Part Two—Clinical Laboratory Standards of Practice

Richard Jenny, Ph.D., Director
Deirdre Astin MS MT(ASCP), Deputy Director
Clinical Laboratory Evaluation Program
New York State Department of Health
Wadsworth Center
518-485-5378
CLEP@health.state.ny.us
NYS DOH Standards of Practice

Development and Adoption Timeline

January 2005: Initiated standards updates and changes in logical design

December 2006: Distributed standards to laboratories with request for comment

February 2007: Comment period “closed”

September 2007: Responded to CDC review of standards for CLIA compliance; substantial equivalence

March 2008: Effective date with quality systems phase in
Reach of DOH Standards
Impetus for Revision of Standards

- Logical Design For Ease of Use
- Need to adopt principles of quality management systems
- 2004 CMS updates to CLIA standards
- Renewal of Exempt Status for the DOH Licensure Program
- GAO Report:
Testimony
Before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform, House of Representatives

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CLINICAL LABS

CMS and Survey Organization Oversight Is Not Sufficient to Ensure Lab Quality

Statement of Leslie G. Aronovitz
Director, Health Care
GAO Comments Relevant to NYSDOH

- Quality of Laboratories is Very Difficult to Measure in a Standardized Manner

- Insufficient Data on the Extent of Serious Laboratory Quality Problems
Influences on Revision of NYSDOH Standards

- CLIA’88
- GAO Critique
- CLSI
- ISO 15189: Medical Laboratories – Particular requirements for quality and competence

Quality Management Systems
Logical Design Objectives

- Consolidate numerous sources of regulatory requirements
- Identify practices that are fundamental to the reliability of services provided to clients
- Specify practice standards that sustain fundamental practices
- Establish a mechanism to document degree of compliance: recognize and acknowledge *Excellence*

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Quality: Characteristic or standard measure of excellence; basic characteristic of something. Quality is a measure of the degree to which something meets a standard. Jack P. Friedman, *Barron's Dictionary of Business Terms, Second Edition*
<table>
<thead>
<tr>
<th>Laboratory Name</th>
<th>Specialty Sustaining Standards</th>
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<tbody>
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**Clinical Laboratory Standards of Practice**

<table>
<thead>
<tr>
<th>Fundamental Practice Compliance Score</th>
<th>Microbiology</th>
<th>Bacteriology</th>
<th>Mycobacteriology</th>
<th>Mycology</th>
<th>Parasitology</th>
<th>Virology</th>
<th>Clinical Chemistry</th>
<th>Endocrinology</th>
<th>Ther Drug Monitoring</th>
<th>Blood pH &amp; Gases</th>
<th>Urinalysis</th>
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<tr>
<td>3.2</td>
<td>Quality Management System</td>
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<td>4</td>
<td>(QMS SSP1): Establishment of Specifications and Requirements</td>
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<td>(QMS SSP2): Internal Audits</td>
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<td>(QMS SSP3): Management Review</td>
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Survey Practices & Expectations: Overarching Principles

Develop a process and tools to fairly and accurately assess and document the quality of laboratory services.

- Effectiveness of leadership and competencies of staff
- Substantiation of reports of examination findings
- Degrees of compliance with practice standards; best practices
- Quality systems for sustained compliance and CQI
Survey Practices
Document Control & Process Validation

Substantiation of reports of examination findings

- Recreate the test process through document control
- Verify the test process complies QMS specifications
Quality Systems Document Control: Cause and Effect

- Human Resources
- SOPM
- Examination Procedures
- Quality Assessment

Training
Competency Assessment

Facilities & Equipment
Pre-Examination Procedures
Post-Examination Procedures

Patient Report

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Quality Systems Document Control

- Human Resources (HR)
  - Training
  - Competency Assessment
- SOPM
  - Approval
  - Version Control
    - Excerpts
- Patient Report
  - Reagents
    - Verification
    - Inventory Control
  - Equipment
    - Function Check
    - Maintenance
  - General Facilities
    - Monitor and Control
- Facility Design & Resource Management (FDRM)
Quality Systems Document Control

