardization in the field of bacteriology relating to the performance of antimicrobial susceptibility devices which are used for testing the susceptibility of bacteria to antibiotics in most medical laboratories. The standards will be developed as a joint activity of ISO/TC 212 and CEN/TC 140.

NCCLS Videotapes

H4-A3-V

Quality Microcollection

Details are given on the importance of blood collection and handling using the skin puncture method. The video also illustrates how to obtain the highest quality skin puncture specimen for laboratory testing. It is divided into six sections: safety, advantages, supplies, skin puncture procedure, handling and labeling, and a review of the skin puncture procedure. Based on H4-A3 standard, the video package includes the video, a copy of the H4-A5 standard, and three laminated summary sheets. For more information on this document, see the entry in the Hematology section. (18 min.)
Members $95 Nonmembers $175

LA4-A3-V

Making a Difference Through Newborn Screening: Blood Collection on Filter Paper

This video provides a visualization of each step in the blood specimen collection process and depicts the standard of practice, as defined by the NCCLS consensus process, for collecting such specimens on filter paper. It explains how to select and prepare the safest puncture site; choose the appropriate equipment; puncture the skin and apply blood to filter paper; care for the puncture site; identify and verify a valid specimen; and handle and mail the specimen to the laboratory. LA4-A4 accompanies the videotape, along with laminated summary sheets. For more information on this document, see the entry in the Immunology and Ligand Assay section. (25 min.)
Members $95 Nonmembers $175

Additional laminated sheets can be purchased separately in sets of 10.
Members $25 Nonmembers $50

Includes M2-A8 and the M100 tables!

M2-A5-V

Disk Susceptibility Testing: Step By Step

This video illustrates preparation and standardization of a test inoculum; inoculation of plates; and reading of zone sizes. It also explains in detail the use of tables when interpreting results and outlines the criteria for quality control testing. A special trouble-shooting section is included, depicting the possible results when an inoculum is incorrectly made, when the plates are streaked improperly, or when the disks are applied inappropriately. The M2-A8 standard accompanies the videotape, along with laminated summary sheets. For more information on this document, see the entry in the Microbiology section. (23 min.)
Members $95 Nonmembers $175

M29-A2-V

Preventing Blood-borne Pathogen Infection: Improved Practice Means Protection

Designed to reduce the risk of acquiring an infectious disease, this educational videotape provides authoritative and practical safety recommendations. This videotape explains standard and contact precautions that should be practiced to protect the laboratorian, and provides a visualization of proper techniques to implement these precautions. Along with the M29-A2 guideline, this educational video will be useful in forming the foundation for your OSHA-required yearly blood-borne pathogen safety training. Laminated summary sheets are also included in the videotape package. For more information on this document, see the entry in the Microbiology section. (21 min.)
Members $115 Nonmembers $200

Also available in DVD.
Please indicate M29-A2-DVD on order form.

VIDEO DISCOUNTS

Discounts for multiple copies of the *same* title are offered.
See page 36.

Visit the NCCLS on-line store at: www.nccls.org

NCCLS

POWERED BY NEXTpage

Infobase 2004

NCCLS Infobase 2004 is a searchable electronic library of 133 approved NCCLS standards and guidelines. Developed using the latest information-management software published by Nextpage, this CD-ROM is intended to help you quickly and easily locate NCCLS's recommendations on clinical laboratory and medical-testing procedures and protocols.

You can query all NCCLS approved standards and guidelines by locating single words or phrases used in the text.

This retrospective database contains all NCCLS approved-level standards and guidelines published as of 31 December 2003.

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- Microsoft Windows 98/2000/XP, or Microsoft Windows NT Workstation operating system version 4.0 or later
- 64 MB of memory for use on Windows 98/2000/XP or NT Workstation (Recommendation: 128 MB of memory for use on Windows 98/2000/XP or NT Workstation)
- One dual-speed CD-ROM drive
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Shipping/Handling (flat rates)

Shipping and handling for within North America	$7.50
Shipping and Handling for outside North America	$25.00

NCCLS TOOLKITS

GP2-A4-C The NCCLS Procedure Manual Toolkit

Improving procedure writing in the clinical laboratory

The major concepts of document control are presented in a user-friendly format that is easy to read and implement, thanks to the Toolkit CD. The CD includes the following nine templates with illustrative examples that provide the framework for developing procedures and communicating and organizing information:

- Analytical quantitative procedures;
- Analytical qualitative procedures (e.g., dipstick, slide, immunohematology tests, etc.);
- Pre- and post-nonanalytical procedures;
- Analyzer procedures;
- Laboratory information system procedures;
- Master document index (an Excel template is also included to facilitate sorting of data);
- Document change request form for approving new documents or changing previously approved documents;
- Comparison of analytic-specific attributes by analyzer type; and
- Analytic attributes for analyzers.

