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# Transfusion Medicine Checklist

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ON-LINE CHECKLIST AVAILABILITY AND RESOURCES

Participants of the CAP accreditation programs may download the checklists from the CAP website (cap.org) by logging into e-LAB Solutions Suite. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory’s activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

A repository of questions and answers and other resources is also available in e-LAB Solutions Suite under Accreditation Resources, Checklist Requirement Q & A.

SUMMARY OF CHECKLIST EDITION CHANGES

Transfusion Medicine Checklist
09/22/2021 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged:
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements

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INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a transfusion medicine laboratory section or department.

NOTE: Many of the requirements in this Checklist reflect United States regulatory requirements, particularly those of the US Food and Drug Administration (FDA). These requirements may not be applicable in other countries for purposes of CAP accreditation. Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations at minimum.

The term "transfusion service medical director" is used generically throughout the checklist to refer to the physician who has oversight responsibility for the different services (eg, transfusion service, donor service, apheresis service, cellular therapy service) addressed by the checklist requirements. Some laboratories may have separate directors providing oversight for these services; however, all directors must meet the required qualifications.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

QUALITY MANAGEMENT

Checklist requirements in this section also apply to the apheresis and cellular therapy products sections, as appropriate.

GENERAL ISSUES

Inspector Instructions:

- Sampling of final disposition
- Blood/tissue supplier agreement
- Timely provision of blood agreement
- CBER notification policy

- What do you do if QC for components is not acceptable?
- What is your laboratory's risk-reduction system for mistransfusion? How do you monitor the system's effectiveness?
- How has your laboratory validated the LIS for blood banking?

- Select several occurrences in which component QC is not acceptable and follow records to determine if the steps taken follow the laboratory procedure for corrective action
The laboratory information systems are validated for blood banking/transfusion medicine activities.

NOTE: The LIS must be validated at initial installation, and when a change is made to the system. All possible anticipated permutations of processes should be checked (eg, electronic crossmatching and release of group specific products). Most laboratories utilize a series of screen captures to demonstrate the processes in the LIS. Records of system validation must be retained for at least two years beyond the service life of the system.

REFERENCES
1) Department of Health and Human Services, Food and Drug Administration. FDA letter to blood establishments, Mar 21, 1994
3) Food and Drug Administration. Revisions to the requirements applicable to blood, blood components, and source plasma. Fed Register. 1999(Aug 19);[42CFR606.15(c]

TRM.30000 Monthly QC Review

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

NOTE: The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

Evidence of Compliance:
 ✓ Records of QC review including follow-up for outliers, trends, or omissions

TRM.30550 Misidentification Risk

The facility has a written program to ensure that the risk of pretransfusion sample misidentification and other causes of mistransfusion are monitored and subjected to continual process improvement.

NOTE: The laboratory must actively monitor the key elements of the transfusion process, including, as applicable, donor management, unit production and handling, sample identification and testing, and the transfusion itself including recipient identification.

Evidence of Compliance:
 ✓ Occurrence records/error logs demonstrating appropriate review and follow-up of significant errors and patterns of errors in identification and other processes AND
 ✓ Records of investigation and appropriate corrective action (eg, education of staff, changes in procedures, etc.) for significant errors, including review of monitoring data for corrective action and process improvement, when appropriate

REFERENCES

**REVISED** 06/04/2020

TRM.30575 Misidentification Risk

The facility has a system to reduce the risk of mistransfusion for non-emergent red cell transfusions.

NOTE: Mistransfusion occurs from misidentification of the intended recipient at the time of specimen collection for pretransfusion testing, during laboratory testing and preparation of
units to be issued, and at the time of transfusion. Misidentification at sample collection occurs approximately once in every 1,000 samples, and in one in every 12,000 transfusions the recipient receives a unit not intended for or not properly selected for him/her.

Risk reduction options that might be considered include:

- Verifying the ABO group of the intended recipient on a second sample collected at a separate phlebotomy (including the recording of the result in the institution's historical record)
- Utilizing a mechanical barrier system
- Utilizing an electronic identification verification system that ensures that the patient from whom the pretransfusion specimen was collected is the same patient who is about to be transfused
- Other approaches capable of reducing the risk of mistransfusion.

The laboratory is expected to participate in monitoring the effectiveness of the system that it implements.

The laboratory should also consider improvements in procedures and/or educational efforts as part of its program to reduce the risk of mistransfusion.

REFERENCES
1) WH Dzik, MF Murphy, G Andreu, MD et al. An international study of the performance of patient sample collection. Vox Sanguinis 2003;85:40-47
2) Lumadue JA, Boyd JS, Ness PM. Adherence to a strict specimen-labeling policy decreases the incidence of erroneous blood grouping of blood bank specimens. Transfusion 1997;37:1169-72
3) Wenz B, Burns ER. Improvement in transfusion safety using a new blood unit and patient identification system as part of safe transfusion practice. Transfusion. 1991;31:401-3

**REVISED** 06/04/2020
TRM.30700 QC Records Phase II

The laboratory has records for components prepared that do not meet the quality control requirements, including investigation, corrective action taken, and final disposition.

REFERENCES

**REVISED** 06/04/2020
TRM.30800 Disposition Records Phase II

There is a record of the disposition of all blood components, derivatives, cellular therapy products, tissues, including the method of destruction, as applicable, or transfer of units unsuitable for transfusion or transplant.

NOTE: The disposition of each product or tissue obtained by the laboratory, including recovered plasma where appropriate, is recorded. "Record of disposition" refers to whether the product, component, derivative, or tissue was transfused, transplanted, discarded or returned. The method of destruction must be specified in the facility’s policies and procedures when applicable.

REFERENCES

**REVISED** 09/22/2021
TRM.30850 Blood/Tissue Supplier Service Agreement Phase II
There is a written agreement or letter of understanding between the transfusion service and its blood/tissue supplier(s) to ensure an adequate and safe blood/tissue supply.

NOTE: This agreement must include the means for maintaining inventory, requirements for notification when a donor or components are found to be seropositive, and redistribution of components for disaster or emergency need, which could include obtaining needed components by drawing donors or by agreement with another facility. For services provided by an outside blood center (eg, provision of blood and blood products, referral laboratory support, donor testing), a hospital must have an agreement approved by the transfusion service medical director and hospital administration. Information regarding means of immediate communication to the blood supplier (eg, phone numbers) must be readily available to laboratory staff.

When immunohematology services are provided by an outside testing laboratory (eg, pre-transfusion, compatibility, transfusion reaction work-ups), the provisions for the procurement, transfer, availability of blood and blood components and the responsibilities of each facility must be specified in the agreement. This provision also applies when services are provided to stand-alone facilities that only store and administer blood and blood products, such as renal dialysis units, infusion centers, nursing homes or hospice care facilities.

The laboratory providing the testing services used for patient management decisions must be CLIA-certified, or meet equivalent requirements as deemed by the Centers for Medicare and Medicaid Services (CMS).

Evidence of Compliance:
✓ Copy of approved agreement (eg, contract) with blood/tissue supplier(s)

REFERENCES
2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24); [42CFR493.1103(a),(b)].

TRM.30866 Service Agreement

There is a written policy or agreement between the transfusion service and the clinical areas for which it provides transfusion and transplantation support (eg, surgery, emergency room, patient care units) to ensure timely provision of blood, blood components and tissue.

NOTE: The policy or agreement should define the expectations for turnaround time, requests for patients with special transfusion needs (eg, CMV negative, leukoreduced), notifications of delays in obtaining suitable products, and transportation of components and products.

Evidence of Compliance:
✓ Copy of approved agreement (eg, policy, transfusion committee meeting minutes, written statement) detailing the transfusion support services that will be provided to the clinical areas

TRM.30882 Supplier Evaluation/Selection Process

The transfusion service laboratory has a process for evaluating and selecting suppliers of critical materials and monitoring suppliers’ ability to meet the laboratory’s needs.

NOTE: The definition of “critical materials” is given in the “Reagents and Critical Materials” section, below.

Evidence of Compliance:
✓ Written procedure for evaluation, selection and monitoring of suppliers AND
✓ Records of supplier monitoring

TRM.30900 Records of Deviation From SOP

Phase II
The transfusion service medical director or designee provides written authorization for deviations from the standard operating procedures.

NOTE: The standard operating procedures constitute the approved procedures of the laboratory and are to be followed at all times. Any deviations from these procedures must either be authorized by the responsible transfusion medicine medical director or designee prior to their performance or, if detected only after the event, must be investigated through the laboratory's quality assurance process. A wide variety of routine procedures may, from time to time, require the transfusion service medical director or designee to authorize an alternative approach because of specific clinical situations. Among these, for example, might be the need to give Rh positive red cells to an Rh negative recipient because of inventory shortages, or to provide a unit of platelets that was not HLA-matched (or “crossmatch compatible” or “antigen-negative,” depending on the laboratory’s routine approach) to an alloimmunized patient in an attempt to control hemorrhage.

REFERENCES

TRM.30950 CBER Notification Phase II

There is a policy requiring notification of the Center for Biologics Evaluation and Research according to US federal regulations when a biological product deviation occurs.

NOTE: Deviations may include compatibility testing, component preparation, labeling, storage, and distribution of units for transfusion. A Biologic Product Deviation (BPD) is reportable to CBER if the transfusion service releases a blood product from its control and the error has the potential to affect the safety, potency or purity of the product, even if it is not administered to a patient. A laboratory or transfusion service that performs manufacturing activities is required to report to the Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) as soon as possible, but not to exceed 45 calendar days from the date of discovery of information reasonably suggesting a reportable event has occurred. In accordance with 21CFR606.171, transfusion facilities that are not licensed or registered with FDA are required to report to FDA any deviations or unexpected events associated with manufacturing that may affect the safety, purity or potency of a distributed product.

Evidence of Compliance:
✓ Records of reportable events, as applicable

REFERENCES

REAGENTS AND CRITICAL MATERIALS

A “critical material” is a good or supply used in the collection, preservation, storage, preparation, or testing of blood components that directly affects quality or patient safety (for example, blood collection sets).
Inspector Instructions:

- Sampling of test procedures for reagent handling
- Sampling of current reagent/critical material package inserts, for consistency with written procedures
- Sampling of records of new reagent and critical material lot inspection and evaluation
- Inventory log
- Sampling of typing sera/reagent cell reactivity QC records

- Sampling of reagents (expiration date, storage)

- How do you store reagents and controls used in test procedures?
- How do you evaluate new lots of critical materials?
- How does your laboratory manage and control reagent inventory?

- Review a sampling of QC data over the previous two-year period. If there is an occurrence in which typing sera/reagent cell QC is not acceptable, follow records to determine if the steps taken follow the laboratory policy for corrective action.

Additional requirements are in the REAGENTS section of the All Common Checklist.

**REVISED** 09/22/2021

TRM.31227  Package Inserts/Manufacturer's Instructions  Phase II

Current package inserts/manufacturer's instructions are available for the reagents and other critical materials used by the laboratory.

NOTE: The laboratory must have a procedure that assures that:
- The most current package inserts/manufacturer's instructions are in use
- The relevant procedures are updated when changes to the instructions occur.

Unless a manufacturer's package insert is being used as part of an approved procedure, laboratories are not required to retain discontinued package inserts; however, the laboratory must have a process to obtain expired package inserts from the manufacturer, if requested.

Manufacturer's instructions for the use of donor collection critical materials must be retained for 10 years beyond the blood/blood component's disposition or expiration, whichever is longer.

TRM.31234  Reagent Handling - Typing Sera and Critical Materials  Phase II

Typing sera and other critical materials are used according to the manufacturers' directions, or if alternative procedures are used, validation records confirm that they perform as intended.

NOTE: Typing sera and other critical materials must be used according to the manufacturers' instructions. Testing methods used for ABO, Rh and antibody screening that are different from the manufacturers' instructions, are acceptable provided they are not prohibited by the
manufacturer, and have been demonstrated to be satisfactory, or, for laboratories subject to US regulations, have been approved by CBER.

For FDA-licensed blood agencies, use of approved reagents in a manner not consistent with manufacturer’s directions may require prior FDA authorization.

REFERENCES
1) Food and Drug Administration. Guide to inspections of blood banks, 1994(Sep)

TRM.31241 Reagent QC Phase II
All new lots of reagents and critical materials (eg, blood collection sets) are inspected and tested, as applicable, before use, with records of acceptance.

TRM.31375 Inventory Control Phase II
An inventory control system tracks the use of all lot numbers of critical materials received.

NOTE: Records must include dates received and placed into use, and the disposition of unacceptable materials.

Evidence of Compliance:
✓ Inventory log (paper or electronic)

**REVISED** 06/04/2020

TRM.31400 Antisera/Reagent Red Cell QC Phase II
There are records of acceptable reactivity and specificity of typing sera and reagent red cells on each day of use, including a check against known positive and negative cells or antisera, or manufacturer’s instructions for daily quality control are followed.

NOTE: Unless manufacturer’s instructions state otherwise, the following apply:

- Typing reagents, including antisera (eg, anti-D, anti-K, anti-Fy(a)) and reagent red cells must be checked for reactivity and specificity on each day of use. Typing antisera must be checked with known positive and negative cells; reagent red cells must be checked with known positive and negative antisera.
- Each cell used for antibody screening must be checked each day of use for reactivity of at least one antigen using antisera of 1+ or greater avidity.
- Anti-IgG reactivity of antiglobulin reagents may be checked during antibody screening and crossmatching.

This checklist requirement can be satisfied by testing one vial of each reagent lot each day of testing.

For red cell antibody panels, manufacturer’s instructions and control processes, as outlined in the facility’s written procedures (eg, ruling out antibodies, antigen typing of patient cells for the corresponding antibody) must be followed.

REFERENCES
INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section should be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

- Procedure for evaluating and approving the use of products that were collected or processed under compromised conditions
- Sampling of semi-annual serologic centrifuge checks (mechanical timer and speed)
- Sampling of blood volume regulator QC records

**REVISED** 09/22/2021
TRM.31900 Serologic Centrifuge Checks Phase II

Mechanical timers on serologic centrifuges, and the speed of the centrifuge, are checked:

- Initially
- After adjustments and repairs
- According to the manufacturer’s recommended interval (or at least every six months, if not specified by the manufacturer).

NOTE: The frequency of such checks should be based on the historical stability of the centrifuge. This requirement does not apply to digital timers.

Evidence of Compliance:
✓ Records of serologic centrifuge checks at defined frequency

REFERENCES

TRM.32200 Blood Volume Standardization Phase II

Equipment used to regulate volume of blood drawn from blood donors or individuals undergoing therapeutic phlebotomy is standardized with a container of known mass or volume before initial use and after repairs or adjustments, and checked according to the manufacturer’s recommended intervals, with result recorded.

NOTE: Devices such as agitators, balances, and scales must be standardized with a container of known mass or volume. This must be done before initial use and after repairs or adjustments, and checked as instructed or recommended by the manufacturer to ensure that the correct volume is drawn. If the manufacturer does not provide or recommend a quality control testing interval, the facility must specify the frequency of testing.

Evidence of Compliance:
✓ QC records showing standardization checks at defined frequency

REFERENCES

TRM.32208 Collection/Processing Equipment Phase II
There is a procedure to assess the conformance of blood, components or tissues when equipment used for collection or processing is found to be out of calibration. Records are retained.

