Patient Blood Management Certification

Patient Blood Management Certification Program

Review Process Guide
For Organizations

2018
What's New in 2018

Updates effective in 2018 are identified by underlined text in the activities noted below.

Competence Assessment and Credentialing Session and Issue Resolution – Updated to reflect the revisions on standard on facility-defined educational requirements

Appendix F – Program Activity Levels – Updated to reflect standard revisions on how PBM program will be evaluated for compliance with the expectations that reflect their designated program activity level. As each activity level addresses organizations with different capabilities, the PBM program’s activity level will determine which EPs are applicable during the certification review.

Appendix G – Frequently Asked Questions (FAQs) – Updated to reflect standard revisions for PBM requirements referencing AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration
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Patient Blood Management Certification Overview

Patient Blood Management (PBM) is an evidence-based, multidisciplinary approach to optimizing care of patients who might need transfusion. It encompasses all aspects of patient evaluation and clinical management surrounding the transfusion decision-making process, including the application of appropriate indications, as well as minimization of blood loss and optimization of patient red cell mass.

The Patient Blood Management certification program is a collaborative effort between AABB and The Joint Commission. The AABB-Joint Commission Patient Blood Management Certification promotes patient safety and quality and will help hospitals realize the maximum benefits of establishing a comprehensive patient blood management program. This voluntary hospital certification is based on the AABB Standards for a Patient Blood Management Program.

The goals for certified organizations include the following:

- Risk reduction in fewer adverse events and incidents
- Improved patient outcomes
- Reduced hospital stays, readmissions, and lengths of stay
- Ensuring blood availability for those most in need
- Optimized care for those who may need transfusion
- Fostering collaboration throughout the hospital
- Providing a competitive edge in the marketplace
- Enhanced staff recruitment and development
- Cost savings

The on-site certification review will be conducted by one or two reviewers, based on whether the organization is accredited by AABB for Blood Banks and Transfusion Services. For organizations that are AABB-accredited for Blood Banks and Transfusion Services, a Joint Commission surveyor will perform a one-day review. Organizations that are not AABB-accredited for Blood Banks and Transfusion Services will be evaluated by two reviewers (one Joint Commission surveyor and one AABB assessor) for a one-day review.
Organization Review Preparation

The Patient Blood Management Certification Review Process Guide describes each activity of the Joint Commission on-site certification review. Organizations should read each of the following activity descriptions, which include:

- The purpose of the activity
- Descriptions of what will happen during the activity
- Discussion topics, if applicable
- Recommended participants
- Any materials required for the session

Share these descriptions organization-wide, as appropriate.

Pre-Review Phone Call
A Joint Commission account executive will contact your organization by phone shortly after receiving your application for certification. The purpose of this call is to:

- Confirm information reported in the application for certification,
- Verify travel planning information and directions to main location for review,
- Confirm your access to The Joint Commission Connect extranet site and the certification-related information available there (on-site visit agenda, Certification Review Process Guide, etc.), and
- Answer any organization questions and address any concerns.

Notice of Initial Certification On-site Review
If this is your program’s first time through the certification process you will receive at least a 30-day advance notice of your on-site review date. The Notification of Scheduled Events link on your organization’s extranet site, The Joint Commission Connect, is populated with the review date, reviewer’s name, biographical sketch and picture 30 days prior to the review date. The account executive can answer questions about the process or put you in contact with other Joint Commission staff that can assist you.

Notice of Re-Certification On-site Review
Your organization will receive notice from The Joint Commission seven business days prior to the day of the scheduled review date for Patient Blood Management re-certification. The notice will be to the certification contact identified in your application and will include the specific review date and the program being reviewed. A follow-up communication with your organization will confirm the information previously provided. Additionally, the Notification of Scheduled Events link on your organization’s extranet site, The Joint Commission Connect, is populated with the review date, reviewer’s name, biographical sketch and picture at 7:30 a.m. in your local time zone on the morning of the review.
Logistics

- While on-site, the reviewer will need workspace for the duration of the visit. A desk or table, telephone, access to an electrical outlet and the internet are desirable.

- Some review activities will require a room or area that will accommodate a group of participants. Group activity participants should be limited, if possible, to key individuals that can provide insight on the topic of discussion. Participant selection is left to the organization’s discretion; however, this guide does offer suggestions.

- The reviewer will want to move throughout the hospital and blood bank during Individual Tracer Activity, talking with staff and observing the day-to-day operations of the organization along the way. The reviewer will rely on organization staff to find locations where discussions can take place that allow for confidentiality and privacy, and that will minimize disruption to areas being visited.

- While the reviewer will focus on current patients that are included in the patient blood management program, they may request to see some closed records as well in order to verify compliance with the Patient Blood Management Certification requirements.

The sample agenda for the on-site review appears later in this guide, and will be posted to your Joint Commission Connect extranet site. The review agenda presents a suggested order and duration of activities. Prior to the review date, please discuss the agenda and activities with the Account Executive. When the reviewer arrives, discuss any agenda changes during the on-site visit.

Documentation Requested from the Program

Although the majority of documentation review will occur as part of individual tracer activity, it is helpful to have the references and resources staff use in their day-to-day activities available.

The reviewer may request the following items to assist in patient tracer selection during the Reviewer Planning session:

- Current list of patients receiving blood transfusions or who may likely receive a blood transfusion (see suggested tracer patient list)

- If there are a limited number of admissions, a list of discharged patients who received blood transfusions
  - This request can go back as far as the past four months for initial reviews

- Performance improvement action plans that demonstrate how data have been used to improve program care and services, when available

- The reviewer may also request the following documents:
  - Organizational chart with hierarchy of responsibilities to the program
  - Executive management roles and responsibilities
  - Interdisciplinary team qualifications, job descriptions, training, and competency
  - Patient-centered quality plan
  - Emergency management plan and communication system
  - Equipment maintenance and information management records
- Supplier evaluations and contract agreements
- Policies and procedures for patient blood management
- Patient information regarding blood transfusion, blood management
- Educational materials given to patient/family
- Record retention policies
- Information management procedures and records
- Procedures for deviations, nonconformances, and adverse events
- Program assessments and performance improvement

Preparing for Patient Tracer Selection
Organizations are encouraged to begin identifying patients for individual tracer activity in advance of the review date. The reviewer will still be involved in the selection of the specific patients, but it will ease the pressure and burden on staff in trying to find the types of patients that the reviewers want to trace. Availability of this information will greatly facilitate the Reviewer Planning session and allow the individual tracer activity to proceed in a timely manner.

If there are a limited number of active patients at the time of the on-site review, or the active patients do not meet all of the selection criteria, closed records may be reviewed to observe the program’s interaction with as much of the target population as possible.

Depending on the services provided by the organization, suggested tracer patients may include:
- Patients receiving a massive transfusion
- Patients receiving regular transfusions
- Patients that refuse blood products or transfusions
- Patients with chronic anemia
- Patients receiving stem cell transplants
- Patients with elective surgery (preoperative, postoperative)
- Patients from the intensive care, pediatrics, obstetrics, or oncology departments

Preparing for Competence Assessment and Credentialing
As the process to obtain personnel and credentials files may be time-consuming, particularly if files are stored off-site, organizations may consider identifying files to request in advance of the on-site review to facilitate the organization’s retrieval efforts. The reviewer will still be involved in the selection of personnel files to review, but the availability of this information will allow the Competence Assessment and Credentialing session to proceed in a timely manner.

Suggested personnel files to request may include:
- PBM medical director
- PBM coordinator
- Midlevel practitioner that orders blood
- Medical technologist in the blood bank
• Perfusionist
• RN from the ICU, ER, or OR
• Anesthesiologist

Questions
Questions about the Patient Blood Management certification standards and elements of performance:
• Contact AABB at standards@aabb.org.

