Changes to the 31st Edition of Standards for Blood Banks and Transfusion Services

Illinois Association of Blood Banks September 28, 2018
Objectives

- Explain the rationale for revised requirements.
- Identify existing policies, processes and procedures that may need to be changed in order to conform to the 31st edition.
- Identify ways to implement the new and revised requirements.
Blood Banks and Transfusion Service Standards Program Unit (BBTS SPU)

- Chair, committee members from blood bank and transfusion medicine field, liaisons from other AABB committees, representatives from other organizations, ethicist, staff from AABB national office
The BB/TS Standards Committee

Committee Members
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ICCBBA—Paul Ashford
Plasma Protein Therapeutics Association—Mary Gustafson, MT(ASCP)SBB
State of California—Ronald N. Harkey
Special Thanks…

In addition to the BBTS committee members, Special Thanks also goes to

• The Standards Department
  – Christopher Bocquet
  – Margaret Harper

• The Accreditation Staff
  – Anne Chenoweth and team

• Regulatory Affairs
  – Sharon Carayiannnis
  – Karen Palmer
Reminder: All AABB Standards Now on a 2 Year Cycle

• BBTS Standards are effective April 1st on even years
  – 31st edition effective April 1, 2018

• Ensures accredited facilities are assessed on each edition
Timeline for the Creation of the 31st edition

Feb. – March 2017  On-line document review in Work Groups
April 6, 7       1.5 day Face-to-Face meeting
April            Technical, Legal, and Regulatory review
April            SPC/BBTS SPU review
April            BoD review
June 23 – August 23  60 day Public Comment Period
September 7, 8   Face-to-Face Meeting #2 (Final) in Bethesda, MD
Sept             Technical, Legal, and Regulatory review
Sept             SPC/BBTS SPU review
Sept. 29        BoD Approval
October          Standards sent to Publications
January, 2018   Standards mailed
January, 2018   Significant Changes to the 31st edition of BBTS Standards Audioconference
April 1, 2018   31st edition of BBTS Standards become effective
Standards Portal Update

- The AABB Standards Portal was unveiled in April 2015 housing only the 7th edition of Standards for Cellular Therapy Services at that time.

- Since that time,
  - 30th edition of Standards for Blood Banks and Transfusion Services
  - 12th and 13th editions of Standards for Relationship Testing Laboratories
  - 9th and 10th editions of Standards for Immunohematology Reference Laboratories
  - 1st and 2nd editions of Standards for a Patient Blood Management Program
  - 3rd edition of Standards for Molecular Testing for Red Cell, Platelet and Neutrophil Antigens
Standards Portal Cont... 

• Benefits of purchasing the 31st edition through the Standards Portal include
  – Customizable profiles based on your accredited activities.
  – Guidance to most standards (including significant changes to this edition).
  – Seamless integration of interim standards when they become effective.
  – Ability to print the entire set of Standards on demand.
  – Discounted pricing structure for facilities or individuals who wish to purchase multiple licenses.
Helpful Hints Included in the Edition

• Definition of activities that are covered by BBTS Standards. Requirements apply only if within the scope of the user.

• BBTS Standards contains requirements for AABB-accredited facilities, does not preempt federal, state and/or local laws and regulations.

• Pen symbol indicates the need to maintain a record.

• Glossary

• Crosswalk to 30th edition

• Don’t forget about the Preface and Introduction!
Supplemental Publications

– AABB Technical Manual
– Circular of Information for the Use of Human Blood and Blood Components
– Donor History Questionnaire
Contact Standards@aabb.org

• Request a clarification of a standard (rationale, how to meet the intent)
• Submit a variance request (for an alternative method or approach to meeting a standard)
Iron Depletion in Blood Donors

• The 31st edition does not add any new requirements addressing the mitigation of iron depletion in blood donors.

• AABB’s Risk Based Decision Making (RBDM) process is currently evaluating options and recommendations.

• Existing Standard 5.2.1, Donor Education applies.
  – 5) Donors are given education materials regarding the risks of post donation iron deficiency

• Association Bulletin# 17-02, Updated Strategies to Limit or Prevent Iron Deficiency in Blood Donors, may also be referenced.
Now...for the changes!
Chapter 1. Organization

• Standard 1.2.2 has been updated

1.2.2 Management Reviews

Management shall assess the effectiveness of the quality system through assessments and scheduled management reviews.

