Proposed Laboratory Blood Services and Immunohematology Standards – Comments and Responses

Proposed Standards were made available to New York State permitted laboratories and laboratories in application for a permit on March 4th, 2020. The announcement was by e-mail to the facility and laboratory contact person's e-mail address and the Proposed Standards were posted to the CLEP website.

The comment period ended June 15th, 2020. Comments received from any regulated parties and responses are shown here.

Standards will be adopted July 13th, 2020, with an effective date of August 1st, 2020.

General Laboratory Blood Services Comment

COMMENT:

- Page 1 deleted standard: Laboratories performing non-automated tests to screen for platelet contamination may do so under their Blood Services permit.
  Please clarify if testing is still conducted, can the Bacteriology activity be removed from the permit.

RESPONSE:

If your laboratory performs platelet contamination testing, it must be done under the permit category of bacteriology. There is no change to the standards based on the comment received.

Laboratory Blood Services and Immunohematology Comments and Responses

Laboratory Blood Services

Laboratory Blood Services	
Proposed Standard	***Proposed Guidance***
Laboratory Blood Services Standard of Practice 1 (LBS S1): Donor Reactions For laboratories that perform donor services, ~~T~~the ~~laboratory~~ blood bank must have a protocol for responding to donor reactions and a policy defining the qualifications of personnel who respond.	10NYCRR subdivision 58-2.4 requires that medical services for emergency care of the donor be available during collection procedures. At a minimum, a nurse or other qualified person specially trained to recognize and treat donor reactions should be ~~immediately~~ available on-site and a physician should be available by telephone or other means for consultation. Persons ~~drawing~~ collecting blood for transfusion should also be trained to recognize donor reactions.

Laboratory Blood Services Standard of Practice 1 (LBS S1): Donor Reactions

COMMENT:

- Laboratory Blood Services Standard of Practice 1 (LBS S1): Donor Reactions
  Page 1: Please clarify how 'immediately available' is defined.
  Page 2: 'Persons drawing blood for transfusion should also be trained to recognize donor reactions.'
  Please clarify if the lab blood services need a special SOP defining who may collect a specimen when you may have an overall lab or hospital policy which covers that since many different types of people can draw, phlebotomists, RN's MD's etc. These people may not be under the auspices of the lab or the blood bank.

RESPONSE:

Based on the comment received, the guidance has been revised to indicate that a nurse or other qualified person specially trained to recognize and treat donor reactions should be available on-site. An overall policy is appropriate.

Laboratory Blood Services	
Proposed Standard	***Proposed Guidance***
Laboratory Blood Services Standard of Practice 5 (LBS S5): Transfusion Reaction Investigation Laboratories performing compatibility testing, or that issue blood or blood products, must have standard operating procedures that ensure prompt investigation and documentation of transfusion reactions, to include: a) review of all transfusion reactions occurring in facilities for which the laboratory has investigational responsibility; b) documentation of root cause analysis of the incident and all necessary preventive and corrective actions taken to prevent recurrences of transfusion reactions; c) a process to provide recommendations to the medical staff regarding improvements in transfusion procedures; d) review of all policies and procedures to assure they are adequate to ensure the safety of individuals being transfused; and e) reporting of ~~serious unexpected reactions and incidents~~ errors and accidents involving blood components that have been issued by the transfusion service to the Department and, if required, to federal authorities.	

Laboratory Blood Services Standard of Practice 5 (LBS S5): Transfusion Reaction Investigation

COMMENT 1:

- Laboratory Blood Services Standard of Practice 5 (LBS S5): Transfusion Reaction Investigation, page 5

b) Please clarify if a root cause analysis would be required for transfusion errors or transfusion reactions and what types of transfusion reactions.
Suggest rewriting the standard that an error that caused the transfusion.
e) Please clarify the definition of a serious unexpected reaction.

RESPONSE 1:

The standard requires a standard operating procedure for the investigation of transfusion reactions. The standard operating procedure, under requirement (b) must provide details as to how/when/why transfusion reaction investigations are performed, as determined by the director. Requirements for (e) in the standard have been revised based on the comment received.