Questions about on-site review process, agenda, scheduling, or other questions:
• Call your Joint Commission Account Executive.
Reviewer Arrival

Logistics

Duration
10 minutes

Participants
- Reception, Security, or Information Desk Staff
- Organization/Program Contact

Procedures

1. The reviewer will arrive at the location identified as the main or primary site between 7:45 and 7:50 a.m.
2. The reviewer will report to the reception area, security officer, information desk, or administrative office upon arrival and provide the reviewer's name, identification and purpose for the visit.
3. If a program contact is not waiting for the reviewer, the reviewer will ask security or reception to phone the program contact. The reviewer will wait for an escort unless instructed to proceed to another location by the organization/program contact.
4. The reviewer will follow organization visitor procedures as instructed by security or the program contact (e.g. sign in, wear organization visitor identification).
5. While this is an announced visit, the reviewer will still confirm that the organization/program contact has been able to access their extranet site and locate information about the review, including
   - Notification of scheduled Joint Commission event authorizing your presence
   - Reviewer name, picture and biographical sketch
   - Scheduled review date
6. Please inform the reviewer about
   - Working space for the day
   - A secure location to place belongings and access them as needed throughout the day
7. Inform the reviewer if there will be a roster of patient blood management program leaders and staff attending the Opening and Orientation activities or if attendees will sign in. A roster or sign in sheet with the names of staff encountered and their roles in the program can be helpful with the review process.
8. Plan to leave at least 15 minutes of the opening conference to review the visit agenda and for questions and answers.
Opening Conference

Logistics

Objectives
1. Introductions of program representatives and reviewer(s)
2. Describe the structure of the review
3. Discuss the review agenda, highlighting any changes necessary to facilitate the site visits or increase participation in group activities
4. Answer any open questions about the visit or review process

Duration
10 minutes

Participants
Program administrative and clinical leadership and others at the discretion of the organization

Other Information
If available, the following items are helpful to the reviewer:

- Roster or sign-in sheet of participants
- Organization chart or names of program leadership, titles and roles

Procedures

During
The reviewer will:

- Provide a brief self-introduction including background and relevant experience.
- Explain the purpose of the certification review.
- Ask organization attendees to introduce themselves.
- Describe each component of the review agenda, discuss the plans for tracer activity, potential tracer patients, and areas to visit. Make changes to the schedule if necessary.
- Explain that the majority of review activity occurs at the point where care, treatment and services are provided. The term “Individual Tracer” denotes the review method used to evaluate organization/program compliance with standards.
- Remind the program that they want to be as least disruptive to patient care as possible. They will suggest that the program limit the number of staff accompanying them on tracer activity to three or less.
• Introduce the new SAFER™ matrix feature of the Summary of Certification Review Findings Report.
• Mention the changes to the post-review Clarification process.
• Ask if there are any questions about the review.
• Answer questions and encourage representatives to ask questions throughout the review.

After
The reviewer will transition into the Orientation to the Patient Blood Management Program session.
Orientation to the Patient Blood Management Program

Logistics

Objectives
Become familiar with the patient blood management program, including:
1. An understanding of the patient blood management program philosophy and approach
2. A better understanding of the patient blood management program structure and scope
3. How well integrated the program is throughout the organization

Duration
50 minutes

Participants
Program administrative and clinical leadership and others at the discretion of the organization

Notes
Materials that may prove useful for this session:
- Organization chart for the program, if available
- Copies of slides, if the program is making a formal presentation

Procedures

During
If a presentation is planned, the reviewer will ask the presenter to indicate if they would like to take questions during or at the conclusion.

The organization is asked to provide a high-level overview of their patient blood management program through either a formal presentation or in discussion with reviewer. The focus should be on the following:
- Program scope
- Program mission, goals and objectives
- Program structure and relationship to the organization structure
- Program leadership and executive management responsibilities
- Interdisciplinary team members, including roles and responsibilities
- Organizational supports for the patient blood management program
• Development and implementation of the program (e.g. timeline, successes and opportunities, challenges and barriers)
• Patient blood management program activities
• Identify the program level designation
• Any unique program communication regarding patient rights and responsibilities and their right of refusal of care, treatment, and services offered
• Assessing practitioner and staff competence in patient blood management
• Organizational support for patient blood management program practitioners and staff education and specialized training
• Processes supporting credentialing, privileging, and licensure/registration/certification, education and experience verifications
• Evaluating and improving the program’s performance

After
Determine if there are additional documents the reviewer would like to see as a result of the orientation discussions.

The reviewer will transition to the System Tracer – Data Use session for a more in-depth discussion regarding how the program is using data to evaluate and improve the program’s performance.
System Tracer – Data Use Session

Logistics

Objectives
1. To learn how the patient blood management program is using data to evaluate the safety and quality of care provided to patients
2. To understand and assess the program’s performance improvement process

Duration
30 minutes

Participants
Program leaders, clinical leaders, and others at the discretion of the program

Data Requirements
• For initial certification, the organization should provide four months of data
• For recertification, the organization should provide twelve months of data

Procedures

During
During this activity, the reviewer and organization will discuss:
• Program performance measurement and improvement activities
  ▪ Performance improvement plan review including priority setting
  ▪ Data collection and data quality monitoring
  ▪ Data analysis and dissemination
• Program data available for, and used in decision-making
• Program evaluation by leaders and staff
• Recently implemented program improvement
• Ongoing performance monitoring
• Taking actions to improve
Reviewer Planning Session

Logistics

Duration
30 minutes

Participants
Program contact or staff, if requested by the reviewers

Procedures

Before
- Explain to the organization the purpose of this session
- Make sure all necessary documents are available, especially patient lists.

During
The reviewer will:
- Describe to program representatives the types of patients they want to trace and request assistance in identifying individuals that fit the description. Tracer selection should include representation of the target population(s).
  
  **Note:** This may or may not be possible to accomplish using a list of active patients. The reviewer and program representative may need to proceed directly to a patient care unit and ask the staff to help identify patients.

- Select a minimum of five (5) tracer patients
  - Patients selected should present the opportunity to trace care, treatment and services through as many of the potential departments, areas, sites or services that support or participate directly in the patient blood management program or support the work of the program in any unique way.
  
  - Patients should have different characteristics, such as demographics, age, sex, or situations or other factors that would influence patient care.
  
  - As blood bank/transfusion services and perioperative services are integral to the patient blood management program, a tracer patient that will incorporate a visit to the blood bank and interaction with staff from perioperative services will be selected.
- Suggested tracer patients may include:
  - Patients receiving a massive transfusion
  - Patients receiving regular transfusions
  - Patients that refuse blood products or transfusions
  - Patients with chronic anemia
  - Patients receiving stem cell transplants
  - Patients with elective surgery (preoperative, postoperative)
  - Patients from the intensive care, pediatrics, obstetrics, or oncology departments
- If there are a limited number of active patients at the time of the on-site review, or the active patients do not meet all of the selection criteria, closed records will be reviewed to observe the program's interaction with as much of the target population as possible.
- As the process to obtain personnel and credentials files may be time-consuming, particularly if files are stored off-site, the reviewer may begin requesting files earlier in the day to facilitate the organization's retrieval efforts. Program staff should inform the reviewer of how much time is needed to retrieve personnel and credentials files.
- Select a minimum of five (5) personnel files to review, which may include:
  - PBM medical director
  - PBM coordinator
  - Midlevel practitioner that orders blood
  - Medical technologist in the blood bank
  - Perfusionist
  - RN from the ICU, ER, or OR
  - Anesthesiologist
  - Additional files may be requested during tracer activity

**Documentation Requested from the Program**
The program is requested to provide the following items to the reviewer to assist in patient tracer selection.

- Current list of patients receiving blood transfusions or who may likely receive a blood transfusion (see suggested tracer patient list)
- If there are a limited number of admissions, a list of discharged patients who received blood transfusions
  - This request can go back as far as the past four months for initial reviews
- Performance improvement action plans that demonstrate how data have been used to improve program care and services, when available
• The reviewer may also request the following documents:
  ▪ Organizational chart with hierarchy of responsibilities to the program
  ▪ Executive management roles and responsibilities
  ▪ Interdisciplinary team qualifications, job descriptions, training, and competency
  ▪ Patient-centered quality plan
  ▪ Emergency management plan and communication system
  ▪ Equipment maintenance and information management records
  ▪ Supplier evaluations and contract agreements
  ▪ Policies and procedures for patient blood management
  ▪ Patient information regarding blood transfusion, blood management
  ▪ Educational materials given to patient/family
  ▪ Record retention policies
  ▪ Information management procedures and records
  ▪ Procedures for deviations, nonconformances, and adverse events
  ▪ Program assessments and performance improvement
Individual Tracer Activity

Logistics

Objectives
1. Follow a patient's care, treatment, and services to confirm the program's compliance with the patient blood management certification requirements.
2. Evaluate the program's design and implementation of processes that facilitate the integration of patient blood management across the organization.