NOTE: Traditional good manufacturing practices generally do not allow for therapeutic use of products collected under compromised conditions, but the life-saving and irreplaceable nature of stem cells and similar components may be a legitimate exception. Although it is impossible to retroactively correct for potential errors in collection and processing when the system is later found to be compromised, the laboratory should have a procedure for dealing with such situations to determine whether the affected component(s) are or can be made to be suitable for their intended use. Records must include the approval of the potentially compromised product by both the transfusion service medical director and clinically responsible physician.

Evidence of Compliance:
✓ Written procedure for evaluating and approving the use of products that were collected or processed under compromised conditions AND
✓ Records of approval for potentially compromised products AND
✓ Records of disposal for unsuitable products

RECORDS

The following routine records must be retained and available as required by applicable national, federal, state (or provincial), and local law; but, in no instance for fewer than five years after the records for processing have been completed, or six months after the latest expiration date for an individual component (whichever is later), in accordance with 21 CFR 606.160 and 42CFR493.1103 through 493.1105.

Inspector Instructions:
- Record retention policy
- Applicable FDA registration or license

- Review a sampling of units (one or more component types) to ensure that all steps from donor draw or receipt of blood components, through storage and testing to final disposition, including transfusion, are recorded. Determine if records provide an adequate audit trail of all activities.

**REVISED** 09/22/2021
TRM.32250 Record Retention - Transfusion Medicine Phase II

Records are retained for an appropriate period.

NOTE: Records must be retained per the current CAP requirements, and in conformity with national, federal, state (or provincial), and local laws and regulations. At the time of this checklist edition, the requirements are as listed in the table below.

Extension of the retention periods may be appropriate for optimal patient care in certain circumstances.

These requirements apply only to donor and transfusion-related testing and activities. Refer to the general retention requirements in the Laboratory General Checklist (GEN.20377) for testing not related to transfusion.
<table>
<thead>
<tr>
<th>TYPE OF RECORD</th>
<th>RETENTION PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Donor Records</strong></td>
<td></td>
</tr>
<tr>
<td>● Blood/component donor information, consent and collection</td>
<td>10 years</td>
</tr>
<tr>
<td>● Donor blood testing</td>
<td></td>
</tr>
<tr>
<td>● Donor notification of significant findings</td>
<td></td>
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<tr>
<td>● Component production</td>
<td></td>
</tr>
<tr>
<td>● Look back investigation/disease reporting</td>
<td></td>
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<tr>
<td>● Final unit disposition</td>
<td></td>
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<tr>
<td>● Irradiation of cellular components</td>
<td></td>
</tr>
<tr>
<td>● Acceptability of returned units into inventory</td>
<td></td>
</tr>
<tr>
<td>● Donor collection package inserts</td>
<td>10 years beyond donor unit disposition or expiration, whichever is longer</td>
</tr>
<tr>
<td>● Indefinitely and permanently deferred donors</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>● Donors placed under surveillance (for recipient protection)</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Records</strong></td>
<td></td>
</tr>
<tr>
<td>● Transfusion administration records (TRM.41450)</td>
<td>10 years</td>
</tr>
<tr>
<td>● Therapeutic phlebotomy/apheresis records</td>
<td></td>
</tr>
<tr>
<td>● Final unit disposition</td>
<td></td>
</tr>
<tr>
<td>● Patient pre-transfusion testing results/interpretation</td>
<td>10 years</td>
</tr>
<tr>
<td>● Immediate evaluation/interpretation of transfusion reactions</td>
<td></td>
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<tr>
<td>● Evaluation/interpretation of delayed transfusion reactions</td>
<td></td>
</tr>
<tr>
<td>● Emergency release of blood, including signature of requesting physician obtained before or after release</td>
<td></td>
</tr>
<tr>
<td>● Transfusion problems such as difficulty in blood typing, transfusion reactions, unexpected antibodies, and special transfusion requirements.</td>
<td>Indefinitely</td>
</tr>
<tr>
<td><strong>Other Records</strong></td>
<td></td>
</tr>
<tr>
<td>● Employee signatures, initials, identification codes, and inclusive dates of employment</td>
<td>10 years</td>
</tr>
<tr>
<td>● Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components</td>
<td></td>
</tr>
<tr>
<td>● Traceability of blood, blood components, and critical materials</td>
<td></td>
</tr>
<tr>
<td>● Final inspection and verification of blood before issue</td>
<td></td>
</tr>
<tr>
<td>● Container (eg, portable coolers) qualification/process validations</td>
<td></td>
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<tr>
<td>● Competency records</td>
<td></td>
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<tr>
<td>● Training records</td>
<td></td>
</tr>
<tr>
<td>● Orders and requests for blood/blood components</td>
<td></td>
</tr>
<tr>
<td>● Blood supplier agreements</td>
<td>5 years</td>
</tr>
</tbody>
</table>
- Review and approval of new and revised policies and procedures
- Discontinued policies and procedures

<table>
<thead>
<tr>
<th>Quality Control Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Management reviews for the effectiveness of the quality system</td>
</tr>
<tr>
<td>- Proficiency testing records</td>
</tr>
<tr>
<td>- Irradiation dose delivery</td>
</tr>
</tbody>
</table>

| 5 years |

<table>
<thead>
<tr>
<th>Control systems for donor testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Retyping of donor units</td>
</tr>
<tr>
<td>- Inspections of blood/critical materials</td>
</tr>
<tr>
<td>- Instrument/equipment quality control and maintenance</td>
</tr>
<tr>
<td>- Control systems for patient testing</td>
</tr>
<tr>
<td>- Inspection of weld for completeness</td>
</tr>
<tr>
<td>- Temperature monitoring (eg, graphs, logs) of refrigerators, freezers, and platelet incubators</td>
</tr>
</tbody>
</table>

| 10 years |

<table>
<thead>
<tr>
<th>Tissue Records (including cellular therapy products)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Collection, transportation, processing, issuing, and disposition</td>
</tr>
<tr>
<td>- Obsolete labels</td>
</tr>
</tbody>
</table>

| 10 yrs beyond tissue's disposition or expiration, whichever is longer |

| - Daily temperature monitoring |
| - Investigation of adverse events |
| - Discontinued policies, procedures and other controlled documents |
| - Quality control |
| - Personnel |
| - Training |
| - Competency |
| - Facility maintenance |
| - Complaints or general facility issues |

| 10 years |

---

**TRM.32275** Component Records

**Phase II**

*Records are retained for each component from collection or receipt through processing, storage, and testing, to final disposition.*

**TRM.32300** Receipt of Blood

**Phase II**

*Records include information about all blood received from outside sources.*

**Evidence of Compliance:**
- Written procedure defining the required information as stipulated by the laboratory **AND**
- Invoices, shipping records and/or logs for all incoming blood components

**TRM.32900** Bacteriologic Studies

**Phase II**

*Records include information about bacteriologic studies (when indicated).*

**Evidence of Compliance:**
- Culture results from transfusion reactions with suspected bacterial contamination **AND**
✓ Records for in-house bacterial contamination testing of random and apheresis platelets not tested by the blood supplier

TRM.33200  Personnel Audit Trail

The laboratory can identify the person performing each significant step in the collection, processing, testing, storage, and distribution of blood and blood components.

NOTE: Records must be complete and all relevant data available, including results, interpretation, dates, and identity of persons performing the work. A personnel audit trail must be maintained for each significant step in the collection, processing, testing, storage, and distribution of blood and blood components.

REFERENCES

TRM.33300  License/Registration of Laboratory

If blood components or cellular therapy products are collected or modified, even if only for autologous collections, the blood bank or transfusion service is licensed or registered appropriately.

NOTE: The blood bank or transfusion service must have appropriate registration or license, as required by the FDA. 21 CFR 607.20 of the Code of Federal Regulations states that all establishments that engage in the manufacture of blood products are required to register with the FDA. This includes blood centers or transfusion services that irradiate, wash, or deglycerolize components. The laboratory must have appropriate FDA registration form(s) available for the Inspector to examine.
# PROCEDURES AND TESTS

## IMMUNOHEMATOLOGICAL PROCEDURES

**Inspector Instructions:**

<table>
<thead>
<tr>
<th>Task</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>READ</strong></td>
<td></td>
</tr>
</tbody>
</table>
  - Sampling of blood type/antibody screen policies and procedures  
  - Sampling of QC policies and procedures  
  - Sampling of QC records  
  - Sampling of critical patient results/log |
| **OBSERVE** |  
  - Technologist performing testing (recording results at the time of testing) |
| **ASK** |  
  - What is your laboratory's course of action when ABO and Rh typing results are not in agreement with the patient's historical record?  
  - How does your laboratory ensure that the direct antiglobulin test detects RBC-bound complement as well as IgG?  
  - How do you confirm negative antiglobulin tests?  
  - How do you determine when quality control is unacceptable and when corrective actions are needed?  
  - How do you document critical results? Who do you contact? |
| **DISCOVER** |  
  - Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory policy for corrective action |

---

**TRM.40050 Agglutination/Hemolysis Criteria**

*Criteria for agglutination and/or hemolysis are defined.*

*NOTE:* Criteria must be defined in the procedure manual to provide uniformity of interpretation of positive and negative agglutination and hemolysis results.

**TRM.40100 Test Result Recording**

*Observations of all test results are recorded properly at the time the test is performed.*

*NOTE:* Test results must be recorded at the time the test is performed in order to reduce the risk of transcription errors from delayed recording.

**TRM.40120 QC Handling**

*Control specimens are tested in the same manner and by the same personnel as patient/donor samples.*
NOTE: QC specimens must be analyzed by personnel who routinely perform patient/donor testing. This does not imply that each operator must perform QC daily, so long as each instrument and/or test system has QC performed at required frequencies, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:
- Records reflecting that QC is performed by the same personnel performing patient testing at defined frequency

REFERENCES

TRM.40130 Alternative Control Procedures Phase II

If the laboratory performs test procedures for which control materials are not commercially available, there are written procedures for an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be recorded.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. Examples of alternative procedures may include split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:
- Written procedures for alternative quality control AND
- Records of alternative control procedures

REFERENCES

TRM.40140 QC Confirmation of Acceptability Phase II

The results of controls are reviewed for acceptability before reporting results.

Evidence of Compliance:
- Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
- Records of control result approval

REFERENCES

TRM.40145 QC Corrective Action Phase II

There are records of corrective action when control results exceed defined acceptability limits.

NOTE: Patient/client test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results. For example, evaluation could include comparison of patient means for the run in question to historical patient means, and/or review of selected patient results against previous results to see if there are consistent biases (all results higher or lower currently than previously) for the test(s) in question.
The corrective action for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified (e.g., trending for repeat failures, etc.).

REFERENCES

TRM.40150 Anti-D Controls

Appropriate control(s) are used for anti-D testing.

NOTE: If an anti-D reagent contains a potentiating diluent, the appropriate control is the diluent alone.

Evidence of Compliance:
✓ Written procedure defining controls used for anti-D testing consistent with manufacturer's instructions AND
✓ Records of anti-D control results

TRM.40200 DAT Controls

When performing an antiglobulin test with anti-IgG or polyspecific antiglobulin reagents, IgG-coated red blood cells are used as a control in all negative antiglobulin tests.

NOTE: IgG-coated red blood cells must be used to confirm all negative antiglobulin test results when the antiglobulin reagent used for testing has anti-IgG reactivity. Tests found negative by tube methodology must be verified by obtaining a positive test result after adding IgG-coated (control) red blood cells. If a licensed blood typing system is used that does not require verification of negative test results using IgG-coated red blood cells, an appropriate quality control procedure must be followed, as recommended by the manufacturer.

Evidence of Compliance:
✓ Records of testing that include control results confirming negative antiglobulin tests

TRM.40210 DAT

When performing an antiglobulin test with anti-C3 antiglobulin reagents, C3-coated red blood cells are used as a control in all negative antiglobulin tests.

NOTE: Complement-coated red blood cells must be used to confirm all negative antiglobulin test results when the antiglobulin reagent used for testing has anti-C3 reactivity. Tests found negative by tube methodology must be verified by obtaining a positive test result after adding C3-coated (control) red blood cells. If a licensed blood typing system is used that does not require verification of negative test results using C3-coated red blood cells, an appropriate quality control procedure must be followed, as recommended by the manufacturer. If a polyspecific antiglobulin reagent is used, refer to checklist item TRM.40200.

Evidence of Compliance:
✓ Records of testing that include control results confirming negative antiglobulin tests

**REVISED** 09/22/2021

TRM.40215 ABO Typing on Solid Organ Donors

Laboratories participating in donor evaluation for solid organ transplantation have a written policy for ABO typing, and A subgroup typing on group A and AB donors.
NOTE: Due to the possibility of misinterpretation of ABO typing, if the organ donor has been transfused with red blood cells in the past three months, ABO subgroup typing must be performed on a pretransfusion sample. A shorter time period may apply if the laboratory has validated an alternate ABO typing method to resolve ABO typing discrepancy and sub typing in this situation.

REFERENCES

COMPATIBILITY TESTING

This section applies whenever crossmatching is performed. The Inspector should pay particular attention to the Laboratory General Checklist - SPECIMEN COLLECTION, DATA HANDLING, AND REPORTING regarding acquisition of samples for testing.

Inspector Instructions:

- Sampling of compatibility testing policies and procedures
- Sampling of historical record checks
- Sampling of confirmation of donor unit ABO/Rh records
- Sampling of worksheets/computer records with forward and reverse grouping, autologous and allogeneic serologic crossmatches

- Collection of blood specimen used for compatibility testing (patient identification, specimen labeling)

- How is the phlebotomist identified who has collected the specimen for compatibility testing?
- What do you do if the specimen label does not match the requisition exactly?
- If applicable, how do you handle neonatal transfusions? What blood groups are transfused?

- If there had been an instance when the ABO and Rh typing results were not in agreement with the patient's historical record, further evaluate the laboratory's responses, corrective actions and resolutions

TRM.40230 Compatibility Specimen Labeling Phase II

All blood samples used for compatibility testing are labeled in the presence of the patient with:

1. Patient's first and last name
2. Unique identification number
3. Date of collection
4. A method to identify the phlebotomist.

NOTE: Blood specimens collected for compatibility testing must be positively and completely identified and labeled before leaving the patient. Acceptable practices for positive identification
of patient and blood specimen labels must be defined in the procedure manual and may include visual inspection and/or an electronic system to read the identifying information contained in bar codes or radio-frequency identification (RFID) microchips or the patient's wristband. Acceptable practices for generating specimen labels must be defined in the procedure manual (refer to GEN.40490) and may include electronic devices utilizing information encoded in bar codes or RFID microchips. There must be a dependable method to identify the phlebotomist who collected the blood sample, such as initials or another identifier on the tube, or an electronic record.

Evidence of Compliance
✓ Written procedure defining labeling requirements of specimens for compatibility testing
✓ Written procedure defining system identifying the phlebotomist collecting compatibility testing specimens

REFERENCES
3) Sandler SG, Langeberg A, Carty K, Dohnalek LJ. Bar codes and radio-frequency technologies can increase safety and efficiency of blood transfusions. LabMedicine 2006;37:436-439

TRM.40250 Specimen/Requisition Verification Phase II
An appropriately trained member of the transfusion service confirms that all identifying data on the transfusion requisition (paper or electronic) is identical to the information on the specimen tube before compatibility testing.

NOTE: Laboratories must have a policy on how to handle truncated names on labels, if applicable.