• Standard edited to add assessments as a means to assess the quality system.
Chapter 2. Resources

No changes
Chapter 3. Equipment

• Standard 3.5.2 has been updated

3.5.2 Investigation and Follow-up

Investigation and follow-up of equipment malfunctions, failures, or adverse events shall include:

1) Assessment of blood, blood components, tissue, derivatives, and services provided since the equipment was last qualified known to be functioning per manufacturer’s written instructions or facility defined specifications.

• Standard edited to ensure that any device that has been repaired, retooled, recalibrated, etc. has shown that an indication exists to determine how far one has to look back to determine the previous acceptable check and the assessment of impact.
Chapter 3. Equipment

• Standards 3.7 and 3.7.1 have been updated.

3.7 Alarm Systems
Storage devices for blood, blood components, tissue, derivatives, and reagents shall have alarms and shall conform to the following standards (Standard 5.1.3 applies):

3.7.1 The alarm shall be set to activate under conditions that will allow proper action to be taken before blood, blood components, tissue, derivatives, or reagents reach unacceptable conditions.

• The term “reagents” have been added to the these standards to remain parallel with the language that exists in the Standards for Immunohematology Reference Laboratories, 10th edition.
Chapter 3. Equipment

• Standard 3.9.2 has been edited, replacing the term “periodically” with “at defined intervals.”

3.9.2 An alternate system shall be maintained to ensure continuous operation in the event that computerized data and computer-assisted functions are unavailable. The alternate system shall be tested periodically at defined intervals. Processes and procedures shall address mitigation of the effects of disasters and include recovery plans.

• This ensures that the alternate system in place be tested on a set schedule.
Chapter 4. Supplier and Customer Issues

No changes
Chapter 5. Process Control

- Standards 5.1.2.1.1 and 5.1.2.1.2 are new to the 31st edition.

5.1.2.1.1 When an external proficiency testing program is not available, there shall be a system for determining the accuracy and reliability of test results.

5.1.2.1.2 Proficiency testing shall include comparison of test results from an outside laboratory.

- New standards added to address facilities outside the United States and the means by which they perform proficiency testing.
Chapter 5. Process Control

• Standard 5.1.5.1 was revised.

5.1.5.1 The BB/TS shall have methods to limit introduction of bacteria into during the collection and manufacturing process. Standard 5.6.2 applies.

• Standard edited to be inclusive of manufacturing in addition to collection.
Chapter 5. Process Control

• Standard 5.1.5.3 was revised.

5.1.5.3 When a true positive culture positive result is obtained and a sample is available, additional testing to identify the organism shall be performed. Additional testing and follow-up shall be defined. Standards 5.2.4 and 7.1 to 7.1.4 apply.

• Standard edited for clarity.
Chapter 5. Process Control

• Standard 5.2.3 Donor Consent was revised.

5.2.3 The consent of all donors shall be obtained on the day of donation and before collection. Elements of the donation procedure shall be explained to the prospective donor in understandable terms. The explanation shall include information about risks of the procedure, tests performed to reduce the risks of relevant transfusion-transmitted infections to the allogeneic recipient, and requirements to report donor information, including test results, to state or local health departments. The donor shall have an opportunity to ask questions and have them answered and to give or refuse consent for donation. In the case of a minor or a legally incompetent adult, consent shall be addressed in accordance with applicable law.

• The term “relevant” added for consistency with FDA terminology and consistent with 21 CFR 630.3 (h)
Chapter 5. Process Control

• Standard 5.5.3.2 has been edited

5.5.3.2 The interval between a Whole Blood donation and If a platelet, granulocyte, or leukocyte donor donates a unit of Whole Blood, at least 8 weeks shall elapse before a subsequent cytapheresis procedure shall be at least 8 weeks, unless the extracorporeal red blood cell volume of the apheresis machine is less than 100 mL in which case the interval shall be at least two calendar days. Standards 5.4.3.2 and 5.5.3.1 apply.

Chapter 5. Process Control

• The clause “or confirmed” has been added to standard 5.5.3.4.1.

5.5.3.4.1 If the result of the predonation platelet count is not available, the donor’s most recent platelet count may be used to qualify the donor. Triple collections of Apheresis Platelets may not be collected from first-time donors unless a qualifying platelet count is obtained or confirmed from a sample collected before donation.*

*21 CFR 640.21 applies.

• Change made for completeness, the addition of the CFR reference mirrors the updated standard.
Chapter 5. Process Control

• Standard 5.6.3.2 has been edited.

5.6.3.2 Tubes for laboratory tests shall be properly labeled before the donation begins, shall accompany the blood container, and shall be re-identified with the blood container immediately after filling and before the tubes and container(s) are separated from the donation.