Duration
Variable per patient tracer conducted; tracing of multiple patients in multiple locations occurs during the blocks of time noted on the agenda

Participants
Staff, program representatives and management who have been involved in an individual’s care, treatment, or services.

The reviewer will require an escort during each of the blocks of tracer time.

Procedures
A significant portion of the agenda is designated to patient tracer activity. The number of patients traced during this time will vary. Tracer activity begins on the inpatient unit where the patient is receiving care, treatment and services, or in the case of a discharged patient, the location from which they were discharged.

During
• The reviewer will use the patient’s record to discuss and map out the patient’s course of care, treatment and services. The number of staff participating in this stage of the tracer should be limited.
• The reviewer will follow the map, moving through the organization, as appropriate, visiting and speaking with staff in all the areas, programs, and services involved in the patient’s encounter. There is no mandated order for visits to these other areas. Reviewers will speak with any staff available in the area.

Throughout tracer activity, the reviewer will:
- Observe program staff and patient interaction
- Interview staff about the care, treatment and services they provide and their knowledge of the patient blood management program
- Interview patients or families, if appropriate and permission is granted by the patient or family
- Review policies, processes, and procedures for patient blood management
- Discuss equipment maintenance and quality control issues
- Inquire about the processes for document control and record retention
- Observe environmental conditions

**Blood Bank/Transfusion Services:**
- For organizations that ARE accredited by AABB for Blood Banks and Transfusion Services, the reviewer will:
  - Confirm that equipment controlled by the blood bank or transfusion service is controlled in accordance with the manufacturer’s instructions and/or the current edition of AABB Standards for Blood Banks and Transfusion Services.
  - Verify that pretransfusion testing policies are consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services.
  - Confirm that documents and records related to transfusion medicine are created and controlled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.
  - Discuss the process to ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current editions of AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.

- For organizations that ARE NOT accredited by AABB for Blood Banks and Transfusion Services (see Appendix B for additional guidance), the reviewer will:
  - Identify the process to make sure equipment controlled by the blood bank or transfusion service is controlled in accordance with the manufacturer’s instructions and/or the current edition of AABB Standards for Blood Banks and Transfusion Services.
  - Review pretransfusion testing policies to make sure they are consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services.
  - Ask staff how documents and records related to transfusion medicine are created and controlled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.
  - Discuss the process to ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current editions of AABB Standards for Blood Banks and Transfusion Services or the requirements of an equivalent accrediting body.

**Perioperative Services (see Appendix C for additional guidance):**
- The reviewer will:
- Confirm that equipment controlled by the perioperative program is controlled in accordance with the manufacturer’s instructions and/or the current edition of AABB Standards for Perioperative Autologous Blood Collection and Administration.

- Verify that document and records related to the perioperative program are created and controlled in accordance with the current edition of the AABB Standards for Perioperative Autologous Blood Collection and Administration or the requirements of an equivalent accrediting body.

- Discuss the process to ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current edition of AABB Standards for Perioperative Autologous Blood Collection and Administration or the requirements of an equivalent accrediting body.

- For Program Activity Level 1 organizations:
  - If the perioperative program is already accredited by AABB, this requirement has been satisfied.
  - If the perioperative program is not accredited by AABB, the reviewer will confirm that the AABB requirements for cell salvage or processing of perioperative blood products (e.g., platelet gel, platelet-rich plasma) are met in accordance with the AABB Standards for Perioperative Autologous Blood Collection and Administration.

After
- As necessary, pull additional records to verify standards compliance issues identified during the Individual Tracer.
- As necessary, request other documentation to confirm procedures and validate practice.
Competence Assessment and Credentialing Session

Logistics

Objectives
1. Learn more about the organization’s competence assessment process for program staff, licensed independent practitioners, and other credentialed practitioners.
2. Learn more about the organization’s orientation, education, and training processes as they relate to program staff, licensed independent practitioners, and other credentialed practitioners encountered during Individual Tracers.
3. Identify competence assessment process-related strengths and potential risk points.

Duration
30 minutes

Participants
Individuals responsible for:
- Aspects of the organization’s human resources processes that support the patient blood management program
- Orientation and education of program staff
- Assessing program staff competency
- Assessing program’s licensed independent practitioners and other credentialed practitioners’ competency, when applicable.

Procedures

During
- The reviewer will participate in a facilitated review of selected files, based on the patient blood management program team and individuals encountered during tracer activity
- Files stored off-site may not need to be reviewed as long as the local files include the following information:
  - Job descriptions for all program staff, licensed independent practitioners, and other credentialed practitioners
  - Experience, education, and abilities assessments for program staff and licensed independent practitioners
- Information on orientation for staff, licensed independent practitioners, and other credentialed practitioners to the organization, to the program, to job responsibilities, and/or clinical responsibilities
- Ongoing education and training for program staff and licensed independent practitioners
- Competency assessment for program staff
- Facility-defined education for individuals that order and transfuse blood
Issue Resolution

Logistics

Objectives
1. Obtain any additional information or documentation required to resolve issues identified during the course of the review.
2. Follow-up on potential findings that could not be resolved in other on-site activities.

Duration
15-30 minutes

Participants
As requested by the reviewer, depending on the issue(s) to be discussed

Procedures

During
• The reviewer may have identified issues during individual tracer activity or other sessions that require further exploration or follow-up with staff.
• This follow-up may include a variety of activities such as:
  ▪ Review of policies and procedures
  ▪ Additional patient records, or components of records, to confirm an Individual Tracer finding
  ▪ Review of personnel or credentials files and facility-defined educational requirements
  ▪ Review of performance improvement data
  ▪ Discussions with selected staff
Reviewer Report Preparation

Logistics

Objectives
1. Complete the entry of observations made throughout the survey
2. Prepare an event summary to share with the program

Duration
45-60 minutes

Participants
Program participation is not required

Procedures
The reviewer will:

- Analyze observations and determine if there are any findings that reflect standards compliance issues.
- Make arrangements with the program representatives to print and copy the report for:
  - The organization, if it is being distributed to Program Exit Conference participants
  - Each reviewer
- Inform the program contact that they are ready to proceed with the Program Exit Conference
Program Exit Conference

Logistics

Objectives
1. Present the Summary of Certification Review Findings Report (only if desired by the CEO)
2. Review identified standards compliance issues and note that all findings of less than full compliance require resolution through an Evidence of Standards Compliance submission
3. Review required follow-up actions

Duration
30 minutes

Participants
- Program and clinical leaders
- Other staff at the discretion of the organization

Procedures

During
- The reviewer will share a report of their on-site experience and observations.
- The reviewer will highlight strengths and progress and will note any potential areas of vulnerability and how these relate to the standards and what the program will see reflected in the Summary of Certification Review Findings. The reviewer will also present the newest feature of the Summary report, the SAFER™ matrix, and will discuss the display of Requirements for Improvement, if any, and the significance of their placement.
- The reviewer will not go through the report item by item with the group assembled for the Program Exit Conference. If the organization desires this level of report discussion, it is recommended that it occur with just a small number of program representatives.
- The reviewer will mention changes to the post-review Clarification process and note any impact these have on the organizations certification review follow-up actions.
### Sample Agenda (1 Reviewer, 1 Day)

**Patient Blood Management Certification**

For use in organizations accredited by AABB for Blood Banks and Transfusion Services