Evidence of Compliance:
✓ Written procedure for verifying that the requisition/computer order matches the information on the specimen label

TRM.40300 Historical Record Check Phase II
ABO, Rh, and antibody screen test results are compared against results of the same tests recorded previously to detect discrepancies and identify patients requiring specially selected units.

NOTE: Comparison of records of previous ABO and Rh typing are an essential step in compatibility testing. Available laboratory records for each patient must be routinely searched whenever compatibility testing is performed. The historical record search can be performed manually by qualified laboratory personnel or by a validated computer system capable of performing historical checks. If no record of the patient's blood type is available from previous determination(s), the transfusion service should be aware that there is an increased probability of an incorrect blood type assignment and, consequently, of a hemolytic transfusion reaction. If a laboratory collects an additional sample for the purpose of verification of patient identity, a repeat antibody screen need not be performed on this specimen.

Evidence of Compliance:
✓ Written procedure for checking ABO/Rh and antibody screening results with historical results AND
✓ Records of historical checks OR
✓ Records of LIS historical check validations

TRM.40350 Typing Discrepancies - Investigation/Reconciliation Phase II
There are records of the investigation and reconciliation of all cases in which the ABO and Rh typing results were not in accord with the patient's historical record.

NOTE: Available laboratory records for each patient must be routinely searched whenever compatibility testing is performed. Quality management records must include an investigation of all cases in which the ABO or Rh typing was not in accordance with the patient's laboratory historical record.

TRM.40450  Donor Unit ABO/Rh Confirmation  Phase II

There are records of the confirmation of the ABO group of all red blood cell components and as appropriate, Rh type, using a sample of red blood cells from an attached segment.

NOTE: All donor red cell units must have the ABO group confirmed, using a sample from an attached segment. The D negativity of units labeled “Rh-negative” must be similarly confirmed. Records must show that the result was acceptable before the unit is made available for transfusion. Tests for weak D are not required for confirmation of Rh-negative units. A transfusion service may choose to omit the confirmation of the unit's ABO/Rh type if the transfusion service patient pre-transfusion and/or compatibility testing was performed at another CAP-accredited or CLIA-certified laboratory, with confirmation of the unit’s ABO/Rh type. For laboratories subject to US regulations, the compatibility testing must have been performed in another CLIA-certified laboratory.

REFERENCES
1) Domen RE. Policies and procedures related to weak D phenotype testing and Rh immune globulin administration. Results from supplementary questions to the comprehensive transfusion medicine survey of the College of American Pathologists. Arch Pathol Lab Med. 2000;124:1118-1121

TRM.40500  Recipient Sample  Phase II

There is a written policy defining the maximum interval during which a sample may be used before obtaining a new sample.

NOTE: The transfusion service must have a policy defining the maximum interval during which a recipient sample may be used for crossmatching. This may not exceed 3 days in patients who have been transfused or pregnant within the past 3 months, or if relevant medical/transfusion history is unknown or uncertain. The day of sample draw is day 0.

TRM.40550  Forward/Reverse Typing  Phase II

For each patient, red blood cells are tested with anti-A, anti-B, and anti-D, and serum/plasma is tested using A1 and B reagent red cells.

NOTE: The ABO/Rh type of the patient's red blood cells must be determined by an appropriate test procedure. Tests on each sample must include forward and reverse grouping.

The use of molecular based screening assays alone is not acceptable for ABO and RhD blood type assignment for the purposes of transfusion or transplantation. ABO and RhD typing by FDA-cleared or approved serological methods must be used for the purpose of transfusion or donor and recipient ABO and RhD typing for transplantation.

Laboratories not subject to US regulations must follow national, state or provincial, and local laws.

Evidence of Compliance:
✓ Written procedure for ABO/Rh typing AND
✓ Logs or computer records with forward and reverse grouping

REFERENCES
TRM.40600 Unexpected Antibody Screen

Prior to transfusing red cell products, a screen to detect unexpected red cell alloantibodies is performed that includes the following:

- Incubation at 37°C
- Use of red cells that are not pooled
- Interpretation at the antiglobulin phase

Evidence of Compliance:
✓ Written procedure for screening for unexpected red cell alloantibodies AND
✓ Logs or computer records indicating the reactions at the different phases of testing

TRM.40650 Serologic Crossmatch

For allogeneic units, a serologic crossmatch is performed to detect serologic incompatibility unless the specimen is eligible for computer crossmatch.

NOTE: Under certain circumstances, a transfusion service may elect to omit the antiglobulin phase of the serologic crossmatch. The antiglobulin test may be omitted if the antibody screen is negative and there is no history of detection of unexpected antibodies. Nevertheless, a procedure to detect ABO incompatibility, either a serologic crossmatch or a computer crossmatch using a system validated for computer crossmatching is required. Typing, screening and crossmatching of infants less than or equal to four months old can be abbreviated if a specific procedure is available.

Evidence of Compliance:
✓ Written procedure for serologic crossmatch, including criteria for omitting the antiglobulin phase AND
✓ Written procedure for crossmatching for infants less than or equal to four months old, if applicable AND
✓ Logs or computer records of serologic crossmatches

TRM.40651 Autologous Unit Crossmatch

For autologous units, a crossmatch procedure is performed (either serologic or electronic) to detect incompatibility.

Evidence of Compliance:
✓ Logs or computer records of autologous crossmatches

TRM.40652 Neonate Transfusion

For non-group O neonates receiving non-group O red blood cells, there is a written procedure to screen the neonate's serum/plasma for anti-A or anti-B if the donor unit and maternal blood ABO blood groups are not compatible.

NOTE: Methods used to detect anti-A or anti-B must include an antiglobulin phase. Neonates include infants up to four months of age.

Evidence of Compliance:
✓ Written procedure for detection of anti-A or anti-B in non-group O neonates AND
✓ Logs or computer records with screening results

TRM.40655 DAT Testing Algorithm
When a direct antiglobulin test is ordered by a patient’s physician, the testing algorithm allows for detection of RBC-bound complement as well as IgG.

NOTE: The testing algorithm is intended to detect patients with complement-mediated hemolysis which may occur in paroxysmal cold hemoglobinuria, autoimmune hemolytic anemia, or drug-induced hemolytic anemia. Detection of complement is not required for the purpose of diagnosing hemolytic disease of the newborn.

The use of anti-IgG alone will fail to detect some cases of complement-mediated hemolysis because not all cases of complement-mediated hemolysis have detectable IgG coating the red blood cell. TRM.40200 and TRM.40210 also apply.

**Evidence of Compliance:**
- Written procedure for DAT testing providing for the detection of RBC-bound complement and IgG AND
- Records for DAT consistent with procedure

**REFERENCES**

**COMPUTER CROSSMATCHES**

A computer crossmatch is an electronic method that is used to confirm that the unit is appropriate for transfusion to the intended recipient through the use of validated software logic to determine compatibility, rather than serologic techniques.

This section does not apply if the laboratory does not perform computer crossmatches.

**Inspector Instructions:**
- Sampling of computer crossmatch policies and procedures
- Sampling of confirmation of donor unit ABO/Rh records
- Sampling of records of the initial/revalidation of the electronic crossmatch system
- What method do you use to verify the recipient's ABO blood group?
- What computer alerts are generated when there are discrepancies?
- In what instances would an electronic crossmatch not be appropriate?

**TRM.40665  Computer Crossmatches  Phase II**

There are written procedures for computer crossmatch methods based on validated decision rules for verifying donor/recipient compatibility.

NOTE: The computer crossmatch may not be used if patients have a current or past history of clinically significant alloantibodies, or if there are unexplained typing discrepancies on the current sample.

**Evidence of Compliance:**
- Written procedure for computer crossmatch, including eligibility criteria AND
- Records of software validation for computer crossmatching
REFERENCES

TRM.40670 ABO Group and Rh(D) Type Verification

The recipient’s ABO group and Rh(D) type has been verified by repeat testing of the same sample, a different sample, or agreement with a historical type in the laboratory’s records.

NOTE: Repeat testing of the same sample is inadequate for computer crossmatching for issuing non-type O red cells, unless the sample has been drawn using technology or methods for ensuring positive identification (eg, mechanical barrier system or digital bedside identification system).

When unexplained ABO typing discrepancies exist on the current sample, serologic crossmatch techniques must be employed.

Evidence of Compliance:
✓ Written procedure defining method for verification of ABO AND
✓ Work records of test results and/or search of records verifying ABO type

REFERENCES

TRM.40680 Donor Unit/Recipient Information

The laboratory information system contains the donor unit number, component type, ABO/Rh type of the component, the interpretation of the unit’s ABO confirmatory test, and the patient’s (recipient’s) ABO/Rh type, when appropriate.

Evidence of Compliance:
✓ Written policy defining information to be stored in the information system

TRM.40690 Data Entry Verification

If a serologic crossmatch is not performed, there is a procedure to verify correct computer data entry before issuing blood or blood components, and the computer alerts the user of any discrepancies.

NOTE: When a serologic crossmatch is not performed, patient safety must be ensured by requiring verification of proper data entry before issuing blood or blood components. The computer system must alert the user of any discrepancies of donor unit labeling, blood group confirmatory test interpretation, and to the existence of any ABO incompatibility.

Evidence of Compliance:
✓ Written procedure for the verification of correct data entry prior to release of blood/blood components AND
✓ Records of verification of correct data entry AND
✓ Written description of computer system alerts used to prevent issuance of blood components when discrepancies exist
SELECTION OF BLOOD AND COMPONENTS FOR TRANSFUSION

Inspector Instructions:

- Sampling of policies and procedures for selection of blood/components
- What is your course of action when receiving a request for blood for a patient with special transfusion requirements (e.g., leukoreduced, CMV negative, aliquoting components for patients at risk of TACO)?
- What is your procedure for emergency release requests?
- What is your course of action when an incompatibility has been discovered with an emergency release?

**REVISED** 06/04/2020
TRM.40700 Selection of Blood Components Phase II

The written procedure for selection of blood components for transfusion requires the use of ABO group-specific whole blood, low-titer group O whole blood, or ABO group-specific or compatible red blood cell-containing components and contains criteria used for selection of plasma or platelet containing components.

NOTE: To avoid potentially life-threatening ABO incompatibility, the laboratory must have written procedures for the selection of appropriate whole blood, red cells or plasma for recipients. ABO group-compatible plasma and platelet components should be used. If transfusion of ABO incompatible plasma is permitted due to blood supply and medical necessity, the laboratory has a written policy on the use of ABO incompatible plasma and platelet components.

If transfusion of low-titer group O whole blood occurs, the procedure must describe:

- Definition of "low-titer" group O whole blood as mutually agreed by the transfusion service and the blood supplier
- Indications for the use of these units.

**REVISED** 09/22/2021
TRM.40710 Rh Negative Transfusion Recipients Phase II

The transfusion service has a written procedure for approving the transfusion of Rh-positive red cell-containing components to Rh-negative patients.

REFERENCES


**REVISED** 06/04/2020
TRM.40720 Provisions for Special Components Phase II

The laboratory has written procedures for providing appropriate components for:
- Patients with immunohematologic conditions (clinically significant red cell antibodies, transplantation, etc.)
- Transfusion of special blood components (red cell antigen-negative, irradiated, CMV-reduced risk, hemoglobin S-negative, etc.)
- Aliquoting or volume reduction of blood components for patients identified to be a risk for transfusion associated circulatory overload (TACO)
- Transfusion of low-titer group O whole blood, including the maximum volume/units allowed per event.

NOTE: Exceptions to the procedure may be made only with the approval of the physician responsible for the transfusion service, or designee.

REFERENCES
1) AABB, the American Red Cross, America's Blood Centers and the Armed Services Blood Center, Circular of information for the Use of Human Blood and Blood Components. Bethesda, MD. October 2017.

TRM.40740 ABO-Incompatible Plasma and Platelet Transfusions in Infants

There is a written procedure to prevent or limit the administration of ABO-incompatible plasma in platelet and plasma components for transfusion given to infants.

NOTE: For infant recipients, plasma in platelet components should be ABO-compatible, as relatively large amounts of ABO-incompatible plasma may cause hemolysis or shortened red cell survival. If necessary, the plasma volume in platelet units can be reduced shortly before transfusion by removing plasma from the platelet unit and resuspending the platelets in an approved alternate solution.

TRM.40760 Granulocytes And/Or Platelets Crossmatch-Compatible

The red cells in granulocytes and/or platelets are crossmatch-compatible with the recipient's plasma, except when the component contains less than 2 mL of donor red cells.

NOTE: If a platelet unit appears abnormally pink or red, the contaminating red cell volume can be determined to assess whether crossmatching is required.

Evidence of Compliance:
- Written procedure for crossmatching red cells in granulocyte or platelet components with recipient plasma for products with greater than 2 mL of donor red cells AND
- Records of crossmatches

TRM.40770 Life-Threatening Situations

Adequate policies and procedures have been established for the investigation and handling of life-threatening situations (such as the use of uncrossmatched blood or abbreviation of testing) that include the written authorization of a qualified physician.

NOTE: Written policies and procedures must be available to expedite testing for transfusion in a life-threatening situation. If an institution's procedure allows abbreviated testing in massive transfusion situations, records should indicate that the procedure was followed. Records must include the authorization by a qualified physician. (If approved by the institution and recorded in the laboratory's procedures, the physician responsible for the transfusion service laboratory may accept this responsibility.) If an incompatibility is discovered on completion of an incomplete crossmatch, the responsible physician must be notified in a timely manner and this notification recorded.
Red blood cells released before testing has been completed must be conspicuously labeled as uncrossmatched on the tag or label. Records of completion of compatibility testing for units released uncrossmatched must be retained.

**Evidence of Compliance:**
✓ Records of emergency release authorization by a qualified physician

**REFERENCES**

**PERINATAL TESTING**

**Inspector Instructions:**

- **READ**
  - Rh immune globulin release policy

- **ASK**
  - How do you ensure that all Rh-negative women receive protection against Rh immunization?
  - How do you evaluate for fetomaternal hemorrhage in those candidates for Rh immune globulin?
  - What procedures are in place to ensure that identified candidates receive Rh immune globulin within 72 hours?

- **DISCOVER**
  - Follow the records of a patient receiving Rh immune globulin. Determine if procedures for testing, dosing and time interval for administration are adequate.

**TRM.40780 RhIG Candidates**

There is a written procedure to identify all potential candidates for Rh immune globulin.

**NOTE:** Information about every pregnant woman's Rh type should be available when the possibility of alloimmunization and subsequent Rh disease of the newborn may occur. The institution must ensure that all Rh-negative women receive the maximum protection against Rh immunization. A test record from any CLIA-licensed or CAP-accredited laboratory is acceptable for establishing the Rh type (positive or negative). Potential Rh immune globulin candidates include: pregnancy termination through delivery or abortion, amniocentesis, invasive obstetric procedures, and abdominal trauma during pregnancy. The procedure should address the RhIG candidacy of women of childbearing age with weak or discrepant RhD typings.

Maternal RhIG candidacy assessment must include the identification of weak-D phenotype newborns.

**Evidence of Compliance:**
✓ Written procedure defining the method for identification of RhIG candidates

**REFERENCES**

**REVISED** 09/22/2021

TRM.40790  Fetomaternal Hemorrhage Detection

**Phase II**

Identified Rh immune globulin candidates are tested after delivery to detect fetomaternal hemorrhages greater than 30 mL of whole blood.

