Clinical Laboratory Evaluation Program
Part One—Program Overview

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
Agenda

Part One: Program Overview

Part Two: Clinical Laboratory Standards of Practice and Survey Tools

Part Three: Case Studies

• Establishment of System Specifications and the Role of the Laboratory Director
• Training and Competency of Laboratory Personnel
• Single-Use Device Quality Control
Part One-Program Overview

Survey Process

- Revised Standards of Practice, Survey Tools

Compliance and Enforcement

- Enforcement Focus

Personnel

- SED Licensure
Reorganized Standards of Practice

Existing Standards Reorganized; Eleven Fundamental Standards, Compliance With Each is Evaluated Using a Set of Sustaining Standards:

Quality Management System
Human Resources
Director Involvement
Facility and Resource Management
Standard Operating Procedures
Pre-Examination Procedures
Examination Procedures
Post-Examination Procedures
Quality Assessment and Improvement
Proficiency Testing Participation
Public Health Preparedness and Reporting
Standards-New Numbering System

Quality Management System

Fundamental Standard of Practice 1 (QMS FSP1)
(QMS SSP1): Establishment of Specifications and Requirements
(QMS SSP2): Internal Audits
(QMS SSP3): Management Review
(QMS SSP4): Documentation of Review Outcomes
(QMS SSP5): Quality Manual

Human Resources

Fundamental Standard of Practice 1 (HR FSP1)
(HR SSP1): Director Responsibilities
(HR SSP2): Director Involvement
(HR SSP3): Organizational Plan
(HR SSP4): Personnel Records
(HR SSP5): Supervision
(HR SSP6): Technologists
(HR SSP7): Competency Assessment
<table>
<thead>
<tr>
<th>Standards-New Requirements</th>
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<tbody>
<tr>
<td><strong>Quality Management System</strong></td>
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<tr>
<td>Existing: Planned and Systematic QA Activities; Director Involvement</td>
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<tr>
<td>New: Laboratory must: establish specifications and monitors for lab operations; have a system to audit these on an ongoing basis; appoint a Quality Manager; and have a Quality Manual</td>
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<td><strong>Human Resources</strong></td>
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<td>Existing: Part 19 and Part 58 Duties and Responsibilities for Personnel, Cytotechnologist Registration and Workload, and Competency Assessment and Continuing Ed</td>
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<tr>
<td>New: Laboratory must: have an organizational plan and job descriptions; conduct competency assessment for all levels of staff (including managers and supervisors). Specific responsibilities for supervisors and techs added to conform to CLIA</td>
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# Standards-New Requirements

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<th>Director Involvement</th>
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<tr>
<td>Incorporates Part 19 and Part 58 requirements for Directors</td>
<td>Focus on ensuring the director takes an active role in the laboratory and fulfills all the duties in 19.3c-now a Fundamental Standard.</td>
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<th>Facility and Resource Management</th>
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<td>Includes requirements for Environmental Controls (temperature monitoring, cleanliness and adequacy of space) Equipment (PM and function checks) Reagents (verification and inventory control) Safety, and LIMS</td>
<td>Laboratory environment must be suitable for the tasks to be performed, all necessary equipment and reagents must be provided; there must be protocols for contingencies (i.e., backup power) and for managing defective equipment.</td>
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# Standards-New Requirements

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<td><strong>Standard Operating Procedures</strong></td>
<td>Includes all current standards (GEN 23 to GEN 30) for content, format, review and approval of SOP's</td>
<td>Manufacturers manuals or package inserts will still be accepted but must be supplemented by lab-specific procedures (such as specimen handling and results reporting). Focus on SOP’s kept accurate and up to date; if bench notes or quick excerpts are used they must be approved.</td>
</tr>
<tr>
<td><strong>Pre-Examination Procedures</strong></td>
<td>Includes current Part 58 requirements for orders, specimen handling, processing and referral</td>
<td>More details required on requisitions; laboratory must ensure that specimens must be transported and stored properly, laboratory must have a collection manual.</td>
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## Standards-New Requirements