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity &amp; Topics</th>
<th>Suggested Organization Participants</th>
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<tbody>
<tr>
<td>8:00 – 8:10</td>
<td><strong>Opening Conference</strong></td>
<td>- Program administrative and clinical leadership</td>
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<td>- Introductions</td>
<td>- Others at program’s discretion</td>
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<td>- Brief review of agenda</td>
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<td>8:10 – 9:00</td>
<td><strong>Orientation to the Program</strong></td>
<td>- Program administrative and clinical leadership</td>
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<td>- Program scope</td>
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<td>- Program performance measurement and improvement activities</td>
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<td></td>
<td>▪ Performance improvement plan review including priority setting</td>
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<td>▪ Data collection and data quality monitoring</td>
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<td>▪ Data analysis and dissemination</td>
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<td></td>
<td>- Program data available for, and used in decision-making</td>
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<td>- Program evaluation by leaders and staff</td>
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<td></td>
<td>- Recently implemented program improvement</td>
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<td></td>
<td>- Program leaders, clinical leaders</td>
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<td></td>
<td>- Others at program’s discretion</td>
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<tr>
<td>9:30 – 10:00</td>
<td><strong>Reviewer Planning Session</strong></td>
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<td></td>
<td>- Individual patient tracer selection</td>
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<td></td>
<td>- Personnel and credentials files</td>
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<td></td>
<td>Note: Tracer selection requires a list, census report or other summary of patients currently receiving blood transfusions or who may likely receive a blood transfusion.</td>
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<td></td>
<td>- Organization’s review coordinator</td>
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<td>10:00 – 12:00</td>
<td><strong>Individual Tracer Activity</strong></td>
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<td>- Tracer activity begins where the patient is currently receiving care, treatment and services</td>
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<td>- Interactive review of patient record(s) with team member or organization staff actively working with the patient—map patient’s course of care, treatment and services up to the present and anticipated for the future</td>
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<td>- May include a patient and family interview, if they are willing to participate</td>
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<td></td>
<td>- Staff, program representatives, and management involved in the patient’s care, treatment, or services</td>
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<tr>
<td>12:00 – 12:30</td>
<td>Lunch</td>
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<tr>
<td>12:30 – 2:30</td>
<td><strong>Individual Tracer Activity – continued</strong></td>
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<td></td>
<td>- Additional tracer activity</td>
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<td></td>
<td>- Blood bank and perioperative services review</td>
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<td></td>
<td>- Note: Personnel and competency files for blood bank and perioperative staff will be reviewed at this time.</td>
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<td></td>
<td>- Staff, program representatives, and management involved in the patient’s care, treatment, or services</td>
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<td>Time</td>
<td>Activity &amp; Topics</td>
<td>Suggested Organization Participants</td>
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<tr>
<td>2:30 – 3:00</td>
<td><strong>Competence Assessment and Credentialing Process</strong></td>
<td>- Individual with authorized access to personnel and credentials files</td>
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<td></td>
<td>- Discussion during this session will focus on:</td>
<td>- Individual familiar with program-specific requirements for team members</td>
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<tr>
<td></td>
<td>- Processes for obtaining team member credentials</td>
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<td></td>
<td>information</td>
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<td></td>
<td>- Orientation and training process for program</td>
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<td>team</td>
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<td></td>
<td>- Methods for assessing competence of practitioners</td>
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<tr>
<td></td>
<td>and team members</td>
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<td></td>
<td>- In-service and other ongoing education activities</td>
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<td></td>
<td>available to program team members</td>
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<td></td>
<td>Note: The reviewer will request personnel records</td>
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<td></td>
<td>and credentials files to review based on team</td>
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<td>members and staff encountered or referred to</td>
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<td>throughout the day. Program staff should inform</td>
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<td>the reviewer of how much time is needed to</td>
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<td></td>
<td>retrieve personnel and credentials files.</td>
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<tr>
<td>3:00 – 4:00</td>
<td><strong>Issue Resolution and Reviewer Report Preparation</strong></td>
<td>- As requested by reviewer depending on the issue</td>
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<tr>
<td>4:00 – 4:30</td>
<td><strong>Program Exit Conference</strong></td>
<td>- Program administrative and clinical leadership</td>
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<td>- Others at program’s discretion</td>
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Sample Agenda (2 Reviewers, 1 Day)
Patient Blood Management Certification

For use in organizations not accredited by AABB for Blood Banks and Transfusion Services

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity &amp; Topics</th>
<th>Suggested Organization Participants</th>
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</thead>
<tbody>
<tr>
<td>8:00 – 8:10</td>
<td><strong>Opening Conference</strong></td>
<td>- Program administrative and clinical leadership</td>
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<tr>
<td></td>
<td>- Introductions</td>
<td>- Others at program’s discretion</td>
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<td></td>
<td>- Brief review of agenda</td>
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<tr>
<td>8:10 – 9:00</td>
<td><strong>Orientation to the Program</strong></td>
<td>- Program administrative and clinical leadership</td>
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<td></td>
<td>- Program scope</td>
<td>- Others at program’s discretion</td>
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<tr>
<td></td>
<td>- Program mission, goals and objectives</td>
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<td></td>
<td>- Program structure, and program relationship to the organization structure</td>
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<tr>
<td></td>
<td>- Program leadership and executive management responsibilities</td>
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<td></td>
<td>- Interdisciplinary team members, including roles and responsibilities</td>
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<td></td>
<td>- Organizational supports for the patient blood management program</td>
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<td></td>
<td>- Development and implementation of the program (e.g. timeline, successes and</td>
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<tr>
<td></td>
<td>opportunities, challenges and barriers)</td>
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<tr>
<td></td>
<td>- Patient blood management program activities</td>
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<td></td>
<td>- Identify the program level designation</td>
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<td></td>
<td>- Any unique program communication regarding patient rights and</td>
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<td></td>
<td>responsibilities and their right of refusal of care, treatment, and services</td>
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<td></td>
<td>offered</td>
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<td></td>
<td>- Assessing practitioner and staff competence in patient blood management</td>
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<td></td>
<td>- Organizational support for patient blood management program practitioners and</td>
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<td></td>
<td>staff education and specialized training</td>
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<td></td>
<td>- Processes supporting credentialing, privileging, and license/ registration/</td>
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<td>certification, education and experience verifications</td>
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<td></td>
<td>- Evaluating and improving the program’s performance</td>
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<tr>
<td>Time</td>
<td>Activity &amp; Topics</td>
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</table>
| 9:00 – 9:30 | **System Tracer – Data Use**  
- Program performance measurement and improvement activities  
  - Performance improvement plan review including priority setting  
  - Data collection and data quality monitoring  
  - Data analysis and dissemination  
- Program data available for, and used in decision-making  
- Program evaluation by leaders and staff  
- Recently implemented program improvement | - Program leaders, clinical leaders  
- Others at program’s discretion |
| 9:30 – 10:00 | **Reviewer Planning Session**  
- Individual patient tracer selection  
- Personnel and credentials files | - Organization’s review coordinator |
|           | Note: Tracer selection requires a list, census report or other summary of patients currently receiving blood transfusions or who may likely receive a blood transfusion. |
| 10:00 – 12:00 | **Reviewer 1: Individual Tracer Activity**  
- Tracer activity begins where the patient is currently receiving care, treatment and services  
- Interactive review of patient record(s) with team member or organization staff actively working with the patient—map patient’s course of care, treatment and services up to the present and anticipated for the future  
- May include a patient and family interview, if they are willing to participate | **Reviewer 2: Blood Bank Review**  
- Equipment  
- Pretransfusion testing  
- Records  
- Nonconformance |
|           | **Reviewer 2: Blood Bank Review**  
- Equipment  
- Pretransfusion testing  
- Records  
- Nonconformance | - Staff, program representatives, and management involved in the patient’s care, treatment, or services |
| 12:00 – 12:30 | **Lunch** | |
| 12:30 – 2:30 | **Reviewer 1: Individual Tracer Activity – continued**  
- Additional tracer activity | **Reviewer 2: Perioperative Services Review**  
- Equipment  
- Records  
- Nonconformance |
|           | **Reviewer 2: Perioperative Services Review**  
- Equipment  
- Records  
- Nonconformance | - Staff, program representatives, and management involved in the patient’s care, treatment, or services |
| 2:30 – 3:00 | **Competence Assessment and Credentialing Process**  
Discussion during this session will focus on:  
- Processes for obtaining team member credentials information  
- Orientation and training process for program team | - Individual with authorized access to personnel and credentials files  
- Individual familiar with program- |
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<td>Methods for assessing competence of practitioners and team members</td>
<td>specific requirements for team members</td>
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<td></td>
<td>In-service and other ongoing education activities available to program team members</td>
<td></td>
</tr>
<tr>
<td>Note:</td>
<td>The reviewer will request personnel records and credentials files to review based on team members and staff encountered or referred to throughout the day. Program staff should inform the reviewer of how much time is needed to retrieve personnel and credentials files.</td>
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</tr>
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<td>- Others at program’s discretion</td>
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Appendix A – Program Activity Levels

Overview
The Patient Blood Management (PBM) Certification program is designed to evaluate organizations with varying levels of complexity. The three program activity levels (Level 1, 2, and 3) are based on the services and capabilities at each organization.