NOTE: A post-partum blood sample from identified Rh immune globulin candidates must be evaluated for fetomaternal hemorrhages. A standard method (Kleihauer-Braun-Betke or flow cytometry) should be used to calculate the recommended dosage of Rh immune globulin, based on the estimated volume of fetal whole blood or red blood cells in the maternal circulation. In the event the laboratory provides RhIG dosage recommendations to physicians, standardized formulas must be used for translating the mL of fetal blood into vials of RhIG.

Quantitative fetomaternal hemorrhage testing is indicated when the neonate has a weak-D phenotype.

Evidence of Compliance:

✓ Written procedures for detection of fetomaternal hemorrhage **AND**
✓ Written procedures for quantification of fetal bleed, including calculations used to determine dose of Rh immune globulin **AND**
✓ Patient reports with screening results, quantification of fetal bleed, and recommended dosage (if applicable)

REFERENCES


**REVISED** 09/22/2021

TRM.40800  RhIG Dosage

**Phase II**

Laboratories performing Rh immune globulin (RhIG) dosage calculations have written procedures to ensure that the appropriate RhIG dose is recommended for all identified candidates within 72 hours of an Rh alloimmunizing event, whenever possible.

NOTE: This requirement does NOT apply if:

• The fetus is Rh-negative
• The patient is known to be alloimmunized to the D antigen
• The laboratory does not perform RhIG dosage calculations.

Evidence of Compliance:

✓ Patient records confirming administration within the appropriate timeframe

**REVISED** 09/22/2021

TRM.40820  Historical Record Check

**Phase II**

There is a written procedure to ensure that laboratory records for ABO/Rh testing are searched for each pregnant patient for at least the preceding 12 months.

NOTE: The purpose of this comparison is to detect sample/patient identification errors or other errors that might lead to the attribution of an incorrect blood type or antibody screen result to
a pregnant patient; this might result in a missed opportunity to provide prophylaxis against or appropriate treatment for perinatal alloimmunization. The historical record search can be performed manually by qualified laboratory personnel or by a validated computer system capable of performing historical checks. If the laboratory performing the testing does not maintain records that would allow this check to be performed, the testing shall be reported with a disclaimer alerting the ordering physician that the check has not been performed and that verifications of the sample's identity and the test results are strongly recommended.

Evidence of Compliance:
✓ Written procedure for checking ABO/Rh results with historical results AND
✓ Records of historical checks OR
✓ Records of LIS historical check validations

TRANFUSION PROCEDURES

Although the transfusion service may not have direct oversight over some aspects of transfusion, such as blood warmers, blood/blood component administration and intraoperative/perioperative services, all checklist requirements in this section apply due to the impact on patient safety and blood component usage.

Inspector Instructions:

- Sampling of transfusion policies and procedures
- Sampling of transfusionist records of initial and annual training
- Sampling of patient records for recording of the required elements of administration and monitoring of transfusion of blood components
- Sampling of blood warming system maintenance records (if applicable)
- If applicable, sampling of transfusion committee or blood utilization committee minutes demonstrating transfusion service medical director participation
- How do you examine blood products just prior to issue?
- What are the sign/symptoms of a transfusion reaction?
- What course of action would you take if you suspect a transfusion reaction?

**REVISED** 09/22/2021

TRM.40875 Transfusion Service Medical Director Responsibility Phase I

There are records of the transfusion service medical director's participation in activities relating to patient safety, including:

1. Oversight of the development of policies and procedures that pertain to patient safety and transfusion service functions
2. Review of processes and documents that support the consent for transfusion
3. Establishing criteria for transfusion
4. Monitoring and auditing transfusion practices
NOTE: The transfusion service medical director must be involved in the policies and patient safety procedures that pertain to transfusion services (eg, review of transfusion practices to ensure the appropriate use of blood components and the ability of the transfusion service to meet patient needs). The monitoring required to do this effectively can be achieved by various mechanisms. Data from the review and monitoring of transfusion practices can be used to suggest improvements in policies and procedures, as well as educational endeavors. The recipient consent procedures must communicate risks and benefits of transfusion, alternatives to transfusion, and the right of the adult patient to refuse transfusion.

Evidence of Compliance:
✓ Written policy defining responsibilities of transfusion service medical director

REFERENCES
1) Saxena S, Ramer L, Shulman IA. A comprehensive assessment program to improve blood-administering practices using the FOCUS-PDCA model. Transfusion. 2004 Sep;44(9):1350-6

TRM.40900 Blood/Tissue Sign-Out Phase II

The procedure for signing blood and tissue out of the laboratory provides adequate protection for the potential recipient.

NOTE: A person authorized by the transfusion medicine service must perform a clerical and visual inspection of each component immediately before it is issued. Transporters of blood components and tissue must be trained in prompt delivery. Training may consist of instruction at the time the product is dispensed.

Evidence of Compliance:
✓ Written procedures for the issue of blood components and tissue AND
✓ Written policy for the instruction of transporters on the proper handling of the product

TRM.40925 Blood/Component Compatibility Label or Tag Phase II

A label or tag with at least the following information is securely attached to each blood or component unit before issuance and remains attached until completion of the transfusion:

• Identification of the recipient with two patient identifiers
• Blood (or component) unit identifier
• Interpretation of crossmatch tests, where applicable

REFERENCES

TRM.40950 Clerical Identification and Transfusion Records Final Check Phase II

There are written procedures for a final check at the time of issuance to verify clerical identification and transfusion records for the following:

• Identification of the recipient with two identifiers
• Donor information number (DIN) or pool number
• Recipient and donor blood types
• Interpretation of crossmatch tests, where applicable
• Donor unit expiration date and time (as applicable)
• Special transfusion requirements (eg, cytomegalovirus (CMV)-reduced-risk, irradiated, antigen-negative components)
• Date and time of issue

Evidence of Compliance:
✓ Written procedures describing the elements checked at the time of issue

REFERENCES
TRM.41000  Blood Administration Procedure

There is a written procedure for blood administration, including the positive identification (ie, two patient identifiers) of transfusion recipients and blood components and observation of recipients.

NOTE: Blood component misidentification causing incompatibility between the donor and recipient may cause acute harm. Some blood product defects (eg, bacterial contamination) may be detected during the process of administration. Patients must be closely observed during and for a period of time after blood administration.

REFERENCES

TRM.41025  Transfusionist Training

There are records for initial training and in-service at least annually for personnel involved in transfusion, in accordance with national, federal, state (or provincial), and local laws and approved institutional policies and procedures, for the following:

- Identification of transfusion recipients and blood components
- Observation of recipients during and after transfusion
- Recognition and reporting of adverse transfusion events

REFERENCES

TRM.41050  Handling of Blood Products

There are written procedures for handling blood outside of the laboratory (avoidance of prolonged warming, need for filter, etc.).

NOTE: Such procedures should be used to train personnel who transport and/or transfuse blood, whether or not they are members of the transfusion medicine laboratory staff. The transfusion service should have appropriate procedures for transfusion offsite or at another institution, if applicable.

TRM.41150  Addition of Fluids/Drugs

There is a policy regarding the addition of drugs, or fluids other than 0.9% NaCl, through the same tubing simultaneously with blood or blood components.

NOTE: Fluids routinely added to or infused through the same tubing with blood or blood components, with the exception of 0.9% NaCl, may be harmful to blood. Drugs or other materials may be added to blood/blood products only if documentation exists that no harm will result to the component or patient, or for laboratories subject to US regulations, they are FDA-approved for that purpose.

REFERENCES

TRM.41300  Donor and Recipient Information Verification

Donor and recipient information is verified immediately before transfusion in the presence of the recipient, and includes the following:

- Conclusive identification of the recipient in the presence of the recipient with two patient identifiers by either two persons (eg, by checking the wristband for name and hospital number), or using bedside patient identification technology
- Patient identifiers on the blood or component unit label match the identity of the recipient
- Intended recipient’s blood type
- Donor unit identification number and donor blood type
- Interpretation of crossmatch tests, if performed
- Donor unit expiration date and time (as applicable)
- Special transfusion requirements (if warranted)

Evidence of Compliance:

✓ Written procedure for blood administration that defines the information verified in the presence of the patient prior to transfusion

REFERENCES


TRM.41450 Blood Administration Record

The blood administration record on the patient chart includes the following:

- Identity of the transfusionist
- Name of the blood component
- Identification number of donor unit transfused
- Date and time of transfusion
- Evidence of patient monitoring pretransfusion, during and after transfusion
- Amount transfused
- Any transfusion-related adverse effects

REFERENCES


TRM.41475 Post-Transfusion Observation

Patients that will not be observed by medical personnel post-transfusion are given instructions on recognizing adverse reactions to transfusion.

NOTE: Examples include out-patient transfusions, home transfusions and situations where the patient is discharged shortly after transfusion. The instructions provided must include information on possible adverse effects from the transfusion, as well as whom to contact in case of a reaction.

TRM.41500 Blood Warming System

If a blood warming system is used during transfusion, it is properly maintained and equipped with special features to alert the user to improper transfusion conditions.

NOTE: An alert feature (eg, a visible thermometer and audible alarm), must be used so that use of the system does not result in damage to the blood component being warmed.
For laboratories subject to US regulations, the system must be FDA-cleared/approved.

Evidence of Compliance:
✓ Records of blood warmer maintenance, including checks of the alert system

TRM.41525  Intraoperative/Perioperative Blood Program  Phase II

The authority, responsibility, and accountability of the intraoperative/perioperative blood recovery and reinfusion program are defined.

Evidence of Compliance:
✓ Memorandum or policy describing the program

REFERENCES

**REVISED** 09/22/2021

TRM.41550  Intraoperative/Perioperative Safety and Efficacy  Phase II

The intraoperative and perioperative blood recovery program ensures the safety and efficacy of the recovered blood components.

NOTE: Safety and efficacy of recovered products can be measured through various mechanisms, such as through the review of data by institutional committees and monitoring of the intraoperative/perioperative transfusion practices.

Evidence of Compliance:
✓ Review of intraoperative/perioperative blood recovery and reinfusion program records AND/OR meeting minutes of institutional meetings

REFERENCES
1) Yawn DH. Ensuring quality during intraoperative blood salvage. Lab Med. 1994;25:626-631

**REVISED** 09/22/2021

TRM.41600  Intraoperative/Perioperative Program Involvement  Phase II

The transfusion service medical director is involved in establishing standard operating policies and procedures related to intra- and perioperative collection and reinfusion procedures.

NOTE: When the laboratory is not responsible for the standard operating procedure manual for intraoperative/perioperative services, the transfusion service medical director’s involvement can be achieved through review of such procedures or through meeting minutes of institutional transfusion committee meetings. The transfusion service medical director must be aware of standard operating policies and procedures to help the institution ensure efficacy and patient safety.

Evidence of Compliance:
✓ Written policy defining responsibilities of transfusion service medical director

REFERENCES
1) Yawn DH. Ensuring quality during intraoperative blood salvage. Lab Med. 1994;25:626-631
**ADVERSE REACTION PROCEDURES**

**Inspector Instructions:**

<table>
<thead>
<tr>
<th>READ</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Sampling of transfusion reaction policies and procedures</td>
</tr>
<tr>
<td>● Sampling of initial and annual personnel training records for recognition of transfusion reactions</td>
</tr>
<tr>
<td>● Sampling of records of transfusion reaction work-ups, investigation, interpretation of findings, and reporting</td>
</tr>
<tr>
<td>● Sampling of records of blood supplier notification</td>
</tr>
<tr>
<td>● Sampling of records of actions taken when notified of quarantine, recall or market withdrawal</td>
</tr>
<tr>
<td>● Records of provider/recipient notification of a potentially infectious blood product and counseling as applicable</td>
</tr>
<tr>
<td>● Notification of suspected transfusion related fatality to appropriate governmental or oversight agency, if applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OBSERVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Donor/recipient transfusion reaction specimens (seven day retention, refrigerated, sealed)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASK</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Are suspected transfusion reactions reported to the laboratory in a timely basis?</td>
</tr>
<tr>
<td>● What action do you take when you have been notified of a quarantine, recall or market withdrawal by your blood supplier?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DISCOVER</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Review the records of several transfusion reaction work-ups. Determine if the policies and procedures provide for thorough investigation and reporting. Determine if transfusion service medical director involvement is sufficient.</td>
</tr>
</tbody>
</table>

**TRM.41650 Transfusion Reaction Recognition Phase II**

There are written procedures describing the criteria for the recognition of transfusion reactions, and the clinical actions to be taken in the event of a suspected transfusion reaction.

*NOTE: These procedures must be readily available to clinical personnel in areas where patients are transfused.*

**Evidence of Compliance:**

✔ Facility transfusion procedure availability to clinical staff administering blood and blood component products

**REFERENCES**


**TRM.41750 Reporting of Transfusion Reactions and Incidents Phase II**
Policies require that suspected transfusion reactions or incidents are reported immediately to the laboratory.

NOTE: Investigation by the laboratory must be initiated as soon as possible to facilitate continuing care of the patient.

TRM.41770  System Failure  Phase I

When an incident investigation indicates a system failure (eg, misadministration of a blood product), the transfusion service medical director is involved in the investigation and resolution of the issue.

Evidence of Compliance:
✓ Records of transfusion service medical director involvement in investigation and resolution

REFERENCES

TRM.41800  Post Transfusion Specimen Storage  Phase II

Donor and recipient blood samples are appropriately stored for at least seven days after transfusion for retesting, in the event of a transfusion reaction.

NOTE: Appropriate storage conditions (refrigeration, sealed containers) are necessary to prevent specimen degradation and contamination.

Evidence of Compliance:
✓ Written procedure defining criteria for storage of donor and recipient samples

REFERENCES

TRM.41850  Investigation of Suspected Hemolytic Transfusion Reaction  Phase II

The immediate investigation of a suspected hemolytic transfusion reaction includes all of the following.

1. Examination of patient identification, blood unit labels, and all pre-reaction records for possible errors in patient or blood identification at the bedside and in the laboratory
2. Visual examination of post-reaction and pre-reaction (if available) serum or plasma for evidence of hemolysis
3. ABO and direct antiglobulin test on post-reaction patient (recipient) blood sample

NOTE: RhD typing of the post-reaction patient (recipient) blood sample is not required. However, it is encouraged to add an additional level of patient verification. The direct antiglobulin test must allow detection of RBC-bound complement as well as IgG.

Evidence of Compliance:
✓ Records of investigation and interpretation of findings

REFERENCES
**TRM.42000 Additional Transfusion Reaction Evaluation**  

*The transfusion service medical director has established a written procedure indicating under what circumstances additional testing will be done after a suspected transfusion reaction (including delayed transfusion reactions), and the nature of that testing.*

**Evidence of Compliance:**
- Records of investigation and interpretation of findings

**REFERENCES**

**TRM.42050 Transfusion Reaction Interpretation**  

*The findings of an adverse reaction investigation are interpreted by the transfusion service medical director or designee, and reported in a timely and effective manner.*

**NOTE:** The patient's physician must be immediately notified of suspected cases of hemolytic transfusion reactions, bacterial contamination, or other serious reactions. A prompt and complete adverse reaction investigation report, including interpretation and evaluation by the transfusion medicine medical director or designee, must be placed in the patient's chart.