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<td>Current validation, calibration, and QC requirements from General Standards</td>
<td>QC systems must be designed to ensure that the intended level of quality is attained; external QC for single-use devices can be run less frequently, depending on the laboratory’s assessment of the integrated controls.</td>
<td></td>
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<p>| Post-Examination Procedures | Reporting, Specimen and Records Retention, Confidentiality | Labs must have criteria for release of results (Process Control) and for interpretation; updated retention requirements for records. |</p>
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<td>Quality Assessment and Improvement</td>
<td>Incorporates many of the existing QA Standards</td>
<td>Requirements for ongoing monitoring and QA, resolution of non-conformances and complaints, corrective action</td>
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<tr>
<td>Proficiency Testing Participation</td>
<td>Existing PT Standards</td>
<td>Increased focus on enforcement, compliance and proper PT handling; included established procedures for handling unsatisfactory and unsuccessful performance</td>
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Standards-New Requirements

Public Health Preparedness and Reporting

**Existing**
- Requirements for reporting communicable diseases and reportable conditions to the Department contained in various regulations

**New**
- All existing reporting requirements now compiled in document.
  - Laboratories must have preparedness protocol, e.g., procedures for handling intentional or natural disasters
Standards-New Challenges

- Quality Management Systems-Expectations for establishing a comprehensive QMS and conducting internal audits will take time to implement.

- Expectations that laboratories should be able to track reagents to specific test runs and have the capability to produce instrument printouts (for two years) to support the test process may require enhanced LIS and/or instrument data storage capabilities.

- Increased focus on training and competency-for technical and non-technical personnel.
Survey Process

Evaluating Degrees of Compliance

Surveys will provide feedback on each Laboratory’s Degree of Compliance with the Fundamental Standards, based on an evaluation of each of the Sustaining Standards.

Part One: Compliance with Fundamental Standards of Practice

Quality Management System Fundamental Standard-The laboratory director and owner are jointly and separately responsible for laboratory operations and shall exercise authority for the design, implementation, maintenance and improvement of a quality management system for the delivery of services that meet the needs of patients and all clinical personnel responsible for patient care.

The laboratory meets minimum requirements for this Fundamental Standard; however, deficiencies have been cited that require correction.

Human Resources Fundamental Standard-The laboratory shall have effective leadership and personnel with education, training and experience commensurate with the complexity of services provided and as necessary for the design, validation and delivery of clinically useful laboratory services.

The laboratory does not meet minimum requirements for this Fundamental Standard; deficiencies have been cited that require immediate correction.

Facility Design and Resource Management Fundamental Standard-The facility design and resource management, applicable to general facilities, laboratory equipment, laboratory information systems, reagents and laboratory safety, must meet specifications established by the laboratory’s quality management system, shall be in substantial compliance with the requirements of this part, and identified non-conformance does not present imminent jeopardy to the integrity of laboratory services, to employee safety, or to patient care.

The laboratory meets minimum requirements for this Fundamental Standard except for the following categories: Bacteriology, Mycobacteriology

Operating Procedures and Compliance Fundamental Standard-The laboratory shall have a standard operating procedure manual (SOPM) that describes completely and accurately all procedures that have been validated and approved for use in the pre-examination, examination, and post-examination phases of laboratory services, and be in substantial compliance with requirements provided in Operating Procedures Sustaining Standards of Practice, SOPM SSP1 through SSP7.

The laboratory exceeds minimum requirements for this Fundamental Standard.

Pre-Examination Procedures Fundamental Standard of Practice-The laboratory shall be in substantial compliance with Examination Requisition and Specimen Processing Sustaining Standards of Practice as required for establishing and maintaining: integrity of patient and specimen identification, stability of specimens, and, completeness and accuracy of information essential to the interpretation and reporting of examination results.