Diagram showing the flow of processes and interactions, including:
- Human Resources (HR)
- SOPM
- Reagents
- Specimen Storage & Processing
- Facility Design & Resource Management (FDRM)
- Pre-Examination Procedures

Key nodes and connections:
- Training
- Competency Assessment
- Version Control
- Approval
- Excerpts
- Accession, Order Entry Verification
- HR
- Facility Collection Manual
- FDRM
Quality Systems Document Control

- Human Resources (HR)
  - Training
  - Competency Assessment
- SOPM
  - Approval
  - Version Control
  - Excerpts
- Examination Procedures
  - Method Validation
  - Reagents (FDRM)
  - Equipment (FDRM)
  - Calibrators, QC
  - Analytical Records (worksheets, instrument)
  - Environmental Controls (FDRM)
- Patient Report

- Reagents
  - inventory control
  - function check
  - maintenance
  - verification
- Equipment
- General Facilities
  - monitor and control
- Facility Design & Resource Management (FDRM)
- Specimen Storage & Processing
  - Aliquot Positive Identification
  - Accession, Order Entry Verification
  - FDRM
- Pre-Examination Procedures
  - Specimen Collection Manual
- Post-Examination Procedures
- Reporting
  - verification of transmission critical values
  - HR
- Process Review
  - Analyst
  - Supervisory
Quality Systems QC Design

Analytical System Design Capabilities

- Performance Characteristics
- Calibration Stability

Historical Performance

- Risk Reduction Requirements

Manufacturer Recommendations

- Regulatory Requirements

PT Allowable Errors

Minimum QC Design Requirements

Consensus Practice Guidelines

Client Physician Requirements

Analytical Goals

Clinical Requirements

Quality Control Design

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Standard: The laboratory shall design internal quality control systems that verify that the intended quality of results is achieved.

Laboratory Practice:

Degree of Compliance: 0 2 3 4
# Table 4. Distribution of laboratories and unsatisfactory PT performance within intervals of internal QC program allowable errors.

<table>
<thead>
<tr>
<th>Allowable error Interval, %</th>
<th>Frequency of use</th>
<th>Number of analytes(a) with unsatisfactory performance rating</th>
<th>Rate of unsatisfactory performance, %</th>
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<tbody>
<tr>
<td></td>
<td>All methods</td>
<td>Abbott X-systems</td>
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</tr>
<tr>
<td>≥2.5 to &lt;7.5</td>
<td>157</td>
<td>91</td>
<td>0.0</td>
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<tr>
<td>≥7.5 to &lt;12.5</td>
<td>290</td>
<td>184</td>
<td>0.7</td>
</tr>
<tr>
<td>≥12.5 to &lt;17.5</td>
<td>123</td>
<td>69</td>
<td>2.4</td>
</tr>
<tr>
<td>≥17.5 to &lt;22.5</td>
<td>188</td>
<td>123</td>
<td>2.7</td>
</tr>
<tr>
<td>≥22.5</td>
<td>32</td>
<td>8</td>
<td>12.5</td>
</tr>
</tbody>
</table>

\(a\) Data are for carbamazepine, phenobarbital, and theophylline methods.

Standard: The QMS shall establish specifications and requirements for quality control practices that monitor the conformance of the entire test process to specified requirements.

Laboratory Practice:

Degree of Compliance: 0 2 3 4
Quality Management System

A system that outlines the policies and procedures necessary to define, control and improve the many processes that will ultimately lead to laboratory services of recognized value.

Value to regulatory agencies with the duty to judge and approve services for patient care: *Confidence* that compliance with practice standards is by design and is systematic; not by chance.
Quality System Cycle

**Define Quality Goals & Process Objectives**

- Establish Policies / Procedures
  - delegation
  - Responsible Person(s)

**Approval**

- **Review**

- Implementation
  - Responsible Person(s)
  - Monitors

**Quality Improvement Initiatives**

- **Outcomes Analysis**

**Director Leadership Imperatives**

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Quality Management System Sustaining Standard of Practice 1 (QMS SSP1): *Establishment of Specifications and Requirements*

