NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED IMMUNOHEMATOLOGY STANDARDS

The Proposed Standards in the areas of Immunohematology were circulated for comment on March 13, 2014. The announcement and copies of the proposed standards with a crosswalk were sent to NYS-permitted facilities that held or were in application for a permit (facilities). This distribution was by e-mail to the facility and laboratory contact person’s e-mail address. The documents were also posted to the CLEP website.

The comment period ended April 28, 2014. There were 3 commenters from regulated parties and coalitions with 2 comments. Clarifications to the guidance of the Immunohematology Standard have been made based on the comments received.

Since there were no substantial changes, the standards are considered to be generally accepted and will be adopted as of June 13, 2014 with an effective date of July 14, 2014.

<table>
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<tr>
<th>Proposed Standard</th>
<th>Proposed Guidance</th>
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| Immunohematology Standard 8 (IH S8) | **Proposed Standard**  
Centrifuges used for testing of red blood cell agglutination:  
a) shall undergo RPM and timer checks quarterly;  
and,  
b) shall undergo a functional calibration to determine optimal centrifugation conditions prior to testing, after any repairs to the centrifuge, and on an annual basis.  

**Documentation of such checks and functional calibrations, which include records of actual results, shall be maintained.** |

Comment 1:  
In regard to Immunohematology Standard 8 (IH S8), the guidance states: “...shall undergo a functional calibration to determine optimal centrifugation conditions prior to testing, after any repairs to the centrifuge, and on an annual basis.”  

[We] propose the following modification: “...shall undergo a functional calibration to determine optimal centrifugation conditions prior to testing, after any functional repairs to the centrifuge, and on an annual basis.”  

[We are] concerned about the use of the word *any*, particularly whether assessors may regard this as a mitigation point. Functional calibration, especially of serological centrifuges, is a lengthy process. The level or stringency of testing performed following a repair is usually commensurate to the repair itself, and that is the correct approach. For example, calibration of the centrifuge following motor repair is certainly warranted, but re-calibration following repair of a lid latch would be inappropriate and overly burdensome. The proposed modification provides a conditional scope to repairs that would require calibration.
RESPONSE:
Guidance has been added to define the repairs to a centrifuge that would require functional calibration prior to use.

<table>
<thead>
<tr>
<th>Adopted Standard</th>
<th>Adopted Guidance</th>
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<tr>
<td>Immunohematology Standard 8 (IH S8)</td>
<td>Repairs that require a functional calibration prior to resumption of use include those that may affect the speed or timer function of the centrifuge.</td>
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<td>Centrifuges used for testing of red blood cell agglutination:</td>
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Comment 2:
Centrifuges used for testing of red blood cell agglutination:

a) Shall undergo RPM and timer checks at least every 6 months

This is the manufacturer’s recommendations for speed and timer checks.

RESPONSE:
The current New York State regulations, Subpart 58-2 of Chapter 10, require RPM and timer checks quarterly.