- A small hospital may have a clinical program and services that meet the program level activities described as Level 3.
- A large hospital might have a clinical program and services that incorporates all of the activities described for Level 1.
- It should be recognized that one level is not superior to another and merely reflects differences in the activities performed by the hospital in which the PBM program resides.

Each organization that applies for Patient Blood Management Certification is required to designate an activity level prior to the on-site review. The electronic application (E-App) includes an Eligibility Requirements section that prompts the organization to select the appropriate activity level for their PBM program.

Applicability of Standard PBMOR.4
During the on-site review, the PBM program will be evaluated for compliance with the expectations that reflect their designated program activity level. The expectations for each activity level are presented in Standard PBMOR.4, Elements of Performance (EPs) 2-21. Standard PBMOR.4, EP 1 applies to all activity levels.

As each activity level addresses organizations with different capabilities, the PBM program’s activity level will determine which EPs are applicable during the certification review:

- Activity Level 1: EPs 2-21 are applicable
- Activity Level 2: EPs 2-17 are applicable
- Activity Level 3: EPs 2-14 are applicable

Additional Guidance
The following table provides examples of questions that can help determine whether a PBM program has addressed all of the applicable EPs. Although there may be some overlap between the items on this list, taken as a whole, the activities described reflect the total scope of activities performed by a PBM program.
Standard PBMOR.4 – The executive management defines, oversees, and monitors the activities of the program.

The program is responsible for, or have direct involvement with, oversight and monitoring of the following activities:

<table>
<thead>
<tr>
<th>Element of Performance</th>
<th>Activity Level 1</th>
<th>Activity Level 2</th>
<th>Activity Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Evidence of institutional support for the patient blood management program at the executive level.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Does the program have the full support of the medical director of the parent facility, including financial support, information technology support, and are there designated IT staff to assist implementation of PBM? Does the program have dedicated transfusion safety officers or PBM coordinators who are directly involved with the program? Is there a direct liaison relationship between the PBM program and the executive management of the parent facility?</td>
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<tr>
<td>3. Patient outcomes related to transfusion.</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Does the PBM program consider short term, intermediate and long term outcomes? Are these data consistently captured? Short term outcomes include transfusion complications and if the transfusion itself was successful. Intermediate term outcomes should include whether the patient survived the hospitalization and if the transfusion was an element in the patient’s overall survival of the process. In the long term, the program should review other patient outcomes, such as rates of hospital-acquired infections and length of stay.</td>
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<tr>
<td>4. Budgeting to the level of care required by the implementation of these PBM Certification Program Standards.</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>The PBM program should take into account direct and indirect costs associated with the program, including the FTEs required to successfully support the program, quality monitoring activities, and the impact on the transfusion service and other departments such as nursing.</td>
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<tr>
<td>5. Pretransfusion patient testing and evaluation.</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>In preparing for a preoperative intervention, the program should ensure that the transfusion history of the patient is considered and that an assessment of the likelihood of the patient requiring a transfusion is performed. This may also include pretransfusion tests for hemoglobin levels and coagulation.</td>
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<tr>
<td>Element of Performance</td>
<td>Activity Level 1</td>
<td>Activity Level 2</td>
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<tr>
<td><strong>6. Patient- or case-specific assessment of potential blood usage.</strong></td>
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<td>X</td>
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<tr>
<td>Is the patient being treated for iron deficiency? Does the patient have special transfusion requirements, a history of surgical bleeding, and is there a blood plan in use? The PBM program should ensure that a maximum surgical blood ordering schedule is current and that it is followed.</td>
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<tr>
<td><strong>7. Ordering of blood, including completion of type and antibody testing before procedure start time with a plan for antibody-positive patients.</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>The PBM program should ensure coordination between clinical care teams and the blood bank or immunohematology reference laboratory. The program should be informed of all special transfusion needs (i.e., specialized testing, rare unit requirements) that could complicate patient care.</td>
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<tr>
<td><strong>8. Preprocedure optimization of patient coagulation function including discontinuation of medications and herbal supplements that impair hemostasis.</strong></td>
<td>X</td>
<td>X</td>
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<tr>
<td>The PBM program should ensure that the patient’s history is evaluated and that medications or other substances that represent a bleeding risk are discontinued.</td>
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<tr>
<td><strong>9. Percentage of blood components wasted by component type (such as red cells, rare unit red cells, platelets, matched platelets, plasma, AB plasma, cryoprecipitate, and granulocytes) and cause for wastage (misordering, mishandling, not releasing in a timely manner, outdating in stock, and so forth.)</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Although this item is often reviewed by the hospital’s blood utilization or transfusion review committee, the PBM program should assist in and support this important activity. The PBM program should also be involved in developing action plans following this review.</td>
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<tr>
<td><strong>10. Minimize blood loss due to laboratory testing.</strong></td>
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<tr>
<td>The PBM program should be engaged in educating other clinical stakeholders about strategies to ensure that hospitalized patients are not subjected to excessive or unnecessary blood draws, which can lead to iatrogenic anemia.</td>
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<tr>
<td>Element of Performance</td>
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<tr>
<td><strong>11. Process for managing the blood needs of unidentified patients and resolving their identification.</strong> (See also PBMDR.5, EP 1)</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>When a patient comes in without preexisting identification, which is common in trauma settings, the PBM program should ensure that there is a set of “John/Jane Doe” numbers ready to assign that are unique and traceable back to the patient once identification has been made. In practice, this activity likely is already performed by hospitals that accept trauma patients. In conjunction with this, the PBM program should be responsible for development of protocols to deal with mass trauma situations where the “John/Jane Doe” numbers are absent due to a large influx of unknown patients.</td>
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<tr>
<td><strong>12. Processes to identify, prior to or upon admission, patients who may refuse transfusion under any circumstances.</strong></td>
<td>X</td>
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<tr>
<td>Patient preferences are often identified through direct discussion with the patient or their family and should be part of the informed consent process. Once patients who may refuse transfusion under any circumstances are identified, there should be a plan for the patient’s care that recognizes this preference. This may include pediatric patients. The PBM program should also have plans in place for patients who will accept blood but would prefer not to, and those who want the minimum amount of blood possible.</td>
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<td><strong>13. Adverse events and incidents related to transfusion.</strong></td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Adverse events may include misidentified samples, misuse of products, and transfusion reactions. The program should consider an incorrect order of blood products and a pattern of misuse or overuse of blood. As with EP 10, it is likely that the hospital’s blood utilization or transfusion review committee already evaluates these incidents; the PBM program should have some involvement in this review and should be involved in corrective or preventive action plans developed in response to the review.</td>
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<tr>
<td><strong>14. Evidence-based massive transfusion protocol that includes treatment of massive blood loss.</strong></td>
<td>X</td>
<td>X</td>
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<tr>
<td>The PBM program should be involved in the development of massive transfusion protocols for all potential recipients, including neonates, infants, children and adults.</td>
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<tr>
<td>Element of Performance</td>
<td>Activity Level 1</td>
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<tr>
<td>15. Processes and/or equipment to facilitate rapid decision making with regard to anemia and coagulation management.</td>
<td>X</td>
<td>X</td>
<td>N/A</td>
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<tr>
<td>The PBM program should have an established point-of-care testing plan or a plan for rapid laboratory testing to ensure that critical information about a patient’s clinical condition is available to the care team in a timely manner.</td>
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<tr>
<td>16. A plan by each service line to reduce perioperative blood loss.</td>
<td>X</td>
<td>X</td>
<td>N/A</td>
</tr>
<tr>
<td>Each service line has a role to play in reducing perioperative blood loss. The PBM program should serve as a hub for these plans. Service lines that should have this type of plan include surgery, interventional radiology, and internal medicine, at a minimum.</td>
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<tr>
<td>17. Strategies to reduce blood loss and manage anemia and coagulopathy in non-operative patients.</td>
<td>X</td>
<td>X</td>
<td>N/A</td>
</tr>
<tr>
<td>What strategies can a PBM program put in place to mitigate the use of blood and manage anemia? Are measures in place to prevent unnecessary iatrogenic blood loss? Are anemia and coagulopathies proactively identified and treated?</td>
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<tr>
<td>18. A formal program to care for patients who decline use of blood or blood-derived products.</td>
<td>X</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>A comprehensive PBM program not only identifies patients who refuse transfusion, but has a formal program in place to provide care for these individuals.</td>
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<tr>
<td>19. Identification and management of pre-surgical anemia before elective procedures for which type and screen or type and crossmatch is recommended.</td>
<td>X</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>The PBM program should have a key role in promoting a coordinated approach to the management of the patient in the presurgical setting.</td>
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<tr>
<td>20. Use of perioperative techniques consistent with current AABB Standards for Perioperative Autologous Blood Collection and Administration.</td>
<td>X</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>If the perioperative program is already accredited by AABB, this requirement has been satisfied. However, if the perioperative program is not accredited by AABB, the PBM program should review the current edition of AABB’s</td>
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</tr>
<tr>
<td>Standards for Perioperative Autologous Blood Collection and Administration to ensure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>that requirements for cell salvage or processing of perioperative blood products (e.g.,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>platelet gel, platelet-rich plasma) are met.</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