• Term “immediately” was removed as it was deemed difficult to assess. However, a timeframe was needed and the elements in bold were added.
Chapter 5. Process Control

• Standard 5.6.5 has been edited. Temperature During Transport from Collection Site to Processing Site

5.6.5 If blood is to be transported from the collection site to the component processing laboratory, it shall be placed in a qualified container having sufficient refrigeration capacity to cool the blood continuously toward a temperature range of 1 to 10°C until it arrives at the processing site laboratory.

• Revised for clarity based on public comment/feedback.
Chapter 5. Process Control

• Standard 5.6.6 – Additional Apheresis Collection Requirements

• Standard 5.6.6.1 has been edited.

5.6.6.1 The process used in performing a phlebotomy and processing the blood shall be designed to ensure safe reinfusion of the autologous non-retained components to the donor.

• Revised for clarity and term deemed redundant.
Chapter 5. Process Control

• Standard 5.6.7 has been edited.

5.6.7  *Therapeutic Phlebotomy and Apheresis*

*Therapeutic phlebotomy and apheresis shall be performed only when ordered by a physician or other authorized health professional.*

• Standard edited to include an “authorized health professional” to add flexibility to include advanced level practitioners such as ARNPs
Chapter 5. Process Control

- Standard 5.6.7.1 has been edited.

5.6.7.1 Units drawn as therapeutic phlebotomies shall not be used for allogeneic transfusion unless the individual undergoing the therapeutic phlebotomy meets all allogeneic donor criteria with the exception of donation interval and:

1) The unit is labeled with the disease/condition of the donor that makes phlebotomy necessary, or
2) The collection phlebotomy is for hereditary hemochromatosis and there is no charge for the procedure or
3) The phlebotomy is for a condition for which the collection procedure has been approved by the FDA Competent Authority *

*21 CFR 630.15(a)(2)

- The standard has been edited to mirror CFR and to expand the focus to allow for other medical conditions approved by the FDA (e.g., erythrocytosis due to testosterone therapy) in addition to hereditary hemochromatosis.
Chapter 5. Process Control

• Standard 5.7.3.1 has been edited.

5.7.3.1 Leukocyte Reduction

Leukocyte-reduced blood and blood components shall be prepared by a method known to reduce the leukocyte number to <5 x 10^6 for Red Blood Cells and Apheresis or Pooled Platelets and to <8.3 x 10^5 for Whole-Blood-derived Platelets. Validation and quality control shall demonstrate that at least \( \geq 95\% \) of units sampled meet this criterion.*

• The standard has been edited to mirror FDA Guidances-Collection of Platelets by Automated Methods – December 17, 2007 and Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion – September 2012, changing “at least” to “greater than or equal to”.

*www.aabb.org
Chapter 5. Process Control

• Standard 5.7.3.2.1 has been edited.

5.7.3.2.1 Verification of dose delivery shall be performed using a fully loaded canister as follows:

1) Annually for cesium-137 as a radiation source.
2) Semiannually for cobalt-60 as a radiation source.
3) Periodically, as recommended by the manufacturer for alternate sources of radiation.
4) Upon installation, major repairs, or relocation of the irradiator.

• “Periodically” removed for clarity and deemed not needed.
Chapter 5. Process Control

• Standards 5.7.4.10 and 5.7.4.11

These standards are for plasma frozen with 24 hours after phlebotomy and within 24 hours after phlebotomy held at room temperature up to 24 hours after phlebotomy.

- We changed the “≤” to “or colder” for consistency with CFR and clarity. This change was also made throughout the Reference Standard table 5.1.8A.

We also added “from whole blood” to 5.7.4.11.

5.7.4.11 Plasma Frozen Within 24 hours After Phlebotomy Held At Room Temperature Up to 24 Hours After Phlebotomy shall be prepared from whole blood or an apheresis plasma collection. The product can be held at room temperature for up to 24 hours after collection and then placed at −18 C or colder.
Chapter 5. Process Control

- Standard 5.16.2.2, now 5.14.5 has been moved and edited.

**5.14.5 Pretransfusion Testing for Allogeneic Transfusion**

There shall be two determinations of the recipient’s ABO group as specified in Standard 5.14.1. The first determination shall be performed on a current sample, and the second determination by one of the following methods:

1) Testing a second current sample.
2) Comparison with previous records.
3) Retesting the same sample if patient identification was verified using an electronic identification system or another process validated to reduce the risk of misidentification.

Standards 5.11 and 5.27.1 apply.

- The standard was moved to the section on “Pretransfusion Testing” as it fits more appropriately than as previously listed under “Computer Crossmatch.”