These templates enable one to establish a starting point for creating one's own laboratory-specific procedure manual. The templates allow the user to enter information into a "boiler plate" file where the parameters are preformatted – headers and footers are set. The user can simply open the template and fill in the blanks. A few samples are provided so that the user has a visual representation of the various sections of the completed procedure.

The *Toolkit* includes a copy of the revised, approved-level document GP2-A4—*Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition* in PDF format and the *Toolkit* User Manual.

This essential *Toolkit* is applicable to any size laboratory, and will be a valuable resource for creating quality procedures.

System Requirements

- Microsoft Windows 98/NT/2000/XP
- Microsoft Word for Windows 2000/2002/2003

Members: $120 **Nonmembers: $235**

HS1-A-C The NCCLS Quality System Toolkit

The **NCCLS Quality System Toolkit** is based on NCCLS document HS1-A—A *Quality System Model for Health Care; Approved Guideline*, which provides useful information for designing, implementing, and maintaining an effective quality system.

The **Toolkit** is a powerful device for implementing HS1-A. It lays the foundation for:

- developing quality policies based on Quality System Essentials;
- outlining quality processes;
- controlling documents; and
- reporting and tracking occurrences.

In addition to the guideline and a *User Manual*, the **Toolkit** includes templates for developing, in a consistent format, documentation that supports your quality system.

The **Toolkit** includes the following Microsoft Word templates:

***Policy or process creation*:**
- Quality Policy Template
- Quality Process Template
- Flowchart Template

***Document management*:**
- Master Document Index*
- Document Change Request Form

***Occurrence management*:**
- Occurrence Report Form Template
- Occurrence Tracking Form Template

*In addition, Excel documents for the Master Document Index and Occurrence Tracking Form are included to facilitate sorting of data.

System Requirements

- Microsoft Windows 98/NT/2000/XP
- Microsoft Word for Windows 2000/2002/2003
- Microsoft Excel (for two templates that are duplicated in Word)

Members: $120 **Nonmembers: $235**

The Complete NCCLS Library of Standards and Guidelines

Pricing for the NCCLS Library

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(set of five)
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Nonmembers $20
plus shipping and handling as follows:
North America – $7.50
Outside North America – $10.00

Pricing for Three-Ring Binder

Members $20
Nonmembers $20
plus shipping and handling as follows:
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EP21-A-C

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This software add-in is based on *EP21-A, Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline*, which provides users with a means to estimate total analytical error for an assay. Total Error Estimator is a powerful tool for implementing the protocols for judgment of the clinical acceptability of new methods using patient specimens and/or monitoring an assay's total analytical error by using quality control samples, as described in EP21-A.

System Requirements:

This software has been developed for the following Microsoft® Excel versions for Office 97 or later using Windows® 95 or later as the operating system.

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M100 CD-ROM

Performance Standards for Antimicrobial Susceptibility Testing

This CD-ROM includes all of the M100-S15 tables for the NCCLS Disk Diffusion (M2) and Aerobic Dilution (M7) susceptibility testing documents. The corresponding methodology documents, M2-A8 and M7-A6, are also included on the CD-ROM.

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X3-R

Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report

This report presents a step-by-step approach for implementing safer medical devices that reduce or eliminate sharps injuries to laboratory personnel. X3-R is written in an expanded checklist format, outlines a process that goes beyond general recommendations, and specifically addresses the needs of professionals performing specimen collection and clinical laboratory procedures. It outlines the important steps laboratory professionals must take to:

- identify devices that have the potential for causing injury;
- select safer medical devices for evaluation;
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- implement a continuous quality improvement process.

Members: $65 **Nonmembers $150**

The NCCLS "Needlestick Report" is an essential reference source for implementing requirements of the *Revised OSHA Bloodborne Pathogen Standard*, as well as analyzing and improving practices, with the goal of providing a safer work environment.

Working Group on Needlestick Prevention

Geraldine L. Barnes, M.T.(ASCP), M.S., NCCLS
M. Clare Edelmayer, M.T.(ASCP), R.N., M.S., Doylestown Hospital
Beverly Kovanda, Ph.D., Columbus State Community College
Donna M. Meyer, Ph.D., CHRISTUS Health
David Sewell, Ph.D., Veterans Affairs Medical Center

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Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

This document provides guidance on steps to be taken by the clinical laboratory to be prepared in the event of an emergency. X4-R is written for use by laboratory managers, directors, and supervisors, and is intended to provide a checklist of considerations to be used to assess preparedness and begin planning for continuance and redirection of clinical laboratory services during emergency situations.