21. An active program with evidence-based metrics and clinician feedback to ensure compliance with transfusion guidelines.

A key aspect of PBM is ensuring that clinicians are informed and educated about blood transfusions, so that ordering practices are driven by the patient’s condition and institutional guidelines rather than habit or culture. This item requires that the PBM program be responsible for a plan to disseminate evidence-based metrics to clinicians.

<table>
<thead>
<tr>
<th></th>
<th>Activity Level 1</th>
<th>Activity Level 2</th>
<th>Activity Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

N/A: EP is not applicable to the activity level
Program Activity Levels Diagram
According to Standard PBMOR.4, a PBM program can be designated as a program activity level 1, 2, or 3. To be designated as such, the program shall be responsible for or have direct involvement with oversight and monitoring of specific activities. A Level 2 program is responsible for activities in Levels 2 and 3. A Level 1 program is responsible for activities in Levels 1, 2, and 3.
Appendix B – Frequently Asked Questions (FAQs)

FAQ: Expectations for PBM Standards Referencing AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration

<table>
<thead>
<tr>
<th>Standard PBMEQ.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program defines quality control activities for equipment controlled by other departments.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Element of Performance 2 [AABB Standard 3.2.1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment controlled by the blood bank, transfusion service, or perioperative program shall be controlled in accordance with the manufacturer’s instructions and/or the current editions of AABB Standards for Blood Banks and Transfusion Services and AABB Standards for Perioperative Autologous Blood Collection and Administration.</td>
</tr>
</tbody>
</table>

Q. What is the responsibility of the Patient Blood Management Program for compliance with this requirement?

A. Examples of equipment that would be covered by this standard include:
   - Blood warmers
   - Storage devices for blood and blood components (including alarm systems)
   - Cell savers
   - Computer systems or information systems

Examples of activities that surveyors may ask about:
   - How is equipment qualified and installed?
   - Is equipment used in conformance with manufacturer’s written instructions?
   - Is equipment uniquely identified and its use recorded in a manner that permits traceability?
   - What is the calibration program in place for equipment?
   - How are equipment malfunctions or failures investigated?

Q. What are required elements of equipment control?

A. If the blood bank or perioperative program are not accredited by AABB, a surveyor would likely seek to learn about the policies, processes, and procedures that are in place for the following activities:
   - A process for selection of equipment, including information systems
   - A process qualification of equipment (installation, operational, and performance qualification)
   - Policies, processes, and/or procedures for unique identification of each piece of equipment and for equipment use
   - A program of monitoring/maintenance to ensure that equipment remains fit for use
   - Record-keeping associated with the activities described above.
In many cases, the PBM program may not have direct control over this equipment; in fact, the PBM program may not be considered the true “owner” of any single piece of equipment. However, equipment requirements contained in the BB/TS and Periop Standards can have a significant impact on transfusion safety and patient care. If the hospital blood bank/transfusion service or perioperative program are AABB-accredited, then these requirements will have been met and additional redundant inspection will not be necessary. However, for facilities where these departments are not accredited by AABB or another equivalent accrediting body, the PBM program should seek to have documented evidence showing that:

1) The appropriate requirements, contained in chapter 3 of these two publications and summarized above, have been shared with the affected departments.

2) That these departments have developed policies, processes, and procedures, based on the quality system of the PBM Standards, to satisfy these requirements.

3) That the continued conformance to these standards by those departments is verified and ensured through occasional assessments or audits.

**Standard PBMPC.8**

The program has guidelines for phlebotomy, transfusion orders, and for pre- and posttransfusion patient care.

**Element of Performance 3 [AABB Standard 5.3.1]**

The program revises, revises, or creates policies, processes, and procedures regarding pretransfusion testing consistent with the current edition of AABB Standards for Blood Banks and Transfusion Services.

Q. What activities are part of “pretransfusion testing?”

A. Pretransfusion testing is an essential aspect of transfusion safety and encompasses a significant portion of transfusion service-related activities. Examples of these activities include:

- Patient samples (collection, identification, and retention)
- Requests for Blood/Blood Components
  - Information
  - Conformance with sample label
- Serologic confirmation of donor blood group/type
- Pretransfusion testing of patient blood
- Comparison of current results with previous records
- Selection of Compatible Blood
  - Routine
  - Special Circumstances
- Crossmatch
- Labeling
- Use of Computer to detect ABO incompatibility
- Resolution of discrepancies between order, records, unit
- Urgent requirements for blood/blood components

Examples of questions a surveyor may ask:

- How are patients uniquely identified?
- What does your institution accept for unique identifiers on the sample?
- Does the written procedure define when and where blood sample tubes should be labeled?
- Show me/describe your procedures for performing an ABO/Rh type.
- What testing do you do to detect unexpected red cell antibodies?
- What patient testing is required before you issue a unit of RBCs? Granulocytes? Plasma or Platelets?
- What is your policy for preparing Whole Blood or Red Blood Cells for transfusion to recipients with a history of clinically significant antibodies?
- Under what circumstances, if any, do you transfuse Rh-positive red cells or platelets to Rh-negative recipients and how is this documented?
- Under what circumstances do you perform computer crossmatches?

Q. Why is pretransfusion testing part of my PBM certification?

A. Pretransfusion testing is an essential aspect of the safe practice of transfusion medicine. The blood bank or transfusion service must ensure that samples for testing are labeled and controlled, and that test results are recorded and communicated. A mistake in the sample collection or identification process, or a failure to ensure that samples for pretransfusion testing are collected from the correct individual, can increase the likelihood of an incompatible blood transfusion. Because non-infectious serious hazards of transfusion, or NISHOTs, are more common than infectious hazards, the control of activities related to pretransfusion testing is of paramount importance.

In addition to preventing NISHOTs, pretransfusion testing is also important to ensure that special transfusion requirements are met — particularly for chronically transfused patients or those with clinically significant antibodies. As such, pretransfusion testing is an important part of clinical decision-making surrounding transfusion.