The quality management system shall establish specifications and requirements for:

a) qualifications, responsibilities, authority and interrelationships of all personnel;

b) adequate training and competency evaluation of all staff and supervision by competent persons conversant with the purpose, procedures, and assessment of results of the relevant examination procedures;

c) management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties;
Quality System Cycle

Quality Goal: A competent, productive and engaged workforce
Process Objectives: Training programs aligned with employee responsibilities and measurable outcomes of competency

Establish Policies / Procedures
- Job descriptions
- Delegation of responsibilities
- Qualifications
- Training
- Competency assessment - performance measures
- Continuing education
- Employee development
- Resources, Support

**Approval**

**Review**

Implementation
- Recruitment
- Timely training and competency assessment
- Measured performance
- Intervention
- CE opportunities & participation
- Engagement in CQI

Responsible Person(s)

Monitors

Quality Improvement Initiatives
- Recruitment
- Resources, Support
- Engagement in CQI

**Outcomes Analysis**

**Director Leadership Imperatives**

New York State Department of Health
Quality Management System Sustaining Standard of Practice 1 (QMS SSP1):

Establishment of Specifications and Requirements

The quality management system shall establish specifications and requirements for:

- protocols for test request, patient preparation, specimen type, collection, handling and processing;
- specimen acceptance and rejection criteria;
**Quality System Cycle**

Quality Goal: Acquisition of proper specimens for examination
Process Objectives: Provision of instructions and resources to personnel responsible for the collection, handling and referral of specimens as necessary to ensure receipt of quality specimens

- Define requirements for specimen collection and handling
- Establish procedures for specimen collection, identification, handling and referral
- Define compliance monitors and intervention strategies

**Delegation**

**Approved Person(s)**

- Collector education
- Measure compliance with information and specimen quality requirements
- Rejection of unsuitable specimens
- Intervention for improved collector compliance

**Quality Improvement Initiatives**

**Outcomes Analysis**

**Director Leadership Imperatives**
The quality management system shall establish specifications and requirements for:

- identification and resolution of nonconformities;
- complaint investigations;
Quality System Cycle

Quality Goal: Timely and effective resolution of non-conformance

Process Objectives: Assess outcomes of non-conformance and need for risk management; identify root causes; timely implementation of plans for resolution; monitor effectiveness of corrective action.

- Establish Policies / Procedures
  - Define process for risk assessment and notification
  - Establish procedures for the identification of root cause and action plans
  - Define conditions and authorization for resumption of examinations

- Implementation
  - Cease examinations and provide notification, as necessary
  - Develop and implement action plans to address root causes
  - Assess effectiveness of intervention
  - Obtain authorization for resumption of examinations

- Responsible Person(s)
- Monitors
- **Outcomes Analysis
  - **Approval
  - **Review
  - Quality Improvement Initiatives

**Director Leadership Imperatives

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QA & Improvement: The laboratory shall have a policy and procedures for the resolution of complaints and other feedback from clinicians, patients and laboratory personnel.
Survey Outcomes

QMS Status

QMS

Ideal Outcome

Investigate System
Address Citation Systematically

Non-Compliant

Standards Compliance

Compliant

No QMS

Quality Systems Watch

Poor Outcome
Administrative Action

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January 2008: Effective date with quality systems phase in

- All laboratories will receive the benefit of a survey to assess degree of compliance with quality system standards
- Quality system survey outcome will be considered educational on first survey
- Evidence of compliance with updated practice standards is expected during surveys commencing January 2008
Communication between DOH and Laboratories is Critical

They’re still laughing about this at IBM.

Apparently the computer giant decided to have some parts manufactured in Japan as a trial project.

In the specifications, they set out that the limit of defective parts would be acceptable at three units per 10,000.

When the delivery came in there was an accompanying letter.

_We Japanese have a hard time understanding North American business practices. But the three defective parts per 10,000 have been included and wrapped separately. Hope this pleases._
Outreach

March 2008 Standards Adoption

- Encourage meetings with laboratory groups
- Webinars
- Toolkit for Best Practices

Contact:
CLEP Mailbox: clep@health.state.ny.us
Richard Jenny: rwj03@health.state.ny.us
Deirdre Astin: daa03@health.state.ny.us
CLEP Phone: 518-402-2972