



# STATE OF NEW YORK DEPARTMENT OF HEALTH

Wadsworth Center

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## **Re: *Clinical Laboratory Standards of Practice***

Dear Laboratory Director:

This is to acknowledge the publication of the *Clinical Laboratory Standards of Practice*, the important contributions made by the laboratory community, and the timeline for implementation.

In December 2006, we sent a notice to all laboratories participating in the New York State Department of Health's clinical laboratory licensure program, announcing proposed revisions to the Laboratory Standards. More than 100 laboratories responded to our invitation to provide feedback and comments. Subsequently, we have received comments from CLIA federal agency reviewers, held an extensive series of outreach events across the State, and conducted field trials of new survey tools that implement the revised standards. The feedback has proven invaluable and is reflected in the final standards.

The *Clinical Laboratory Standards of Practice* document is comprised of two parts: *General Systems* and *Specialty Requirements*. The standards documents, responses to comments and the compilation of the changes made to the proposed standards are available at [www.wadsworth.org/labcert/clep/standards.htm](http://www.wadsworth.org/labcert/clep/standards.htm).

**The standards become effective March 1, 2008**, with the exception of a two year phase-in for full compliance with Quality Management Systems (QMS) requirements. All those commenting on QMS standards expressed support, but the majority stated concerns about their ability to institute change for full compliance in a short timeframe. Therefore, evaluations for compliance with QMS requirements on the initial survey beginning March 2008 will be educational. Laboratories will be expected to demonstrate a good-faith effort towards compliance with QMS standards. Effective March 2010, compliance with the QMS standards will become mandatory. Please be certain to review the compilation of changes to the standards, available on the website, as there have been some key changes in the areas of Quality Management Systems, Human Resources and Proficiency Testing Requirements.

Changes to *Specialty Requirements* were prompted by federal agency review for CLIA compliance. The *Specialty Requirements* will be revised further over the next year to incorporate technical updates and will be reorganized to conform to the hierarchy of the *General Systems* standards, with the exception of the specialty requirements for Forensic Identity and Forensic Toxicology, which have already been updated.

## **Program Updates**

The revision and reorganization of standards have prompted the evaluation of survey practices and policies. Program updates were discussed during outreach events this past year and are summarized below.

### *Laboratory Survey Practices and Resources*

A standardized approach to laboratory survey, including survey tools, has been developed. A key objective will be the assessment of the laboratory's ability to substantiate its reports of patient test findings and the integrity of resources used to produce those reports. Laboratories will be evaluated for compliance with practice standards and for the integrity of its quality systems. A handbook for laboratory quality assessment is being prepared to describe fully the survey process, tools used for quality assessment, and the laboratory's role in facilitating the survey.

### *Survey Reports*

The *General Systems* requirements are grounded in eleven *Fundamental Standards of Practice*. Each Fundamental Standard has associated Sustaining Standards that will be used to evaluate whether a laboratory is in compliance with the Department's minimum requirements for operation. Beginning March 2008, laboratories will receive, in addition to the standard Laboratory Evaluation Report or Deficiency Statement, a summary report that indicates the laboratory's degree of compliance for the respective Fundamental Standards. Laboratories will be informed whether they exceed, meet, or fail to meet minimum requirements. In the process of evaluating laboratories for degree of compliance, we expect to identify and build a database of best practices as a resource for quality improvement initiatives.

### *Proficiency Testing*

A message delivered at outreach events over the past year is the importance of the proper handling of proficiency test specimens. Sanctions for improper handling of proficiency test specimens, including referral of specimens to another laboratory for analysis **as well as** interlaboratory communication regarding proficiency testing results, are severe. Under federal regulations, a laboratory can lose its CLIA number and the laboratory owner and director can be banned from owning or operating (directing) a laboratory for two years. It is critical that you implement controls within your laboratory to ensure that **all** proficiency testing samples, regardless of source or purpose, are processed as routine patient specimens, and only to the extent that patient specimens are analyzed. Conditions that pose added risks for interlaboratory communications, requiring administrative policy for mitigation, include networked laboratories with shared management and resources, and staff working in more than one laboratory. In outreach events, we recommended that laboratory directors personally verify proper handling of proficiency test specimens prior to providing attestation and releasing test results.

Again, we thank the laboratory community for the opportunity to discuss laboratory practice standards and for the constructive feedback. Should you have additional questions or comments, please direct them to [clep@health.state.ny.us](mailto:clep@health.state.ny.us).

Sincerely,

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