Sample Handling and Labeling

The use of two independent identifiers for the patient helps ensure accurate and positive identification of patients, samples, and blood components. The label on a patient sample must be affixed to the sample containers before the individual obtaining the sample leaves the side of the patient, and there must be a mechanism to identify the date of sample collection and the individual(s) who collected the sample. Labels must be complete, accurate, and legible. The transfusion service must confirm that all identifying information on the request is an agreement with the sample label, and in the case of a discrepancy, a new sample must be obtained. (See standard 5.11.2 in the Standards for Blood Banks and Transfusion Services)

Testing

Patient blood must be tested for ABO group, Rh type. If the unit to be transfused is either Red Blood Cells, Granulocytes, or Whole Blood, pretransfusion testing for unexpected antibodies to red cell antigens must also be performed as well. If discrepant results are obtained for ABO group, only group O Red Blood Cells may be issued.

Methods of testing for unexpected antibodies to red cell antigens shall be validated and must demonstrate clinically significant antibodies. Additional testing must be performed when clinically significant antibodies are detected. Control systems must be in place to ensure the validity and accuracy of antibody testing results. And in patients who have been transfused in the preceding 3 months, or patients who have been pregnant during that timeframe, or if the
patient’s transfusion or pregnancy history are uncertain or unavailable, the sample for testing must be drawn within 3 days of the scheduled transfusion.

**Standard PBMDR.1**
The program develops, validates, and implements policies and procedures or documents and records.

**Element of Performance 3 [AABB Standard 6.0]**
Documents and records related to transfusion medicine or perioperative programs shall be created and controlled in accordance with the current edition of the AABB Standards for Blood Banks and Transfusion Services, AABB Standards for Perioperative Autologous Blood Collection and Administration, or the requirements of an equivalent accrediting body.

**Standard PBMDN.1**
The program captures, investigates, and reports deviations, nonconformances, and adverse events.

**Element of Performance 5 [AABB Standard 7.0]**
The program shall ensure that all deviations, nonconformances, and adverse events related to blood transfusion are managed in accordance with the current editions of AABB Standards for Blood Banks and Transfusion Services, AABB Standards for Perioperative Autologous Blood Collection and Administration, or the requirements of an equivalent accrediting body.

Q. Which records are included here?

A. Just as with equipment, a PBM program may not possess extensive records of its own. PBM programs must have the ability to pull meaningful information from existing systems – patient medical records and the laboratory information system, for example – in order to report on their overall performance. In order for this information to be recorded and available, a system for record-keeping must be established to ensure that records are complete, accurate, and retrievable.

Examples of questions a surveyor might ask include:

- How are records ensured to be complete?
- How does the records system provide for retrieval in a time period appropriate to the circumstances?
- What is the process for protection of manual and electronic records from unauthorized or accidental destruction or modification?
- Were any records found that were not recorded in permanent media?
- How does the record system make it possible to
  - Trace any blood or blood component, product, or tissue from source to final disposition?
  - Review the records applying to the specific component?
  - Investigate adverse reactions manifested by the recipient?
- How are archived records accessed after the method/hardware used to archive them has been changed or updated?

Q. What are my responsibilities in capturing and investigating adverse events and deviations?
A. An important aspect of monitoring the efficacy of a PBM program and of transfusion safety is to ensure that adverse reactions to transfusion are captured, investigated, and reported. These requirements therefore are designed to provide an infrastructure of record-keeping and adverse event reporting that will allow the PBM program to accurately assess its own performance with respect to patient outcomes.

Many of these requirements are mirrored in the requirements of other accrediting bodies. In hospitals where the blood bank and/or perioperative program are not accredited, a careful review of these two standards should be performed to ensure that current practices are consistent with AABB Standards.

Examples of questions a surveyor might ask include:

- What is the process for capturing information about deviations from policies, processes, and procedures and failures to meet specified requirements?
- What is the process to ensure that deviations from or failures to meet specified requirements are:
  - Assessed?
  - Investigated?
  - Monitored?
- What is the process for investigating these events and determining their cause(s)?
- How is the medical director involved in development of adverse transfusion event protocols?
- Where are the signs and symptoms of a transfusion reaction recorded?
- Who is notified? At what stage of the evaluation do you notify them?
- When do you decide to interrupt or discontinue the transfusion?
- When there is a suspected adverse event related to perioperative product collection and/or administration, how does the policy address ensuring that this evaluation does not delay proper clinical management of the patient?
- How does the procedure address possible hemolytic reactions?
- What is the process for comparing patient identification with product labels & records?
FAQ: Expectations for PBMRS.2, EP 6 (Facility-Defined Credentials)

<table>
<thead>
<tr>
<th>Standard PBMRS.2</th>
</tr>
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<tbody>
<tr>
<td>Staff are qualified, trained, and competent to perform their responsibilities.</td>
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</table>

<table>
<thead>
<tr>
<th>Element of Performance (EP) 6 [AABB Standard 2.1.4]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals who order and/or transfuse blood shall meet facility-defined requirements for education related to patient blood management</td>
</tr>
</tbody>
</table>

Q: What is the expectation for compliance with PBMRS.2, EP 6?

A: This standard requires credentialing of all individuals who order and/or transfuse blood. The glossary defines credentials as follows:

“Defined requirements for training, education, and experience within each facility that qualify individuals to perform specific procedures.”

The goal of this standard is to ensure that blood transfusions, which are one of the most frequently performed procedures during hospitalizations in the United States, are only ordered by individuals with knowledge of the indications for that particular therapy. Similarly, individuals responsible for the transfusion of blood should be qualified to recognize problems and adverse reactions, and to understand the appropriate course of action in the event an adverse reaction is suspected.

In order to satisfy the requirement, patient blood management (PBM) programs should:

1. Develop requirements for the qualification of individuals who can order and/or transfuse blood.
2. Ensure that these requirements are met for any individual allowed to order and/or transfuse blood.
3. Be able to demonstrate to surveyors, through documents and records, that individuals who order and/or transfuse blood are qualified to do so. (This is required by Standard PBMRS.2, EP 3, Qualification, which states that “[p]ersonnel performing critical tasks shall be qualified to perform assigned activities…”)

Credentialing or qualification of these individuals should include educational content that is relevant to the activity in question. For example, education required for individuals who order blood should include indications for transfusion of blood components and also information about situations under which transfusions may not be appropriate or indicated. The educational requirements for individuals who transfuse blood should include information about risks of transfusion and recognition of transfusion reactions. Both sets of individuals should also be familiar with hospital policies and protocols around informed consent for transfusion. The educational programs may be developed internally or may be offered by external organizations such as AABB. In some cases, a PBM program may want to test the knowledge of individuals who order blood.

The educational content or certification materials used to meet this requirement can be developed by the PBM program or can be purchased from an external source (e.g., AABB’s Patient Blood Management modules.) Regardless of the educational content used to credential these individuals, the program should be able to demonstrate that requirements for credentialing have been defined and met for all individuals who order and/or transfuse blood in the hospital.
Note: It is recognized that in the initial phase of this certification, some hospitals may not have completed credentialing of all individuals. However, the expectation is that all hospitals applying for certification should have defined the educational or training criteria for internal credentialing. The actual delivery of the education or training may be folded into the next annual cycle of training and competency assessments for these individuals. Hospitals in the process of implementing this credentialing program should be able to demonstrate to surveyors that the credentialing requirements are in place, that educational or training materials have been prepared, and that there is a timeline for the credentialing of all individuals who order or transfuse blood.
Appendix C – Additional Guidance for Perioperative Services

The following is a list of potential questions to ask during the perioperative services review. DO NOT use this as a checklist of topics to cover, but rather as suggested areas to explore.

- What is your perioperative autologous blood management program’s organizational structure?
  Show me your current organizational chart or written top down description of organizational structure.

- Show me evidence of your program’s quality system.
  How do you ensure that your quality system is understood and implemented by all personnel?

- What is the process to ensure that the requirements of AABB Standards and of regulatory agencies are incorporated into your documents and practices?
  Who is the approving authority for medical and technical policies, processes, and procedures?
  How are clinical situations that warrant exceptions to policies, processes, and procedures handled?