This Fundamental Standard Practice has not been evaluated during this survey.
Survey Process - Degrees of Compliance

Compliance with each set of Sustaining Standards will be used to determine the laboratory’s Degree of Compliance with the corresponding Fundamentals

- Initially a qualitative assessment (does not meet minimum requirements, meets minimum requirements, exceeds minimum requirements)
- Eventually the Degree of Compliance will be a quantitative assessment (numerical grades to be phased in as laboratories and survey staff gain confidence in the new system)

Long-range: Grades may be made a matter of public record (DOH already makes public the evaluations of hospitals and physicians)
Survey Process-Plan of Correction

Increased expectations for Plans of Correction - Plans must *adequately* respond to the following questions:

1. Provide a brief explanation outlining the reasons why the deficiency occurred;

2. Describe the actions taken to correct this deficiency, and include the effective date;

3. Describe the steps that were taken to apply the corrective action to related areas of laboratory operations. Indicate whether any impact to patient care was identified and how it was resolved;

4. Describe in detail the systems that will be put into place to monitor the effective action and ensure it is maintained over time.
Survey Process-Plan of Correction

Top Ten Ways to Get Your Plan of Correction Rejected (and maybe even returned to you)

1. Omit the signature of the director or owner

2. Fail to provide an answer to all four parts of the corrective action template, or provide a non-answer, i.e., “not applicable”.

3. Refute the citation by claiming that the surveyor did not really see what they cited.

4. Attempt to reverse the citation by providing documents that were located after the surveyor left.

5. Don’t provide an effective date for implementing your plan of corrective action, or provide an unrealistic date (we fixed that yesterday….)
Survey Process-Plan of Correction

Top Ten Ways to Get Your Plan of Correction Rejected (and maybe even returned to you) continued…

6. Engage in finger pointing or lay blame on one individual instead of looking for root causes. If a mistake is made, it usually the system that is faulty and that’s what we want fixed.

7. State that the problem will be corrected because so-and-so was fired (See #6). Chances are this won’t solve the problem.

8. State there was no impact to patient care when the citation is clearly something that would adversely affect patient results.

9. Provide unrealistic plans to monitor whether corrective action is being sustained, or don’t provide any monitors at all.

10. Fail to “connect the dots” and don’t take a systemic approach towards corrective action (citations in different categories may be related…look for patterns).
Survey Process-Standardized Tools

Development of a Standardized Framework for the Survey Process-Survey Tools

- Entrance Conference
- Document Control (for selected analytes, laboratory must recreate the entire test process—will be used to assess compliance with the majority of the Standards of Practice)
- Laboratory Orientation—trace specimen path
- Quality Management System Review
- Specialty Surveys
- Personnel Interviews
- Assessment of Safety Practices
- Observed Practices (Transfusion, Point of Care)
- Public Health Preparedness and Reporting
- Exit Conference
Survey Process-Standardized Tools

Entrance Conference

- Key staff (including the director and owner/administrator) should attend (by phone if necessary). Surveyor will verify that the director has been informed of the survey.

- Surveyor will review prior surveys and any areas of concern, discuss objectives and propose a schedule and workflow for the survey, discuss documents that will be needed.

- Laboratory staff will present changes in operations since the last survey (new equipment, staffing, client base, additions and deletions to test menu, outreach services).

- Surveyor will review the laboratory’s table of organization; laboratory must provide job descriptions for key personnel and an orientation to lines of authority.

- Surveyor and laboratory staff will agree on the tests to be used for the Document Control survey tool.
Survey
Process-
Standardized
Tools
Document
Control-Exhibit 2

Laboratory must recreate the entire test process for selected patients, for selected analytes.