Members: $65 **Nonmembers $150**

Working Group on Emergency Response

J. Rex Astles, Ph.D., FACB, Centers for Disease Control and Prevention
Thomas L. Hearn, Ph. D., Centers for Disease Control and Prevention
Lawrence B. Kaplan, Ph.D., FACB, Bellevue Hospital Center
Anthony R. Sambol, MA, SM(NRM), SV(ASCP), CBSP, Nebraska Health and Human Services System
Thomas L. Williams, M.D., FACB, FASCP, FCAP, Methodist Hospital

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Performance Standards for Antimicrobial Susceptibility Testing

Clinicians depend heavily on information from the clinical microbiology laboratory for treatment of their seriously ill patients. The clinical importance of antimicrobial susceptibility test results requires that these tests be done under optimal conditions and that laboratories have the capability to provide results for the newest antimicrobial agents.

This document includes all of the tables from the NCCLS Disk Diffusion (M2) and Aerobic Dilution (M7) susceptibility testing documents. M100-S15 includes new antibiotic breakpoints. There are significant changes to the tables that have resulted from recent meetings of the Subcommittee on Antimicrobial Susceptibility Testing.

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Active Members include professional, clinical, and trade associations; government agencies; medical-testing consultants; and large and small companies in the medical-testing and *in vitro* diagnostic products fields. These organizations participate through representation on committees and voting on technical and administrative issues in the development and evaluation of standards and guidelines. Government, professional societies, and trade organizations can have two representatives, a delegate and an alternate delegate.

Associate Active Members are those Corresponding Member institutions interested in a broader level of participation in the voluntary consensus process. This membership allows institutions to receive all proposed and tentative standards and guidelines and to vote on all candidate-for-advancement standards and guidelines.

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- **Comprehensive** is for institutions interested in receiving documents in both printed and electronic formats.
- **Core** is well suited for institutions performing a broad spectrum of medical testing in all disciplines covered by NCCLS standards and guidelines at a single site.

Corresponding Members include teaching institutions, hospitals, clinics, and independent laboratories. These members receive NCCLS approved-level documents. NCCLS offers a wide range of Corresponding Membership categories from which an organization can choose based on its level of involvement in medical testing and specific interests and needs. There are four levels of Corresponding Membership from which to choose:

- **Comprehensive** is for institutions interested in receiving documents in both printed and electronic formats.
- **Core** is well suited for institutions performing a broad spectrum of medical testing in all disciplines covered by NCCLS standards and guidelines at a single site.
- **Customized** is tailored for small institutions or departments performing specialized, discipline-specific, or a limited number or variety of medical tests.

  NEW — Choice of receiving documents in electronic or printed format.
- **Basic** is our basic membership category. This level is designed specifically for organizations interested in, and who want to stay informed of, NCCLS activities, and who may only need to purchase an occasional standard, guideline, or other NCCLS product.

Education Members are formally organized education programs concerned with the primary education of professionals involved with medical testing. The membership provides an important communication network allowing educators to seek solutions to educational issues from other professionals in the field.

NOTE: The approved-level Automation documents (AUTO 1-5) must be purchased separately.

Special Thanks to NCCLS's Sustaining Members

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NCCLS Membership Application

Date: _____

Please Indicate Level of Membership
(See previous page for description)

ACTIVE MEMBERS

Please indicate organization type, and details on annual dues and benefits will be forwarded to you (check one):

☐ **Industry** (any manufacturer or supplier to the patient testing and *in vitro* diagnostic fields)
Annual dues are based on gross sales of products and proportional sales in allied fields.

- ☐ $2,000 (Gross sales to $500,000)
- ☐ $3,500 (To $2 million)
- ☐ $4,750 (To $5 million)
- ☐ $6,500 (To $10 million)
- ☐ $8,250 (To $25 million)
- ☐ $10,000 (To $50 million)
- ☐ $11,750 (To $100 million)
- ☐ $13,500 (To $250 million)
- ☐ $15,500 (To $500 million)
- ☐ $17,500 (To $750 million)
- ☐ $19,500 (To $1 billion)
- ☐ $21,500 (Over $1 billion)

Start-up Company dues are $1,000 per year.

☐ **Trade Assn.** ☐ **Gov't. Agency** ☐ **Prof. Society**
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Broad Interest dues are $3,300 per year.

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Annual dues are $700 for firms with 1-2 employees and $1,000 for firms with more than 3 employees.

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_____ Comprehensive $1,800 $ _____

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☐ **Comprehensive** $1,500**

☐ **Core** $1,100

****In order to be eligible for Healthcare Delivery Systems membership, contact names and addresses for each site MUST be included.***

*****Includes the Infobase on CD-ROM***

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☐ **Comprehensive** $1,300** ☐ **Core** $900

☐ **Customized** $600 ☐ **Basic** $300

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It's Official!

NCCLS's new organizational name, effective January 2005, has been approved:

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NCCLS

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