In addition, a title was added to the standard which reads, “Pretransfusion Testing for Allogeneic Transfusion.”
Chapter 5. Process Control

• Standard 5.15.1 has been edited for this edition.

5.15.1 Recipients shall receive ABO group-compatible Red Blood Cell components, ABO group-specific Whole Blood, or low titer group O Whole Blood (for non group O or for recipients whose ABO group is unknown) or ABO group compatible Red Blood Cell components. Standards 5.15.4, 5.27.1 – 5.27.1.1 apply.

• Standard edited to allow the use of low titer group O Whole Blood in facility defined policies, processes and procedures.
Chapter 5. Process Control

• Standard 5.15.4 has been edited for this edition.

5.15.4 The transfusion service shall have a policy concerning transfusion of significant volumes of plasma containing incompatible ABO antibodies or unexpected red blood cell antibodies.

• Standard edited for clarity.
Chapter 5. Process Control

• Standard 5.19.3.1 – not revised, but included here for reinforcement

5.19.3.1 Methods known to prevent transfusion associated graft-vs-host disease shall be used, and include either irradiation or the use of a pathogen reduction technology that is known to inactivate residual leukocytes and is cleared or approved by the FDA or Competent Authority

• For the prevention of GVHD, Standards require either irradiation or PRT, not both.
Chapter 5. Process Control

• Standards 5.27.1 – 5.27.2 have been edited in this edition.

5.27.1 Recipients whose ABO group is not known or has not been confirmed shall receive group O Red Blood Cells or low titer group O Whole Blood. Standards 5.14.1 and 5.14.5 apply.

5.27.1.1 If low titer group O Whole Blood is used the BB/TS shall define low titer group O Whole Blood and shall have policies, processes and procedures for:
1) The use of low titer group O Whole Blood
2) The maximum volume/units allowed per event
3) Patient monitoring for adverse effects.
Standard 5.15.4 applies.

5.27.2 If blood is issued before completion of compatibility testing, recipients whose ABO group has been determined as in Standard 5.14.1 by the transfusing facility shall receive only ABO group-specific Whole Blood, low titer group O Whole Blood or ABO group-compatible Red Blood Cell components.

• Standards 5.27.1 – 5.27.2 have been edited in conjunction with standard 5.15.4, further expanding on the use of group O Whole Blood.
Chapter 5. Process Control

• Standard 5.29.1 Medical Record Documentation was edited

5.29.1 The patient’s medical record shall include the transfusion order, documentation of patient consent, the component name, the donation identification number, **the donor ABO/Rh type**, the date and time of transfusion, pre- and post-transfusion vital signs, the amount transfused, the identification of the transfusionist, and, if applicable, transfusion-related adverse events.

• Added donor ABO/Rh type for completeness.
Reference Standard 5.1.6A – Requirements for Labeling Blood and Blood Components

• Reference Standard 5.1.6.A, #29 was edited.

<table>
<thead>
<tr>
<th>Labeling Requirements for Recovered Plasma(^\text{14})</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
</tr>
</tbody>
</table>

• Wording consistent with 21 CFR 606.121 (c) (10)
Reference Standard 5.1.8A – Requirements for Storage, Transportation, and Expiration

- Reference Standard 5.1.8A, #14 – 22, Platelet Components have been edited.

<table>
<thead>
<tr>
<th>Platelet Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
</tr>
<tr>
<td>Platelets</td>
</tr>
<tr>
<td>20-24°C with continuous gentle agitation</td>
</tr>
<tr>
<td>As close as possible to 20-24°C³</td>
</tr>
<tr>
<td>Maximum time without agitation: 30 hours</td>
</tr>
<tr>
<td>24 hours to 5 days, depending on collection system</td>
</tr>
</tbody>
</table>

- Maximum time without agitation has been lengthened from 24 to 30 hrs, and moved from “Additional Criteria” column to “Transport”.
- Study (Transfusion 2008;48:1072-1080) supported lengthened storage time that would minimize product wastage.
Reference Standard 5.4.1A – Requirements for Allogeneic Donor Qualification

• Reference Standard 5.4.1A has been expanded

| 2) Blood Pressure | • 90-180 mm Hg systolic |
| • 50-100 mm Hg diastolic |

• The committee elected to reintroduce the requirement that blood pressure and pulse be reinserted into reference standard 5.4.1A. The committee received feedback from AABB’s Regulatory Affairs Department and the FDA that for clarity these entries should be reinserted.