**Evidence of Compliance:**
- Adverse reaction investigation reports in patient charts

**REFERENCES**

**TRM.42060 Transfusion Reaction Monitoring**  

*The transfusion service tracks the incidence of transfusion reactions and monitors the rate of transfusion reactions by each reaction type (eg, febrile, hemolytic, TRALI, etc.).*

**Evidence of Compliance:**
- Records of transfusion reaction data

**REFERENCES**

**TRM.42100 Blood Supplier/Testing Laboratory Notification**  

*There is a written procedure to notify the blood supplier or laboratory responsible for the pretransfusion testing (if performed by another laboratory) when blood components are a suspected primary cause of an adverse reaction (eg, hemolytic transfusion reaction, transfusion-related acute lung injury, transfusion-transmitted infection).*

**Evidence of Compliance:**
- Records of notifications to the blood supplier or pretransfusion testing laboratory (where applicable)

**REFERENCES**

**TRM.42110 TRALI**  

*The laboratory has written policies and procedures to recognize, investigate and reduce the risk of transfusion-related acute lung injury (TRALI).*
Evidence of Compliance:
✓ Written transfusion service procedure to investigate suspected TRALI cases AND
✓ Records from blood supplier regarding TRALI mitigation strategies for plasma, apheresis platelets and whole blood

REFERENCES

TRM.42120 Blood Component Recall and Quarantine Phase II

There is a procedure to identify and quarantine suspect blood components in the inventory when notice is received about donors who have tested reactive for an infectious disease and/or have been recalled by the supplier.

NOTE: Because the FDA requires blood suppliers to notify transfusion facilities when donors are found to have reactive infectious disease testing or have other reasons for recalling donor components, there must be a procedure to ensure that all suspect components in current inventory are quarantined.

Evidence of Compliance:
✓ Records of actions taken for each notification AND
✓ Written procedure for quarantine of blood components

REFERENCES

TRM.42135 Blood Supplier Notifications Phase II

The transfusion service has a procedure for managing quarantines, recalls, and market withdrawals issued by its blood suppliers.

Evidence of Compliance:
✓ Records of actions taken for each notification

REFERENCES

**REVISED** 09/22/2021

TRM.42170 Notifications for Potentially Infectious Blood and Blood Component Units Phase II

The transfusion service has a written procedure for notifying and counseling recipients or their caregivers about potentially infectious blood components, such as, HIV and HCV.

NOTE: When the recipient of potentially infectious blood components is deceased, attempts to notify the recipient’s physician of record, next of kin or legal representative, consistent with national, federal, state (or provincial), and local regulations, is required.

Evidence of Compliance:
✓ Records of provider or recipient or next of kin or legal representative notifications and counseling, as applicable AND
✓ Written procedure stating when notification and counseling is warranted to providers and recipients of infectious blood components
REFERENCES
1) CMS. Condition of participation: laboratory services Washington, DC: US Government Printing Office, 2011(42CFR482.27(b)
   Printing Office, 2020(Apr 1):[21CFR610.46].
   Printing Office, 2020(Apr 1):[21CFR610.47].
4) Guidance for industry: Nucleic acid testing (NAT) for human immunodeficiency virus type 1 (HIV-1) and hepatitis C virus (HCV):
   testing, product disposition, and donor deferral and reentry. Rockville, MD, Food and Drug Administration, May 2010
5) Guidance for Industry: “Lookback” for hepatitis C virus (HCV); product quarantine, consignee notification, further testing, product
   disposition, and notification of transfusion recipients based on donor test results indication infection with HCV. Rockville, MD, Food
   and Drug Administration, December 2010
6) Guidance and rules may be found at http://www.fda.gov/BiologicsBloodVaccines/default.htm

TRM.42185 CBER Notification

There is a policy requiring notification of the appropriate agency when a transfusion-related fatality occurs following transfusion of any component.

NOTE: For laboratories subject to US regulations, this agency is the Center for Biologics Evaluation and Research (CBER). CBER requires notification by telephone, facsimile, express mail, or electronic mail “as soon as possible,” with a written report of the investigation within 7 days.

Evidence of Compliance:
✓ Records of reportable events, if applicable

REFERENCES
1) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Adverse

APHERESIS

DONOR APHERESIS

Please note that the checklist requirements in the Blood/Component Donor Selection and Collection section also apply to donor apheresis.

Inspector Instructions:

- Sampling of donor apheresis policies and procedures
- Sampling of donor apheresis procedure records and test results
- Sampling of personnel training records

- Apheresis components (labeling)

TRM.42212 Donor Safety and Protection

The apheresis equipment and procedures are designed to ensure sterility of the donor’s blood and safe return after separation of components.

NOTE: The equipment used must be appropriately maintained and monitored.
Written procedures must include criteria for the administration and dose of medications and ancillary agents (eg, calcium supplements, hetastarch, etc.) used during the apheresis procedures.

TRM.42213 Staff Training  Phase II

Persons responsible for apheresis donations are qualified, trained, and competent for these tasks, including the recognition of procedural complications, adverse reactions, and donor care.

Evidence of Compliance:
✓ Records of education and training of personnel involved in apheresis

TRM.42214 Donor Eligibility  Phase II

A policy defining donor apheresis eligibility criteria is available.

NOTE: Prior to the start of each apheresis procedure, the prospective donor’s history and physical examination findings are evaluated against the eligibility criteria to ensure that the procedure will be safe for the donor and the blood components safe for the recipient.

Evidence of Compliance:
✓ Donor eligibility criteria for each apheresis procedure performed (eg, RBC apheresis, platelet apheresis, plasmapheresis) AND
✓ Records of donor evaluation prior to the procedure

REFERENCES

TRM.42215 Extended Donor Evaluation  Phase II

Additional criteria beyond routine donor screening and testing, appropriate for the type of apheresis collection, are used to evaluate donors

NOTE: Additional testing may be required to evaluate donors in serial apheresis programs.

Examples of additional measures may include:
● Total serum protein (no less than 6 g/dL), protein electrophoresis, and serum immunoglobulin quantification before plasmapheresis
● Platelet concentration before plateletpheresis and granulocyte collections

Evidence of Compliance:
✓ Written policy defining criteria for extended testing of donors AND
✓ Donor records with test results

REFERENCES
5) FDA Memorandum, March 10, 1996, "Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasmapheresis Donors"
6) FDA Memorandum, November 4, 1992, "Volume Limits for Automated Collection of Source Plasma"

TRM.42220 Plateletpheresis Donor Deferral  Phase II

Plateletpheresis donors who have taken medications known to inhibit platelet function are deferred for an appropriate time based upon the half-life of the medication.
Evidence of Compliance:
✓ Records of deferral AND
✓ Medication deferral list

TRM.42222  Donor Informed Consent  Phase II
An informed consent explaining the risks and benefits of apheresis donation is reviewed and signed by the donor prior to donation.

NOTE: The donor must have the opportunity to ask questions and sign a document indicating consent to the procedure.

Evidence of Compliance:
✓ Records of the signed donor consent forms

REFERENCES

TRM.42223  Donor Apheresis Records  Phase II
Records are kept of each apheresis procedure including, the following elements:
1. Informed consent
2. Donor identification
3. Pertinent laboratory test results
4. Lot numbers of disposables and replacement fluids used
5. Component(s) collected
6. Volume of components
7. Anticoagulants used
8. Medications administered
9. Reactions and treatment, if any

TRM.42224  Adverse Reactions - Donor Apheresis  Phase II
There is a written procedure for the recognition, treatment, tracking, and trending of adverse donor reactions to apheresis.

Evidence of Compliance:
✓ Records of training for adverse reactions AND
✓ Records of donor reactions, including data on trending AND
✓ Procedure for recognizing and treating adverse reactions

TRM.42230  Volume Limits  Phase II
During apheresis, the total volume deficit is limited to the following criteria:
1. No greater than 15% of the donor’s estimated blood volume, including the total volume of products being collected and the total volume of blood in the extracorporeal circuit OR
2. No greater than 10.5 mL/kg of blood including the volume of products being collected and the blood in the extracorporeal circuit OR
3. The laboratory has written procedures in place to compensate for donors with smaller blood volumes.

NOTE: The laboratory must have policies and procedures that limit the total volume deficit and prevent hypotension.
TRM.42235 Apheresis Component Labeling

The apheresis components are properly labeled and meet all current labeling requirements.

Evidence of Compliance:
✓ Written procedure defining labeling requirements

TRM.42240 Donation Interval

For allogeneic apheresis donations, the time interval since prior donations meets current requirements.

NOTE:
1. Apheresis donors who give a two-unit red cell apheresis must be deferred for 16 weeks.
2. A donor who gave a unit of whole blood may donate by apheresis within eight weeks only if the anticipated extracorporeal red cell volume of the intended apheresis procedure is less than 100 mL.
3. If the red cell loss during an apheresis donation is 200 mL, but less than 300 mL, the donor must be deferred for eight weeks. If the loss is equal to or greater than 300 mL, the donor must be deferred for 16 weeks.
4. Total donor red cell losses during any 16-week period and any 12-month period must not exceed the loss of red cells permitted for whole blood donations (one per eight weeks).
5. The interval between each platelethpheresis for a single platelet unit should be at least two days with no more than two procedures in a seven-day period. The interval between collection of double or triple platelet units and any subsequent collection by platelethpheresis should be at least seven days. There must be no more than 24 donations in 12 months.
6. If platelethpheresis is performed more frequently than once every four weeks, the donor platelet count must be no less than 150 X 10^9 before the procedure or at the conclusion of the previous procedure.
7. If plasmapheresis is performed more frequently than once every four weeks, the FDA guidelines must be followed.

Evidence of Compliance:
✓ Written procedure with defined donation intervals for the different products collected AND
✓ Donor records consistent with defined procedure

REFERENCES

THERAPEUTIC APHERESIS

Inspector Instructions:
- Sampling of therapeutic apheresis policies and procedures
- Sampling of therapeutic apheresis patient records, including initial device placement
- Sampling of physician evaluation records and informed consents
- Sampling of personnel records of education and training
If you use venous access devices, how do you verify the placement?

What information is confirmed in a "time-out"?

To what degree is the transfusion service medical director involved in the apheresis procedure?

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**TRM.42245 Responsibility for Therapeutic Apheresis**

There is a record in the patient’s chart that the transfusion service medical director or a designated, qualified physician has accepted responsibility for the oversight of the therapeutic apheresis procedures.

**NOTE:** The oversight responsibility includes quality assurance measures and medical responsibility relating to patient care, such as consultation to determine whether a patient is a candidate for therapeutic apheresis, rationale and appropriateness of treatment, patient assessment and monitoring, treatment plan and endpoint, and care for adverse events.

**Evidence of Compliance:**
- Written policy defining transfusion service medical director/designated physician responsibility for the apheresis service AND
- Patient records/charts showing evidence of transfusion service director/designated physician oversight

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**TRM.42246 Therapeutic Apheresis Records**

Complete records are retained of each apheresis procedure, including the following elements:

1. Physician order to perform apheresis
2. Patient identification (two identifiers required)
3. Patient diagnosis
4. Type of apheresis procedure
5. Results of pertinent laboratory tests
6. Anticoagulant used
7. Blood fraction and volume removed and replacement fluid(s) type and volume
8. Medications administered
9. Lot numbers of disposables and replacement fluids used
10. Patient monitoring
11. Reactions and treatment, if any
12. Informed consent

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**TRM.42248 Patient Safety and Protection**

The apheresis equipment and procedures are designed to ensure sterility of the patient’s blood, and safe return after separation of component parts.

**NOTE:** The equipment must be appropriately maintained and monitored.

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**TRM.42255 Staff Training**

All personnel performing and/or supervising therapeutic apheresis procedures are qualified by education and training.

**NOTE:** The personnel involved in provision of therapeutic apheresis, including operators and supervising physicians, shall be appropriately qualified. This training includes recognition of complications and patient care. Records of training may include in-house training programs,
vendor/manufacturer training, education from third parties (eg, professional societies), and continuing education courses (if applicable).

Evidence of Compliance:
✓ Record of education and training of personnel involved in therapeutic apheresis

TRM.42260 Evaluation and Approval for Therapeutic Apheresis Phase I

There is a policy for timely evaluation and approval of requests for therapeutic apheresis.

NOTE: This policy should address routine, urgent (treatment within 24 hours) and emergency (treatment as soon as feasible) apheresis.

TRM.42265 Apheresis Patient Evaluation Phase I

A qualified physician is responsible for evaluating apheresis patients, including indications for the procedure, therapeutic goals, and selection of replacement solutions.

NOTE: Therapeutic apheresis should be performed using an evidence-based approach.

REFERENCES

TRM.42267 Patient Informed Consent Phase II

A qualified physician is responsible for ensuring that an explanation of risks of the procedure is provided and informed consent is obtained.

NOTE: The patient must have the opportunity to ask questions, and sign a document indicating consent to the procedure. A process must be in place for obtaining consent from authorized representatives when a patient is unable to give consent or in emergent situations where consent cannot be obtained.

Evidence of Compliance:
✓ Copy of the consent form AND
✓ Records of physician evaluation of the patient prior to procedure

REFERENCES

TRM.42270 Venous Access Verification Phase I

The placement of the venous access device is verified by the operator prior to each use.

NOTE: Verifications of the appropriate placement of central venous access can be achieved by reviewing radiologic images or reports prior to the first use or after repositioning. Verification of central venous access and peripheral access prior to each use should also be confirmed through the examination of the vascular access site, as well as ensuring the free flow of blood when drawing and returning through the vascular access device prior to connecting the apheresis device. Inappropriate placements have been reported to be the cause of severe complications including fatalities.

TRM.42275 Time-Out Phase II
A "time-out" is called and the following information confirmed prior to initiation of each therapeutic apheresis procedure.

1. Two patient identifiers to verify patient identity
2. Type of apheresis
3. Informed consent
4. Written physician’s order
5. Availability of a qualified physician

Evidence of Compliance:
✓ Written apheresis procedure with steps to verify information AND
✓ Records of time-out verification for each procedure

TRM.42280 Adverse Reactions - Therapeutic Apheresis

There is a written procedure that describes the evaluation of the apheresis patient for risks, as well as the monitoring and treatment of patients for any adverse reaction to therapeutic apheresis.

NOTE: Therapeutic apheresis can result in complications necessitating prompt medical treatment. Procedures must provide information on monitoring for and treatment of potential complications including the loss of consciousness, hypocalcemia, hypotension, allergic reactions, air embolus, and hemolysis.

THERAPEUTIC PHLEBOTOMIES

Inspector Instructions:

- Sampling of therapeutic phlebotomy policies and procedures
- Sampling of therapeutic phlebotomy patient records
- Sampling of physician orders with required information

- What patient goals have been established for the therapeutic phlebotomy?

TRM.42285 Therapeutic Phlebotomy Units for Transfusion

If blood collected by therapeutic phlebotomies is intended for transfusion without specific labeling, the patient/donor meets all the criteria for allogeneic donation.

NOTE: For laboratories subject to US regulations, as of May 22, 2015, the final rule, Requirements for blood and blood components intended for transfusion or further manufacturing use (21CFR630), eliminated the requirement to obtain a variance from the FDA in order to use blood collected from therapeutic phlebotomies for transfusion.

Evidence of Compliance:
✓ Written procedure for using blood collected for therapeutic phlebotomy for allogeneic donation including inclusion criteria AND
✓ Records of patient/donors meeting the criteria for allogeneic donations

REFERENCES

TRM.42290  Therapeutic Phlebotomy Responsibility  Phase II

If therapeutic phlebotomies are performed by laboratory staff, the transfusion service medical director or qualified physician designee has accepted medical responsibility for the procedures.