Document Control & Process Verification

Patient Report Selection

Specialty(ies): __________________________

The entrance interview will be used to identify those analytes and patient specimens to be selected for document control review. Criteria used to select examination procedure and patient report (check all that apply):

☐ Newly introduced test
☐ Newly hired or reassigned personnel
☐ Point-of-care tests
☐ High risk to patient management if erroneous results
☐ Proficiency testing poor performance
☐ Critical values
☐ Timely reporting required
☐ Specimen stability challenges
☐ Reportable to public health
☐ Consensus practice standards exist
☐ Examination platform encompasses multiple subspecialties

Examination Selection: __________________________

Patient Accession Identified: __________________________

Report Date: __________________________
Survey Process-Standardized Tools

Laboratory Orientation

- Tour of laboratory
- Trace path of specimen through the laboratory, starting with point of collection/accession

  - Specimen Handling: STATs, problem specimens, rejection protocols, ensuring integrity of specimen ID throughout the lab
  
  - Observation: (Safety practices, cleanliness, organized workflow, data entry verification)
  
  - Informal discussions with personnel (ask staff to explain what they are doing, why they are doing it, how they handle problems, etc)
Survey Process—Standardized Tools

Quality Management System Review

- Interview Quality Manager
- Review Quality Manual
- Discuss Quality Goals—how are specifications for the laboratory established (Hint—Director must be actively involved)
- Determine the measures the laboratory has in place to ensure specifications and goals are met
Survey Process-Standardized Tools

Specialty Surveys

- Go through requirements for applicable Specialty Standards of Practice
- May be done only for selected specialties, depending on samples selected for Document Control
- Evaluation of Proficiency Test Performance
- Participation by Assistant directors/ responsible CQ holders should participate
Survey Process - Standardized Tools

Personnel Interviews

- Go through Document Control packets
- Select individuals identified in Document Control others (including Directors, to verify degree of involvement in laboratory operations and knowledge of QMS)
- Verify job descriptions, reporting lines, knowledge of SOP, evaluate training and competency,
Assessment of Safety Practices

- Integrated throughout survey (specific category requirements e.g., TB)
- Observation of personal protective equipment use, eyewash stations, etc
- Training on safety, MSDS
- Medical Waste storage and disposal
Survey Process-Standardized Tools

Observation

- Required part of a survey for transfusion practice
- May be used to verify training and competency
- Point of Care testing practices can be observed

Show me.....
Survey Process-Standardized Tools

Public Health Preparedness and Reporting

- Verify compliance with reporting requirements (Communicable Disease, Blood Lead, Cancer Registry, Heavy Metals)
- Sampling of reports in selected areas to verify compliance

Laboratories have a vital role in Public Health Reporting…….
Survey Process-Standardized Tools

Exit Interview

- Discuss major areas of concern
- Review findings
- Give an assessment for each Fundamental Standard of Practice and discuss any specialty concerns
- Director and any Assistant Directors are expected to attend
Compliance and Enforcement

Intervention at the program level-before laboratories reach the stage where permit denial and/or fines are necessary

- Restrict test menu-no new categories or analytes will be approved if laboratory has substandard history
- Deny approval for new or additional directorships, if the individual has not demonstrated sufficient involvement and competence in other laboratories he/she directs
- Directed Plan of Correction, e.g., laboratory can be required to conduct a look-back and notify clients if survey reveals problems with test systems

These sanctions are reportable to CMS and will become part of their web-based laboratory registry.
Compliance and Enforcement

Enforcement Referrals

- Repeat Deficiencies—failure to implement a Plan of Correction considered misrepresentation, which is grounds for permit and/or CQ denial,
- Proficiency Testing—zero tolerance for referral of specimens or interlaboratory communication
- Director Oversight—directors must be actively involved in laboratory operations; assistant directorship where the individual has the only CQ for a category is treated as a directorship, for purposes of site limits
Laboratory Personnel Issues

State Education Department Licensure

- Special Provisions (*Grandparenting*) period is over as of September 1, 2007
- Survey staff will monitor compliance with SED licensure requirements
- Non-compliance will be reported to SED
Laboratory Personnel Issues

State Education Department Licensure

- Database of laboratory personnel will be compiled; goal is to have it available on the HPN for laboratories to update
- DOH will retain authority to qualify supervisors—currently must have six years of experience subsequent to qualifying (either via DOH or SED)
- Part 58 to be revised to align with SED requirements, DOH will continue to qualify non-NYS personnel.
What’s Next ????

Stay Informed

http://www.wadsworth.org/labcert/clep/clep.html

Stay in Touch

clep@health.state.ny.us