• Consistent with FDA Final Rule – Requirements for Blood and Blood Components Intended for Further Manufacturing Use – Effective May 23, 2016
Reference Standard 5.4.1A – Requirements for Allogeneic Donor Qualification

• Reference Standard 5.4.1A has been expanded.

<table>
<thead>
<tr>
<th>Drug Therapy†</th>
<th>Generic medication name [example of trade name(s)]</th>
<th>24 months after last dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vismodegib (eg, Erivedge)</td>
<td>Sonidegib (eg Odomzo)</td>
<td>24 months after last dose</td>
</tr>
</tbody>
</table>

• The inclusion of Sonidegib has been included to mirror an addition to the next version the Donor History Questionnaire
• Package insert states do not donate blood for 7 months (vismodegib) and 20 months (sonidegib)
• 24 months for both minimize errors
Reference Standard 5.4.1A – Requirements for Allogeneic Donor Qualification

- Reference Standard 5.4.1A has been expanded.

| 13) Xenotransplantation | Receipt of live cells, live tissues or live organs from a non-human animal source. Note: Nonliving biological products or materials from nonhuman animals, such as porcine or bovine heart valves and porcine insulin, are acceptable. | Indefinite | Permanent |

- The committee elected to replace the deferral period for Xenotransplantation from “Permanent” with “Indefinite” as this is the more accurate term.
Chapter 6. Documents and Records

• Standard 6.2.7.1.2 has been edited.

6.2.7.1.2 Backup data shall be stored in an off-site location and be secured to prevent unauthorized access.

• The addition was included for completeness.
Chapter 7. Deviations, Nonconformances, and Adverse Events

• Standard 7.1.1 has been edited.

7.1.1 Nonconforming blood, blood components, tissue, and derivatives shall be quarantined and/or destroyed.

• Added for completeness.
Chapter 7. Deviations, Nonconformances, and Adverse Events

• Standard 7.1.3 has been edited.

• **7.1.3** The BB/TS shall have a process for:
  1) The identification, quarantine, retrieval, recall **and disposition** of nonconforming blood, blood components, tissue, and derivatives.

• Added for completeness.
Chapter 7. Deviations, Nonconformances, and Adverse Events

• Standard 7.3 has been edited.

7.3 Classifying Adverse Events
The BB/TS shall use standardized definitions to classify nationally recognized classifications for donor and patient adverse events. The medical director shall participate in the development of protocols used by the staff to identify, evaluate, and report adverse events.

• Standard has been expanded to recognize the growing familiarity with this concept and to minimize conflicting or duplicative nomenclatures.
Chapter 7. Deviations, Nonconformances, and Adverse Events

• Standard 7.3.1 is new to this edition

7.3.1 *Internationally recognized classifications shall be used when no national classifications exist.*

• This standard was *included for facilities located where no national classification system exists (primarily overseas).*
Chapter 7. Deviations, Nonconformances, and Adverse Events

- Standard 7.5.1 and 7.5.2

7.5.1 Recognition of and Response to Immediate Transfusion Reactions
There shall be processes and procedures for the transfusing staff for the recognition of and response to immediate transfusion reactions and for the recording of relevant information in the patient’s medical record.

7.5.2 Laboratory Evaluation and Reporting of Immediate Transfusion Reactions
The BB/TS shall have policies, processes, and procedures for the evaluation and reporting of suspected transfusion reactions, including prompt evaluation, review of clerical information by the BB/TS, and notification of the BB/TS medical director.

- These standards were edited for consistency and clarity.
Glossary Additions

• **Blood group specific:** When the component is blood group identical (e.g., a group A patient is transfused with group A RBCs and group A plasma).

• **Blood group compatible:** When there is no anticipated harm to the recipient due to identity of the donor antigens or absence of an alloimmune response (e.g., a patient of unknown blood type is transfused with group O RBCs or AB plasma, and for a group A transfusion recipient, group A or O RBCs and group A or AB plasma is used).

• **Intermediate Facility:** A facility that imports a product and then ships it to another facility.
Glossary Edits

• **Backup**: Digital data storage media (magnetic tape, flash drive, CD, etc) and/or physical storage containing copies of relevant data.

• **Transfusion-Transmitted Infection Transmissible Disease**: A disease or condition caused by a virus, bacteria, fungus, parasite, or agent of transmissible spongiform encephalopathy that may be transmitted by transfusion of blood or blood components or by tissue implantation or transplantation or administration of derivatives.

• **Xenotransplantation**: Any procedure that involves the transplantation, implantation, or infusion into a human recipient of live cells, live tissues, or live organs from a nonhuman animal source.
Thank you!
What questions do you have?