NOTE: If the laboratory is responsible for therapeutic phlebotomies, the transfusion service medical director or qualified physician designee must accept medical responsibility for the patient undergoing this procedure. This involvement is in addition to responsibility for overall management of the therapeutic phlebotomy program, establishment of eligibility criteria for therapeutic phlebotomy, provision of medical support for reactions, and oversight of quality assurance measures.

Evidence of Compliance:
✓ Written policy defining responsibility for therapeutic phlebotomy procedures AND
✓ Patient records/charts showing evidence of transfusion service medical director or qualified physician designee review

TRM.42295  Patient Protection  Phase II

The procedures for therapeutic phlebotomy provide adequate protection for the patient.

NOTE: The procedures should include proper patient identification, adequate training of laboratory staff, proper sterile technique, and appropriate volume to be removed.

**REVISED** 09/22/2021

TRM.42300  Therapeutic Phlebotomy Records  Phase II

Records are retained for each therapeutic phlebotomy procedure, including the following elements:
1. Physician order to perform therapeutic phlebotomy
2. Patient identification (two identifiers required)
3. Patient diagnosis
4. Type of procedure performed
5. Lot numbers of disposables and replacement fluids used
6. Nature and volume of blood removed and replaced
7. Patient data and criteria for measuring patient response, as available
8. Reactions and treatment, if any
9. Informed consent

**REVISED** 06/04/2020

TRM.42305  Therapeutic Plan  Phase I

A designated physician has developed a therapeutic plan for patients undergoing therapeutic phlebotomies and the goals for the therapeutic phlebotomy have been clearly stated.

Evidence of Compliance:
✓ Patient/donor records indicating plan and timeline

REFERENCES
1) Tavill SA, Diagnosis and Management of Hemochromatosis. Hepatology 2003: 33(5);1321-1328
The physician’s order for therapeutic phlebotomy, includes at a minimum, the frequency, the volume to be removed and the laboratory values to be monitored.

**TRM.42315 Indications For Therapeutic Phlebotomy Review**

*Phase II*

The indications for therapeutic phlebotomy are reviewed by the physician responsible for performance of therapeutic phlebotomy prior to initiation and not less frequently than every 12 months thereafter.

**Evidence of Compliance:**

✓ Records of approval for therapeutic phlebotomy

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**COMPONENT PREPARATION, STORAGE AND MODIFICATION**

*Checklist requirements relating to blood storage temperature apply to the transfusion service and other blood storage areas located within the facility (eg, surgery, nursing and dialysis units) for all blood and blood components.*

*The following component definitions are offered as a convenience:*

<table>
<thead>
<tr>
<th>Component</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh Frozen Plasma (FFP)</td>
<td>Plasma frozen within 8 hours of collection after being separated from a unit of whole blood or frozen within 6 hours after collection by apheresis</td>
</tr>
<tr>
<td>Plasma Frozen Within 24 Hours After Phlebotomy</td>
<td>Plasma separated from whole blood and frozen between 8-24 hours after collection</td>
</tr>
<tr>
<td>FFP, Thawed</td>
<td>Fresh Frozen Plasma thawed between 30-37°C, then stored at 1-6°C for up to 24 hours</td>
</tr>
<tr>
<td>Plasma Frozen Within 24 Hours After Phlebotomy, Thawed</td>
<td>Plasma frozen within 24 hours of collection that has been thawed between 30-37°C, then stored at 1-6°C for up to 24 hours</td>
</tr>
<tr>
<td>Thawed Plasma</td>
<td>“FFP, Thawed” or “Plasma Frozen Within 24 hours After Phlebotomy, Thawed” which is stored in a closed system at 1-6°C for 1-5 days after thawing</td>
</tr>
</tbody>
</table>
Inspector Instructions:

- Sampling of blood component storage and handling policies and procedures
- Sampling of storage unit temperature logs (4 weeks of recordings), including recording charts when high/low alarm testing performed, and remote storage, as applicable
- Sampling of records of corrective action when storage unit temperatures fall outside of the defined range
- Sampling of blood component records of inspection
- Records of staff training on alarm response

- Refrigerator storage unit (organization, sufficient space, placement and number of temperature probes, separation of units), including remote storage, as applicable
- Sampling of blood/blood components (labeling with all required elements, assigned expiration date)
- Active alarm system(s) in place for all storage units

- How are blood components received/shipped from the facility?
- If you receive blood back into inventory, how did you validate your procedure?
- What back-up options are available in the event of an electrical power outage?
- At what range do you set your alarms to sound?
- How is the storage unit alarm system monitored? How was the response time validated?

TRM.42350  Blood Component Storage  Phase II

There is adequate blood component storage space to meet the needs of the facility.

NOTE: Adequate refrigerated, room temperature, and freezer storage space is needed for proper storage and organization of blood components. Insufficient storage space can compromise the organization of blood components in the laboratory.

TRM.42400  Issuance/Release Control  Phase II

The storage system for blood components minimizes the inadvertent issuance or release of the wrong unit.

NOTE: The blood in the refrigerator must be arranged to facilitate the location and separation of units. Examples of such organization include, but are not limited to, different groups and types of blood, unprocessed blood, blood that is suitable for issue or release, quarantined or rejected or outdated units, autologous units, and crossmatched and non-crossmatched units. Such a system is important to minimize the inadvertent transfusion of the wrong unit.

TRM.42450  Blood/Blood Component Inspection  Phase II

All blood/blood components and tissues are inspected upon receipt from the supplier and at the time of issue, and records are retained of these checks.

NOTE: Upon receipt from the supplier, each product must be inspected for proper labeling and shipping conditions, including an inspection of the shipping container and condition of the coolant. Temperature measurement is not required unless a problem is suspected. Products must be checked for expiration date and abnormal appearance, such as color, hemolysis, clots, and bag integrity, upon receipt from the supplier and at the time of issue. Comparison of bag
and segment color should be performed for red blood cell units as an aid in detecting bacterially-contaminated units.

REFERENCES

**REVISED** 09/22/2021

**TRM.42460** Blood and Blood Component Shipping

For blood/blood components shipped outside of the facility there are written procedures for proper packaging to prevent damage and control shipping temperatures.

NOTE: Containers (eg, portable coolers) must be initially validated by the laboratory to ensure that they maintain appropriate temperature for a maximum time period (as specified by the validation study). Ongoing verification checks (eg, visual checks for cracks and excessive wear and tear) must be performed at intervals defined by the laboratory.

Cellular therapy products must not be passed through x-ray irradiation devices. This can be accomplished by placing instructions on the outside of the shipping container to only allow visual inspection of such products.

**TRM.42470** Acceptance Back Into Inventory

There is a written procedure, validated by the laboratory, for accepting blood/blood components back into inventory after they have been issued.

NOTE: The procedure must include steps to verify the integrity and appearance of the blood/blood component and maintenance at appropriate temperatures.

The steps and criteria defined in the procedure for acceptance of units back into inventory, such as the use of transport containers (eg, portable coolers) must be validated by the laboratory.

**TRM.42480** Blood Components Storage Requirements and Expiration Dates

The expiration dates and storage requirements of all blood components comply with the most recent edition of the Circular of Information and the manufacturer's recommendations. For laboratories not subject to US regulations, expiration dates conform to national, state or provincial, and local laws and regulations for all approved component storage systems in use.

REFERENCES

**REVISED** 09/22/2021

**TRM.42500** Blood/Component Storage Monitoring

For blood/blood component storage units (eg, refrigerators, freezers, and platelet incubators) that lack continuous automated temperature recording, the temperatures are recorded at least every four hours.

NOTE: This checklist requirement applies to all blood component storage devices in the facility, including those located outside of the transfusion service (eg, in surgery, nursing and dialysis units). When platelets are stored outside of a platelet incubator (eg, in ambient temperature), the temperature of the room must be monitored.

All blood and components must be stored at an appropriate temperature to maintain viability and function. The storage temperatures must be monitored continuously or at least every four
hours, such that appropriate action can be taken should the temperature in the storage device reach a temperature that might result in harm to the blood or component. There must be written procedures for evaluating these systems as well as maintenance of temperature when power failures and other problems occur.

Temperatures may be recorded either manually, or using a recording device or system by: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature. If temperatures are recorded manually, the identity of the individual recording the temperature(s) must be recorded (recording the initials of the individual is adequate).

If an automated (including remote) temperature monitoring systems is used instead of manual temperature monitoring, laboratory personnel must have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is outside of the acceptable range. System records must demonstrate daily functionality of the automated system in accordance with manufacturer's instructions.

Evidence of Compliance:
✓ Written procedure defining criteria and frequency for evaluation of blood/component storage units to include maintenance of temperature under all conditions AND
✓ QC records for continuous temperature monitoring OR records of checks at defined frequency

REFERENCES

TRM.42550 Storage Temperature Range Corrective Action Phase II

If the proper storage temperature range is not maintained (inspector will check 4 weeks of recordings), there is evidence that timely corrective action has been taken, to include records of the disposition of any affected components.

**REVISED** 06/04/2020
TRM.42600 Consistent Temperature Phase II

There are records that refrigeration unit devices maintain the proper temperature throughout the unit.

NOTE: On refrigeration units, thermometers must be placed in appropriate areas, or multiple point readings taken on a periodic basis to ensure that a 1 to 6°C temperature is maintained throughout. The placement and number of probes needed is based on the size of the temperature-dependent unit. There must be records that such readings have been taken. Unrestricted air circulation within the unit reduces the potential for warmer or colder areas that may have detrimental effects on blood/component units without detection by the monitoring system.

Data from temperature mapping performed when refrigeration units are placed in service, after repairs, and when unit devices are relocated can be used to determine the appropriate number and placement of temperature probes or thermometers.

TRM.42650 Monitored Temperature Phase I

The temperature of refrigerators is monitored in a manner that will mimic the temperature characteristics of a component stored in the device.
NOTE: For example, placement of the temperature sensor probe in liquid with heat transfer characteristics similar to blood, and a volume similar to the smallest units stored, is recommended, but other procedures are also acceptable.

TRM.42700 Emergency Power Supply

The blood/blood components and tissue refrigerator(s) and freezer(s) have an emergency power supply.

**REVISED** 06/04/2020

TRM.42750 Storage Unit Alarms

All component storage units are equipped with an alarm system that is monitored 24 hours/day (in laboratory or remote), with alarm checks (for both low and high settings) performed according to the manufacturer's recommended interval, or at least quarterly if not specified by the manufacturer, with results recorded.

NOTE: The laboratory must demonstrate that all components of the alarm system (including chart/graph recordings) work as expected and that there is a process to ensure a timely response to alarms, including remote alarms.

When facilities perform alarm checks, the temperature at which the alarm sounds must be compared to the temperature on the recording chart/log. Examples of recording systems include:

- Paper chart records
- Paper graphs
- Electronic records
- Event logs

Evidence of Compliance:
✓ Records of alarm checks at defined frequency

REFERENCES

TRM.42850 Alarm Adjustment

Alarms are adjusted to be triggered before the temperature falls outside the 1 to 6°C acceptable temperature range for refrigerators, or outside the acceptable range for freezers, liquid nitrogen storage units, and platelet incubators.

NOTE: Refrigerators, freezers and platelet incubators must have alarm systems that provide opportunity to take action before the temperature of blood or components is outside of acceptable ranges (eg, alarms set to trigger at 1°C or 6°C do not provide adequate time for staff to respond to the alarm before temperature ranges are exceeded).

Red cell units stored at temperatures higher than 6°C may be subject to accelerated bacterial growth. Temperatures below the freezing point may induce hemolysis. Freezers need not be operated at their lowest possible temperature, since some plastic plasma containers held at temperatures lower than -25°C may exhibit increased breakage rates upon handling.

Evidence of Compliance:
✓ Records of trigger temperatures during alarm checks AND
✓ Records of corrective action, when appropriate

TRM.42900 Power Failure Back-Up

The alarms will continue to function if the power is interrupted.
NOTE: Alarm systems must continue to function during a power failure. This may be accomplished by having the alarm on a separate circuit, installing battery power back-up, or having a power failure alarm.

TRM.42950  Storage Temperature Variances  Phase II
There are written procedures to follow if there are variances outside acceptable storage temperature limits.

NOTE: Specific procedures must be available and understood by personnel regarding handling blood and blood components if storage temperature limits cannot be maintained. The primary concern is the preservation of blood. If there is a power failure, arrangements must be made for service, and for alternative storage of blood.

TRM.43500  Component Processing/Storage  Phase II
There are written procedures for the processing and storage (including expiration, quarantine criteria, additives, pooling, etc.) of all components prepared and stored in the laboratory.

TRM.43600  Component Labeling  Phase II
For each component, the label specifies all of the required information, and requirements for proper labeling of components are defined.

NOTE: Required information may be offered separately in an approved "circular of information," provided that the component label refers to the circular. All steps of blood component labeling must be defined in the procedure manual and conform to the International Society of Blood Transfusion labeling system (ISBT). The laboratory must have a valid system to receive and manage all blood components that come into inventory, including those labeled with legacy labeling systems such as the 1985 Uniform Labeling Guideline system (CODABAR).

REFERENCES

**NEW** 06/04/2020
TRM.43605  Component Labeling - Final Inspection  Phase II
Final inspection of the component labeling process includes verifying that all the information is correct on the label by:

● One appropriately trained member of the transfusion service using a validated process, such as an electronic system capable of preventing the release of mislabeled components OR
● Two appropriately trained members of the transfusion service.

NOTE: When using a validated process where each barcode quadrant of the component label is scanned and compared to the electronic record of the laboratory computer system, it is acceptable for one member of the transfusion service to perform this check.

Evidence of Compliance:
✓ Written procedure for verifying the accuracy of the component labeling process

TRM.43610  Red Blood Cell Unit Labeling With Historical Antigen Typing  Phase II
There are written procedures for the labeling of red blood cell units with historical antigen typing results of non-ABO/Rh antigens.
NOTE: Written procedures must describe the non-ABO/Rh(D) antigen typing process using manufacturer's instructions. Labeling of red cell units with historical antigen typing results must follow current FDA guidelines. Units may be labeled as antigen negative, without testing the current donation, if units from two previous separate donations were found to be concordant in the records from the same collection facility. Concordant antigen typing results may be obtained using serological or approved molecular tests or a combination thereof.

Laboratories not subject to US regulations must follow national, state (or provincial) and local laws and regulations.

REFERENCES
1) Food and Drug Administration, Guidance for Industry: Labeling of Red Cell Units with Historical Antigen Typing Results. December, 2018.

TRM.43625 Label Approval

There is a written procedure to approve the content and use of all new blood product labels including inspection for acceptable label content.

NOTE: The procedure should include phasing out old labels and implementing new labels.

TRM.43650 Component Handling

For each component, there are written procedures for maintaining sterility, including pooling and the use of sterile connecting devices, and there is evidence that these procedures are followed.

NOTE: If a sterile connecting device is used, the integrity of the weld and maintenance of the closed system must be assessed and recorded after each weld. If the integrity of the weld is incomplete, the unit must be considered an open system and the expiration date on the product label must be modified accordingly.

REFERENCES
1) Food and Drug Administration. Use of an FDA-cleared or approved sterile connecting device (STCD) in blood bank practice. Memorandum, 1994(Jul 29)

TRM.43700 Pooled Components

If components are pooled, records are maintained to include the individual unit identification numbers contained within the pool.