COMMENT 2:

The term “root cause analysis” should not be used in section b of **LBS S5** ("documentation of root cause analysis of the incident and all necessary preventive and corrective actions taken to prevent recurrences of transfusion reactions").
The NYSDOH “General Systems Standards” provides the following definition for RCA: **“Root cause analysis**: Analysis performed to identify the source of a nonconformance.”
In most cases a transfusion reaction is not a “nonconformance”, it is a reaction to substances present in the unit even when all transfusion procedures were correctly performed. LBS S5 should more closely follow the language used in CLIA 493.1271(e)(1) and (e)(2):
(e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.
(e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

RESPONSE 2:

Root cause analysis is warranted to determine if there is a cause for an error or accident. The standard requires a standard operating procedure which must provide details as to how/when/why transfusion reaction investigations are performed, as determined by the director. There is no change to the standard based on the comment received.

Immunohematology

Immunohematology	
Proposed Standard	***Proposed Guidance***
Immunohematology Standard of Practice 4 (IH S4): Standard Operating Procedure The laboratory must have standard operating procedures that meet the requirements of Test Procedure Content Standard of Practice 1, and includes: a) requirements for establishing performance specifications; b) all testing requirements including ABO blood grouping and D(Rho) typing; and c) all transfusion-related testing, prenatal testing, and neonatal testing.	

Immunohematology Standard of Practice 4 (IH S4): Standard Operating Procedure

COMMENT:

- Immunohematology Standard of Practice 4 (IH S4): Standard Operating Procedure, page 9
  Please clarify whether the SOP should include testing even if the testing is not performed as described in 'c' of the standard.

RESPONSE:

Laboratories and blood banks must comply with all applicable New York State Clinical Laboratory Standards of Practice. There is no change to the standard based on the comment received.

Immunohematology	
Proposed Standard	***Proposed Guidance***
Immunohematology Standard of Practice 6 (IH S6): Serologic Centrifuge Verification In addition to the requirements in Laboratory Equipment and Instruments Standard of Practice 3, centrifuges used for testing of red blood cell agglutination, the laboratory must perform and document: a) verification of revolutions per minute (RPM) and timer checks quarterly; and b) functional calibration to determine optimal centrifugation conditions prior to testing, after any repairs to the centrifuge, and on an annual basis.	Repairs that require a functional calibration prior to resumption of use include those that may affect the speed or timer function of the centrifuge.

Immunohematology Standard of Practice 6 (IH S6): Serologic Centrifuge Verification

COMMENT 1:
If a repair is made to a centrifuge that would not affect the functional operation of the centrifuge, for example replacement of a lid latch, would the centrifuge still require functional calibration?

RESPONSE 1:
Based on the comment received, guidance related to repairs and the need for functional calibration has been added.

COMMENT 2:
We are requesting clarification on if there would be a requirement to calibrate a centrifuge that had repairs done to fix or replace a part that did not have an effect on function, such as a lid hinge or latch?

RESPONSE 2:

Based on the comment received, guidance related to repairs and the need for functional calibration has been added

Immunohematology	
Proposed Standard	***Proposed Guidance***
Immunohematology Standard of Practice 9 (IH S9): Blood Retention and Disposal Transfused ~~B~~blood that has not been retained for further testing according to Document and Specimen Retention Standard of Practice 10, and that has passed its expiration date, must be promptly disposed of by the laboratory.	

Immunohematology Standard of Practice 9 (IH S9): Blood Retention and Disposal

COMMENT 1:

- Immunohematology Standard of Practice 9 (IH S9), page 12
  Please clarify if the meaning of patient sample relates to units of RBC, frozen units, etc.

RESPONSE 1:

The standard is related to blood retention and disposal requirements. There is no change to the standard based on the comment received.

COMENT 2:

It is acknowledged that the language in the proposed standard aligns with CLIA 493.1271 (d), however "promptly" allows for a range of interpretation of the timeframe. It is recommended the proposed standard language be changed to reflect the language in 10 NYCRR section 58-2.24 - Disposal of untranfused and expired blood units which states "All expired blood components shall be

transferred to a separate storage location within 24 hours of expiration. All such components shall be destroyed, discarded, or removed for non-transfusion purposes within 72 hours of expiration, or returned to the collection facility within one week of expiration".

RESPONSE 2:

In accordance with 10NYCRR 58-2.9(i), a sample of red cells or whole blood from each red cell product issued for transfusion shall be retained for a minimum of seven days after the transfusion for further testing in the event of an adverse reaction. This standard and DSR S10 have been revised based on the comment received.