- What evidence exists that all devices have been validated for their intended use from collection through administration?

- What is the process to ensure that equipment monitoring and maintenance conforms to manufacturer’s written instructions, applicable regulations, and requirements?

- What is the process for investigating equipment malfunctions, failures, or adverse events associated with equipment, removal from service and reporting to the manufacturer when indicated?
  What is the process to assess the effect on patient safety when equipment is found to be out of calibration?
  What is the process used to alert personnel to malfunctioning/out-of-service equipment?
  What is the process to ensure that necessary requalification is performed after equipment repair?

- Where do you store perioperative autologous blood components?
  What temperatures are defined as acceptable for storage of collected perioperative products?

- Is the storage device used exclusively for perioperative salvaged products? If not, how are these products distinguished and/or kept separate from any other blood products?

- Is there validation to show that the storage device maintains proper temperature?
• Who is responsible for maintenance of the storage devices?
  How are storage temperatures monitored? If not continuously monitored, is monitoring done at least every 4 hours? How are storage temperatures recorded every 4 hours?
  If there is an automatic temperature monitoring process: what is your downtime procedure?

• If a third party provider is used for perioperative autologous blood collection and administration, where can I find documentation that defines the qualifications of your third party provider?
  If the perioperative services are provided by a contract group, what involvement does the local medical director have in the oversight of the program?

• What is the process for developing, validating, and implementing new or changed processes and procedures (to include SOP, equipment, labels)?

• Show me/describe how you would prepare (assessor selected perioperative products).
  How do you ensure that aseptic methods are used throughout your processes?

• Review records for compliance with AABB Reference Standards 5.1.8A-C (pages 66-68)

• How is the medical director involved in the development of perioperative processes and procedures?

• What is the process to ensure that perioperative products are collected with a physician’s order? (Acceptable documentation can include: standing orders based on certain procedures, verbal orders if documented, surgical listings/schedules, procedure record, documentation on the anesthesia record.)

• How do you document the inspection of perioperative products prior to transfusion?

• How are products labeled to identify the patient, the product content, and the expiration of the product?

• Are inspection criteria clearly defined and do they comply with manufacturer’s written instructions?

• What do you do to ensure the risk of air embolism is minimized?
  Can you show me a written policy that pertains to prevention of air emboli?

• Review a sample of patient medical records for required product administration documentation.
  Review records of disposition for products that were not transfused.

• Are criteria for reporting adverse events documented?
  Were there any adverse events reported?
  Review documentation of any adverse events.
• How does the record system make it possible to trace any perioperative product from source to final disposition?
  How does the record system make it possible to review the records applying to the specific product and to investigate adverse reactions manifested by the patient?

• What is the process for investigating possible adverse events related to administration of perioperative products?
  Does the procedure state that administration of the product will be interrupted if the recipient experiences complications?
  When there is a suspected adverse event related to perioperative product collection and/or administration, how does the policy address ensuring that this evaluation does not delay proper clinical management of the patient?

• What quality indicator data are collected and evaluated?
## Reference Standard 5.1.8A—Handling, Storage, and Expiration of Perioperative Autologous Red Cell Blood Components

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Collection Type</th>
<th>Storage Temperature</th>
<th>Time from the Start of Collection to Expiration #</th>
<th>Time from Completion of Processing to Expiration #</th>
<th>Special Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Acute normovolemic hemodilution (whole blood)</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>N/A</td>
<td>None</td>
</tr>
<tr>
<td>2.</td>
<td>Acute normovolemic hemodilution (whole blood)</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>N/A</td>
<td>Storage at 1-6 C shall begin within 8 hours of start of collection</td>
</tr>
<tr>
<td>3.</td>
<td>Intraoperative blood recovery with processing (centrifugation and/or washing and/or ultrafiltration)</td>
<td>Room temperature</td>
<td>N/A</td>
<td>8 hours</td>
<td>None</td>
</tr>
<tr>
<td>4.</td>
<td>Intraoperative blood recovery with processing (centrifugation and/or washing and/or ultrafiltration)</td>
<td>1-6 C (N/A if bacterial contamination is suspected)</td>
<td>24 hours</td>
<td>N/A</td>
<td>Storage at 1-6 C shall begin within 4 hours of completion of processing</td>
</tr>
<tr>
<td>5.</td>
<td>Intraoperative blood recovery without processing</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>N/A</td>
<td>None</td>
</tr>
<tr>
<td>Item No.</td>
<td>Component Type</td>
<td>Storage Temperature</td>
<td>Expiration time from start of collection</td>
<td>Special Conditions</td>
<td></td>
</tr>
<tr>
<td>---------</td>
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<td>------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Shed blood under postoperative or posttraumatic conditions with or without processing</td>
<td>N/A</td>
<td>8 hours</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Combined intraoperative and postoperative blood recovery with processing</td>
<td>Room temperature</td>
<td>Postoperatively processed units: 8 hours from the start of postoperative collection</td>
<td>Intraoperatively processed units: 8 hours</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Red Blood Cells prepared by apheresis and intended for reinfusion</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Red Blood Cells prepared by apheresis and intended for reinfusion</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>Storage at 1-6 C shall begin within 8 hours of collection</td>
<td></td>
</tr>
</tbody>
</table>

^ Can include blood recovered from surgical sponges
# If manufacturer’s written instructions are more stringent than this requirement, they shall be followed.

Reference Standard 5.1.8B—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Reinfusion

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Component Type</th>
<th>Storage Temperature</th>
<th>Expiration time from start of collection</th>
<th>Special Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Platelet-rich plasma intended for reinfusion</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>None</td>
</tr>
<tr>
<td>2.</td>
<td>Platelet-rich plasma intended for reinfusion *</td>
<td>1-6 C</td>
<td>24 hours</td>
<td>Storage at 1-6 C shall begin within 8 hours of collection</td>
</tr>
<tr>
<td>3.</td>
<td>Plasma intended for reinfusion</td>
<td>Room temperature</td>
<td>8 hours</td>
<td>None</td>
</tr>
</tbody>
</table>
4. Plasma intended for reinfusion | 1-6 C | 24 hours | Storage at 1-6 C shall begin within 8 hours of collection

* The storage requirements herein apply only to components not intended for platelet activity.

Reference Standard 5.1.8C—Handling, Storage, and Expiration of Perioperative Autologous Non-Red-Cell Blood Components for Topical Application or Injectable Application

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Component Type</th>
<th>Storage Temperature</th>
<th>Expiration#</th>
<th>Special Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Platelet-rich plasma intended for topical use or injectable use</td>
<td>Room temperature</td>
<td>N/A</td>
<td>Shall be used before the patient leaves the operating room or clinical procedure area</td>
</tr>
<tr>
<td>2.</td>
<td>Platelet-poor plasma intended for topical use or injectable use</td>
<td>Room temperature</td>
<td>N/A</td>
<td>Shall be used before the patient leaves the operating room or clinical procedure area</td>
</tr>
<tr>
<td>3.</td>
<td>Thrombin intended for topical use</td>
<td>Room temperature</td>
<td>Within 8 hours after component preparation (or not to exceed device manufacturer’s recommendations)</td>
<td>Shall be used before the patient leaves the operating room or clinical procedure area</td>
</tr>
<tr>
<td>4.</td>
<td>Bone Marrow Aspirate Concentrate intended for topical use</td>
<td>Room temperature</td>
<td>N/A</td>
<td>Shall be used before the patient leaves the operating room or clinical procedure area</td>
</tr>
</tbody>
</table>

# If manufacturer’s written instructions are more stringent than this requirement, they shall be followed.
Appendix D – Additional Resources

**AABB Educational Resources**

AABB has several resources available to help organizations develop a comprehensive PBM program. Please visit the following websites for more information:

http://www.aabb.org/pbm/Pages/default.aspx
AABB offers resources that address the various aspects of PBM, helping organizations achieve their goals of optimizing patient outcomes, preventing unnecessary blood usage and auditing physician compliance with established criteria for transfusion.

http://www.aabb.org/pbm/Pages/pbm-resources.aspx
Access the AABB PBM resources available to address the various challenges within your facility and improve patient care.