Evidence of Compliance:
✓ Log or computer records with the identity of each donor unit in a pooled product

RED BLOOD CELLS

Inspector Instructions:

- RBC processing policy or procedure
- Sampling of RBC component processing and QC records

TRM.43750 24 Hour Expiration
If a unit is entered for any reason without appropriate use of a sterile connection device, a 24 hour expiration time is assigned to refrigerated components.

**NOTE:** Closed systems retain the same expiration date as the original whole blood unit.

**Evidence of Compliance:**
- Written procedure for changing the expiration date when a unit is entered with an open system **AND**
- Component processing records showing modified expiration dates when appropriate

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**TRM.43800 RBC Hematocrit Limit**  
**Phase II**

The method for preparing Red Blood Cells ensures that the final hematocrit does not exceed 80% if the component is to be stored for an extended interval. (This item does not apply if an additive solution is used.)

**NOTE:** If an insufficient amount of plasma is left on the red cells, the cells may not have enough nutrients to survive.

**Evidence of Compliance:**
- Records of component QC documented at defined frequency

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**RED BLOOD CELLS WASHED**

**Inspector Instructions:**
- RBC washing policy or procedure

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**TRM.43850 Plasma Removal**  
**Phase II**

Methods are adequate to ensure removal of almost all of the plasma.

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**RED BLOOD CELLS FROZEN**

**Inspector Instructions:**
- Red cell cryopreservation policy or procedure
- Sampling of temperature records
- Sampling of inventory records

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**TRM.43900 RBC Storage**  
**Phase II**

Storage facilities are adequate to meet the requirements for preserving and retrieving frozen Red Blood Cells.

**NOTE:** Frozen Red Blood Cell units must be maintained at temperatures appropriate for the cryopreservation technique. Inventory records should be retained to permit prompt retrieval.
RBC Freezing Method

Red Blood Cells are frozen by an approved method.

NOTE: RBCs should be frozen within six days of collection if anticoagulated with CPD or CPDA-1 or promptly after rejuvenation. Laboratories subject to US regulations must use methods and solutions approved by the FDA. Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations.

REFERENCES

Pre-Transfusion Testing

Red blood cell samples from the unit are available for pre-transfusion testing.

NOTE: Red blood cells must be available for pre-transfusion testing in a manner that guarantees linkage with the unit.

RED BLOOD CELLS DEGLYCEROLIZED

Inspector Instructions:

- RBC deglycerolization policy or procedure
- Sampling of inventory records

Open System Preparation Usage

Reconstituted deglycerolized Red Blood Cells that have been prepared with an open system are used within 24 hours.

NOTE: Post-thaw storage is also allowed for up to 14 days in a functionally closed, approved system.

Evidence of Compliance:
✓ Inventory records showing deglycerolization and expiration dates

REFERENCES

Deglycerolization Requirements

The method of deglycerolized Red Blood Cell preparation ensures at least 80% physical recovery of cells, adequate removal of cryoprotective agent, and minimum hemolysis.

NOTE: The deglycerolization process must ensure the adequate removal of cryoprotective agents and minimal hemolysis, as failure to return the red cells to an isosmotic state may result in hemolysis upon transfusion.
RED BLOOD CELLS LEUKOCYTE-REDUCED (LABORATORY-PREPARED)

Inspector Instructions:

- Leukoreduced policy or procedure
- Sampling of leukocyte-reduced RBC component QC records

TRM.44250  Leukocyte-Reduced RBC Criteria  Phase II

Records indicate that leukocyte-reduced Red Blood Cells contain less than $5 \times 10^6$ leukocytes and retain at least 85% of the original red blood cells.

NOTE: The method of preparation of leukocyte-reduced Red Blood Cells must be shown to retain at least 85% of the original red cells and to reduce the leukocyte concentration to less than the maximum amount prescribed by the FDA. Units with lower leukocyte concentrations are associated with decreased febrile transfusion reactions, reduced alloimmunization potential, reduced cytomegalovirus transmission, and other benefits. For quality control, the FDA requires 95% confidence that 95% of each leukoreduced product meets specifications.

Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations.

REFERENCES

FRESH FROZEN PLASMA

Inspector Instructions:

- FFP policy or procedure
- Sampling of temperature monitoring records

TRM.44350  Plasma Collection/Storage  Phase II

The plasma is separated from the whole blood and placed at -18°C or lower within eight hours of collection if the anticoagulant is CPD, CP2D, or CPDA-1.
NOTE: Fresh Frozen Plasma must be separated within eight hours of collection when using CPD, CP2D, or CPDA-1 as the anticoagulant. Plasma may be separated from whole blood as long as 24 hours after collection and frozen at -18°C or lower, but it may not be labeled “Fresh Frozen” Plasma -- it is called “Plasma, Frozen Within 24 Hours of Collection.” Freezers need not be operated at their lowest possible temperature, since some plastic plasma containers held at temperatures lower than -25°C may exhibit increased breakage rates upon handling.

Evidence of Compliance:
✓ Written procedure for plasma component preparation and storage for the different types of products prepared AND
✓ Component records

TRM.44400  Plasma Freezer Monitoring  Phase II
The temperature required for proper storage in freezers is maintained and recorded.

NOTE: Freezer storage temperatures must be maintained at -18°C or below for preservation of procoagulants in the plasma.

TRM.44450  Plasma and Cryoprecipitate Thawing  Phase II
Frozen plasma components and cryoprecipitate are thawed at 30 to 37°C with protection against water contamination of outlet ports or thawed using an FDA-cleared device.

NOTE: If a microwave oven is used, any manufacturer's claim that the temperature of the contents does not exceed 37°C must be verified by the laboratory. In the absence of such claim, the laboratory must validate the device's preservation of labile coagulation factors.

If frozen plasma components are thawed in a waterbath, an overwrap bag or other similar protection must be used to prevent water from coming in contact with outlet ports and possibly introducing bacterial contamination.

TRM.44525  Thawed Plasma Label  Phase II
If Fresh Frozen Plasma or plasma frozen within 24 hours of collection is thawed at 30 to 37°C and maintained at 1 to 6°C for one to five days, it is relabeled as "Thawed Plasma".

TRM.44537  Thawed Cryoprecipitate-Reduced Plasma Usage  Phase II
If cryoprecipitate-reduced plasma is thawed between 30 to 37°C and maintained at 1 to 6°C, it is used within five days.

REFERENCES

CYPRECIPITATE

Inspector Instructions:
• Cryoprecipitate policy or procedure
• Sampling of records of component processing
Cryoprecipitated AHF is prepared to preserve fibrinogen and factor VIII activity:

1. Fresh frozen plasma is thawed at 1 to 6°C
2. The thawed plasma is immediately centrifuged at 1 to 6°C to separate the cryoprecipitate from the plasma, and
3. The cryoprecipitate is frozen within one hour

Evidence of Compliance:
✓ Written procedure for preparation of cryoprecipitate AND
✓ Records of temperature monitoring for the refrigerated centrifuge AND
✓ Records of component processing

PLATELETS

Inspector Instructions:

- Platelet component policy or procedure
- Sampling of records of component processing QC

- How have you verified your platelet count method for the expected concentration range?
- What system are you using to control the risk of bacterial contamination in platelet components?
- What actions do you take if a platelet component is suspected of having bacterial contamination?

Platelets are prepared within eight hours of the collection of whole blood that has NOT been cooled below 20°C or, if prepared by apheresis methods, they are prepared according to the instrument manufacturer’s instructions.

NOTE: Platelets must be separated within eight hours from whole blood that has not been cooled to below 20°C to allow appropriate refrigerated storage of Red Blood Cells and storage of platelets at room temperature (20 to 24°C) with agitation. However, whole blood may be held for a longer period at room temperature prior to separation of components, not to exceed 24 hours, provided that safety and efficacy of the components are recorded. Storage at lower temperatures may result in reduced platelet survival. Apheresis platelets must be prepared according to the instructions of the manufacturer.

REFERENCES
NOTE: Platelet concentrates are required to have a minimum of $5.5 \times 10^{10}$ platelets/unit and Apheresis Platelets are to have a minimum of $3 \times 10^{11}$ platelets/unit in at least 90% of units tested. Plastics currently approved and commonly used for platelet unit storage permit adequate gas exchange to maintain pH of at least 6.2.

Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations.

REFERENCES

TRM.44925 Platelet Count Verification

Platelet counts on platelet components are determined, when required, using a method that has been verified to be accurate in the expected concentration range.

NOTE: Automated whole blood hematology analyzers may yield inaccurate, non-linear results in the range of platelet counts encountered in platelet components (generally 1,000,000-2,000,000/µL). Predilution of samples from components, alone, may not avoid this problem. The entire method used for determining platelet concentrations in platelet components (including any manual manipulations in addition to the automated instrument's functions) should be verified periodically using a preparation of known concentration (such as provided commercially or determined through a reference method).

Evidence of Compliance:
✓ Written procedure defining criteria and frequency for verification of the instrument for accuracy of platelet concentrations in the expected range AND
✓ Records of verification at defined frequency

REFERENCES

**REVISED** 09/22/2021

TRM.44950 Platelet Component Storage

Platelet components are stored under appropriate conditions and are transfused within the approved storage time for the particular container and collection method used.

NOTE: The following include appropriate conditions for platelet storage:
- At 20 to 24°C with continuous gentle agitation. Agitation during storage ensures optimal gas exchange and maintenance of pH. Data in the literature suggest that platelets may be stored up to 24 hours without agitation. Platelet bags currently approved and used for five-day storage maintain adequate platelet viability and can function for up to seven days. However, platelet bag manufacturer’s instructions must be followed if more stringent.
- At 1-6°C with optional agitation. The storage period is defined by the platelet bag manufacturer when applicable, or based on platelet manufacturing facility validation studies.

**REFERENCES**


**REVISED** 09/22/2021

TRM.44955 Bacterial Contamination in Platelets Phase II

The laboratory (or its blood supplier) assures that the risk of bacterial contamination of platelets is adequately controlled using 1) FDA-cleared/approved devices or an equivalent system for bacterial detection in platelets, and follow FDA recommended bacterial testing intervals and sampling volumes or 2) other adequate and appropriate methods found acceptable by the FDA (eg, pathogen reduction).

**NOTE:** Equivalent system is defined as a system that has been validated to demonstrate comparable or improved sensitivity in CFU/mL. If testing is performed by the supplier of platelet components, the laboratory can satisfy this checklist requirement by having a written agreement with the supplier to be notified of supply units suspected of containing bacteria.

**Evidence of Compliance:**

✓ Records of use of individual units of whole blood derived (WBD) platelets or pools of up to six units of such platelets that have been tested by an FDA-cleared/approved method OR
✓ Records of use of pre-pooled WBD platelets tested with an FDA-cleared/approved culture-based QC test by the supplier OR
✓ Records of use of apheresis platelets tested with an FDA-cleared/approved culture-based QC test by the supplier OR
✓ Records of culture of aliquots from individual WBD platelet units destined for pooling OR
✓ Records of testing by methods that are not FDA-cleared/approved but have been validated to be of equivalent clinical sensitivity to an FDA-cleared/approved assay OR
✓ Records for use of other adequate/appropriate methods found acceptable by the FDA (eg, pathogen reduction)

**REFERENCES**


TRM.44957 Bacterial Contamination in Platelets Notification Phase II

If the transfusion service laboratory performs testing to detect bacterial contamination of platelets, there are written procedures for the handling and investigation of platelet components that are suspected of having bacterial contamination that prohibit release of the units for transfusion and include notification to the blood supplier and appropriate steps to identify the contaminating organism(s).
NOTE: If testing to identify the contaminating organism(s) is not performed by the laboratory, appropriate steps may include having an agreement with the blood supplier or another laboratory to identify the organism(s). The notification to the blood supplier must include information about the species of the contaminating organism, where possible.

**Evidence of Compliance:**
- Records of investigation and interpretation of findings AND
- Records of blood supplier notification for contaminated platelet(s) with organism identified

**REFERENCES**

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**PLATELETS LEUKOCYTE-REDUCED**

**Inspector Instructions:**
- Platelet leukoreduced policy or procedure
- Sampling of leukocyte-reduced platelet component QC records

**TRM.44960 Method of Preparation**

**Phase II**

The method of preparation ensures acceptable leukocyte-reduction and platelet concentration in the final component.

**NOTE:** The WBC content for leukocyte reduced whole-blood-derived platelets must be less than $8.3 \times 10^5$ WBCs, and for plateletpheresis units, less than $5 \times 10^6$ WBCs. After filtration, platelet recovery must be at least 85% of the original content.

Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations.

**REFERENCES**
1) Lutz P., Dzik WH. Large-volume hemocytometer chamber for accurate counting of white cells (WBCs) in WBC-reduced platelets; validation and application for quality control of WBC-reduced platelets prepared by apheresis and filtration. *Transfusion*. 1993;33:408-412

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**IRRADIATED CELLULAR COMPONENTS**

**Inspector Instructions:**
- Irradiated component policy or procedure
- Sampling of records of component processing QC
- Sampling of indicator system QC records
- Sampling of maintenance records
- Certificate or letter of compliance with US NRC
• How do you ensure that your equipment meets the standards of the US Nuclear Regulatory Commission?

• Select a patient who has received an irradiated unit. Follow the handling of the component including processing and relabeling.

TRM.44970  Radiation Dose  Phase II

If the facility irradiates blood and components, there is a written procedure to ensure that the procedure delivers the anticipated radiation dose.

NOTE: The radiation dose delivered must be verified by measurement at the time of the installation of the equipment and after mechanical maintenance, particularly the parts of the equipment that handle the specimen such as the turntable. There should be verification records (annually for Cesium-137 and semi-annually for Cobalt-60) that the procedure delivers a minimum of 2500 cGy targeted to the midplane of the canister if a free-standing irradiator is used, or to the central midplane of an irradiation field if a radiotherapy instrument is used. The minimum dose at any point in the canister or irradiation field should be 1500 cGy. The procedure should define the maximum number of units of blood or blood components that can be irradiated in a batch. There should be a quality control program for the indicator system in use.

REFERENCES

TRM.44977  Blood Component Labeling And Expiration Dates  Phase II

Irradiated blood and blood components are permanently labeled as irradiated and expiration dates for irradiated Red Blood Cell products are modified not to exceed 28 days from the date of irradiation or the original outdate, whichever is sooner.

Evidence of Compliance:
✓ Written procedure for labeling irradiated units

TRM.44984  Blood Irradiator Maintenance  Phase II

There is a schedule and records of maintenance and function checks for all blood irradiation equipment including timer checks, back-up timer checks, turntable inspection, and radiation leakage testing.

TRM.44987  US NRC Requirements  Phase II

The laboratory meets the requirements of the US Nuclear Regulatory Commission for blood irradiation devices that contain radioactive materials.

NOTE: This checklist element can be satisfied by a certificate or letter stating that the laboratory is in compliance with the US Nuclear Regulatory Commission for blood irradiation devices containing radioactive materials.

REFERENCES


**Irradiated Blood/Blood Component Records (Phase II)**

Records are maintained for blood and blood component irradiation for at least 10 years, to include unit numbers, duration of procedure, dose of irradiation for each batch, identity of the person performing the irradiation, as well as date, time and site of procedure.

**STORAGE AND ISSUE OF TISSUES**

This section applies only to the storage and issue of tissues OTHER than blood, bone marrow and progenitor cells. Please note that other sections of the TRM checklist, such as record retention, donor selection and testing, quality management, and component preparation/storage, apply as appropriate.

**Inspector Instructions:**

- Sampling of tissue storage policies and procedures
- Source facility registration/license
- Sampling of tissue storage records
- How are you informed of an adverse reaction to implanted tissue?
- Follow the records of receipt of tissue from donor facility through preparation, issuing, acceptance and disposition. Confirm that procedures and records ensure adequate tracing of all tissues.

**Tissue Program (Phase II)**

The authority, responsibility and accountability of the tissue-handling program are defined in a written policy.

*NOTE:* The authority and responsibility for all aspects of the tissue-handling program should be adequately defined to ensure compliance. The program should be coordinated on a hospital-wide basis.

**Evidence of Compliance:**

- Written policy defining the responsibilities for the tissue-handling program AND
- QM records documenting hospital-wide involvement

**Source Facility Criteria (Phase II)**

All source facilities are registered or licensed as required by national, federal, state (or provincial), and local regulations.
TRM.45100  Tissue Records

There are records of the infectious disease testing and type of processing performed for each tissue stored.

TRM.45125  Donor Infections/Adverse Events Investigation

There are procedures for investigating donor infections or adverse events after tissues are received and implanted.

NOTE: Possible tissue-transmitted infections and other adverse events must be investigated and reported to the tissue source facility when appropriate.

If the source facility notifies the user facility about a donor's infection or reactive infectious-disease test, procedures are required for quarantining tissue or notifying the tissue recipient when appropriate. There should be look-back and recipient notification for HIV, HTLV-I/II, Hepatitis B, Hepatitis C, or other tissue-transmissible infectious agents subsequently found in tissue donors after the tissue has been implanted.

Evidence of Compliance:
✓ Records of investigation of tissue-transmitted infections or adverse events AND
✓ Records indicating action taken following source facility recalls

TRM.45150  Tissue Storage Conditions

The written policies and procedures define the storage conditions of the different tissues handled, records retained, and process for return of each tissue type to storage, as appropriate, after issuance for use.

TRM.45160  Specimen Handling/Storage

All tissues are transported, handled, stored, and issued or disposed of according to the source facility’s written directions.

TRM.45165  Blood Vessel Storage

Blood vessels stored by the laboratory from organ donors are managed in accordance with requirements of the US Organ Procurement and Transplantation Network (OPTN).

NOTE: The OPTN in the US Department of Health and Human Services regulates blood vessels from organ donors as organs. Stored vessels are sometimes used in recipients different from the organ recipients, raising the possibility of disease transmission. Laboratories with responsibilities for storing or managing blood vessels must collaborate with their transplant centers to establish applicable procedures and records for the laboratory’s duties, as required by OPTN Policies. For example, OPTN requirements include refrigeration monitored at 2 to 8°C, maximum storage time 14 days after recovery, prohibition against storing vessels from donors with hepatitis C antibody or hepatitis B surface antigen, inventory logs, and disposition records.

Evidence of Compliance:
✓ Policies and procedures for laboratory responsibilities in storing or managing organ-donor blood vessels AND
✓ Records as required in the laboratory’s duties, such as refrigerator temperature records and alarm checks, inventory logs, and disposition records

REFERENCES
TRM.45170 Specimen Tracking  Phase II

There are written procedures for the receipt, product identification, preparation, issue, and disposition of each tissue received.

NOTE: Procedures and records are required for receipt and acceptability (e.g., transport conditions, package integrity); source facility; donor and lot alphanumeric identifiers; expiration date; the date, time, and staff involved in preparing, issuing, and acceptance; and disposition. Records must permit tracing of all tissues from source facility to recipient or other disposition.

TRM.45180 Issue Usage Cards  Phase I

There is a written procedure for completing and returning issue usage cards to the source facility, if applicable.

TRM.45190 Record Retention - Tissues  Phase II

Procedures and records are retained for at least 10 years, or longer if required by national, federal, state (or provincial), or local regulations.

NOTE: Hospital accreditation may require record retention of tracking information and expiration dates for at least 10 years after the tissue's disposition or expiration date, whichever is longer.

TRM.45200 Tissue Storage Temperature  Phase II

The records show that tissues were stored at the required temperatures.

NOTE: Storage of tissues must be appropriate for the type of tissue and its means of preservation. Failure to adhere to requirements could result in a unit not being suitable for the purpose for which it was intended. Good manufacturing practices require a clear statement of these conditions.

TRM.45250 Donor/Recipient Tracking Records  Phase II

Records allow for the identification of the donor and the recipient of each tissue handled, as well as tracking from donor to recipient and vice-versa.

NOTE: Records must allow association of donor and recipient to allow withdrawals/recalls to be directed appropriately and to allow problems in transplanted tissues to be tracked to their source.

BLOOD/COMPONENT DONOR SELECTION AND COLLECTION

This section applies to both autologous (self) donations and donations for others (allogeneic, including apheresis donations). Checklist requirements in this section also apply to Donor Apheresis and Cellular Therapy sections, as applicable.

Autologous collections should be transfused only to the individual for whom they were collected. If exceptional circumstances warrant and are adequately documented, the transfusion service medical director can direct that these units be converted to the allogeneic supply. In that case, the units must meet all criteria for allogeneic donation.
Autologous units that are reactive or positive for ANY infectious disease marker, including a serologic test for syphilis, must be labeled with a "BIOHAZARD" label in addition to the usual labeling. Units that are prepared on site and are not tested must be labeled “DONOR UNTESTED.”

Requirements posed in this section do not imply that a donor must be deferred from donation because of a positive response, but rather that the information is recorded and that an evaluation of that donor response ensues.

In addition to the requirements in this section, there immediately follows an additional section entitled “Allogeneic Donors Only”.

ALL DONORS (ALLOGENEIC AND AUTOLOGOUS)

Inspector Instructions:

READ

- Sampling of donor policies and procedures
- Sampling of donor history, physical exam and screening test records
- Sampling of personnel training and competency records

OBSERVE

- Donor arm preparation, if possible

ASK

- How do you determine if a donor is qualified to donate?
- What are the signs/symptoms of a donor adverse reaction? What action is taken?
- What collection process do you follow to reduce bacterial contamination?

DISCOVER

- Follow a donor record through all phases of collection. Further evaluate evidence of follow up for significant findings in donor history, physical examination or screening test results.

TRM.45251 Regulatory Documents  Phase I

Appropriate regulatory documents for donor collection and selection are readily available (paper or electronic), and there is evidence of their use in policy and procedure development.

NOTE: For laboratories subject to US regulations, the following documents must be available and used:

1. Latest version of applicable sections of 21CFR
2. Current FDA guidance
3. Latest version of applicable state and local laws

Laboratories not subject to US regulations must follow national, state (or provincial), and local laws and regulations.

REFERENCES
1) FDA Guidelines: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrSearch.cfm?CFRPart=606&showFR=1
TRM.45252  Donor Procedures

There are written procedures in compliance with CAP requirements and FDA regulations for the following:

- Donor identification
- Donor selection
- Physical examination of the donor
- Arm preparation
- Phlebotomy
- Handling of collected units
- Treatment/prevention of donor reactions

TRM.45253  Donor Privacy/Confidentiality

There are written policies and procedures to ensure privacy of donor interviews and confidentiality of all donor records.

NOTE: To ensure accurate and truthful answers to the screening questions by donors, the donor interview must be done in a manner to ensure privacy. Donor records and test results must be kept confidential, except as required by law.

**REVISED** 09/22/2021

TRM.45254  Training and Competency for Donor Collection Personnel

Personnel responsible for donor collection, (including therapeutic phlebotomy activities) and donor selection, predonation examination, and phlebotomy are trained and assessed for competency at least annually.

NOTE: It is the laboratory director’s responsibility to determine:

- How competency is assessed
- Qualifications of individual assessing competency.

Evidence of Compliance:

✓ Records of training and annual competency

REFERENCES


TRM.45255  Physician Availability

There is a qualified and licensed physician available to answer donor suitability questions, and there are procedures to obtain emergency services for treatment of adverse donation reactions.

REFERENCES


TRM.45256  Donor Demographics

Donor demographics include date of birth and address.

NOTE: All donor demographics must include a birthdate. In the US, allogeneic donors should generally be at least 16 years old or conform to applicable state law. Consent from a parent or guardian must be obtained if a donor is less than 17 years old, unless State law specifies a different age for donor consent. Furthermore, date of birth is a standard donor identification tool. The donor’s address is required for notification of abnormal test results and deferral.
Evidence of Compliance:
✓ Donor selection records consistent with defined inclusion criteria

REFERENCES

TRM.45257 Inclusion Requirements  Phase II

Donor physiologic measurements (including temperature, pulse and blood pressure) meet inclusion requirements.

NOTE: Donor physiologic measurements must meet inclusion criteria. FDA-defined inclusion criteria include:
1. Body temperature less than or equal to 37.5° C (99.5º F)
2. Pulse between 50-100 beats/minute and regular
3. Diastolic blood pressure less than or equal to 100 mm Hg and greater than or equal to 50 mm Hg
4. Systolic blood pressure less than or equal to 180 mm Hg and greater than or equal to 90 mm Hg

Deviations for pulse and blood pressure require medical evaluation. The responsible physician must perform the examination onsite for donors with blood pressure values outside the specified range; the determination for pulse outside the specified range can be obtained by telephonic or other offsite evaluation.

Evidence of Compliance:
✓ Donor screening records

REFERENCES

TRM.45258 Inclusion Requirements  Phase II

The laboratory has records indicating that donor weights meet inclusion requirements.

NOTE: The donor must weigh at least 50 kg (110 pounds). Certain apheresis procedures may require different minimum weights.

REFERENCES

**REVISED** 09/22/2021

TRM.45259 Inclusion Requirements  Phase II

The donor’s blood hemoglobin concentration or hematocrit is determined, and meets inclusion requirements.

NOTE 1: Donor blood hemoglobin concentration or hematocrit must be measured before donation:

- For female allogeneic donors, the hemoglobin concentration must be no less than 12.5 g/dL, or a hematocrit no less than 38%. The facility may collect blood from female allogeneic donors who have a hemoglobin level between 12.0-12.5 g/dl or a hematocrit value between 36% and 38% provided the facility uses a procedure that has been found acceptable by the FDA to ensure the health of the donor will not be adversely affected.
• For male allogeneic donors, the hemoglobin concentration must be no less than 13.0 g/dl or a hematocrit no less than 39%.

NOTE 2: For certain apheresis collections procedures (eg, collection of two units of red blood cells), the FDA has established a specific algorithm for donor acceptance.

NOTE 3: For autologous donors only, the transfusion service medical director may establish less stringent erythrocyte mass measurement criteria. Autologous donors must have a hemoglobin level no less than 11.0 g/dl or a hematocrit no less than 33%.

Evidence of Compliance:
✓ Donor screening records AND
✓ Record of FDA acceptance of procedure(s), if applicable

REFERENCES
2) Food and Drug Administration. Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use. US Government Printing Office. 2020(September 10):[21CFR630.10].

TRM.45260 Instrument QC
Phase II

For methods used to determine donor hemoglobin concentration or hematocrit, the laboratory follows manufacturer's instructions for quality control, reviews results, and records acceptability prior to use in donor screening.

Evidence of Compliance:
✓ QC records
✓ Written procedure consistent with manufacturer's instructions

TRM.45261 Health Interview
Phase II

A general health interview is performed to ensure that donation will not be harmful to the individual.

NOTE: Allogeneic donors should be healthy, and free of acute or symptomatic significant disease. Prospective donors with significant disease should be evaluated for risk to themselves and for risk of disease transmission to the transfusion recipient by the responsible qualified physician.

Evidence of Compliance:
✓ Donor screening records

TRM.45263 Informed Consent for Donation
Phase II

Prior to each donation, informed consent, including the FDA-required elements, is obtained from the donor with a written signature or other record of acknowledgement.

NOTE: The FDA-required elements of informed consent include the following:
1. The donor has reviewed the required educational material about relevant transfusion-transmitted diseases.
2. The donor agrees not to donate if the donation could result in a potential risk to recipients as defined in the educational material.
3. The donor is informed that a sample of their blood will be tested for relevant transfusion-transmitted diseases.
4. The donor is informed that if the donation is determined to be not suitable or if the donor is deferred, the record will identify the donor as ineligible and the donor will be notified of the basis for the deferral and the period of deferral.
5. The donor is provided with information about the risks and hazards of the specific donation procedure.

6. The donor is given the opportunity to ask questions and withdraw from the donation procedure.

REFERENCES
3) Shaz BH, Demmons DG, Hillyer CD. Critical evaluation of informed consent forms for adult and minor aged whole blood donation used by United States blood centers. Transfusion 2009;49:1136-1145
4) Food and Drug Administration. Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use. US Government Printing Office. 2020(Apr 1);[21CFR630.10(g)(2)(ii)].

TRM.45264 Donor Record

The donor history, physical examination, and screening test results are recorded (paper or electronic).

TRM.45265 Follow-Up

There is evidence of follow-up for significant findings in donor history, physical examination and screening test results.

TRM.45266 Numeric Identification Agreement

There is a written procedure to ensure that the numeric identification on pilot tubes, bags and related donor records are in agreement.

TRM.45267 Donor Arm Preparation

A written procedure requiring the use of FDA-approved methods for skin disinfection prior to phlebotomy is followed for donor arm preparation to reduce the risk of bacterial contamination of the donor unit.

NOTE: The specific procedure used may vary but should include directions for the chemicals to be used, the time and manner that each is applied and the EXACT sequence of the steps taken. Donor arm preparation should be monitored to assure that the laboratory’s procedure is followed.

Appropriate skin preparation methods must be used, allowing alternative procedures for those who are allergic to the primary method. For laboratories subject to US regulations, the FDA recognizes several methods for arm preparation.

REFERENCES

TRM.45268 First Volume Diverted From Collection for Platelets

The first volume of the phlebotomy from which a platelet component will be derived is diverted from the whole blood or component collection.

NOTE: The diverted volume should be at least 10 mL.

Evidence of Compliance:
✓ Written procedures defining the use of collection bags with diversion pouches when platelet products are to be prepared

**REVISED** 09/22/2021
**TRM.45269**  Adverse Reactions - Donor Collection  Phase II

There is a written procedure for recognition, treatment, tracking, and trending of adverse donor reactions.

Evidence of Compliance:
✓ Record of training for adverse reactions AND
✓ Records of donor reactions, including data on trending AND
✓ Procedure for recognizing and treating adverse reactions

**REVISED** 06/04/2020

**TRM.45270**  Directed Donation Requirements  Phase II

There is a written procedure to ensure that all directed donations between blood relatives are irradiated or treated by a method approved by the FDA to prevent transfusion associated graft-versus-host disease (TA-GVHD).

NOTE: The blood relationship of directed donors to recipients must be determined to ensure that components are irradiated or treated by the FDA approved method (eg, pathogen reduction) to minimize the risk of graft versus host disease.

REFERENCES
1) Irradiation of units from blood relatives: Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products - 7/22/93 CBER

**TRM.45271**  Physician Request - Autologous Collection  Phase II

For autologous blood collections, there is a written request by the donor/patient’s physician.

**TRM.45272**  Autologous Donation Guidelines  Phase II

The transfusion service medical director has approved a policy to allow for the safe collection of autologous blood under certain guidelines, and if a patient falls outside those guidelines, the policy requires consent of the transfusion service medical director or physician designee.

Evidence of Compliance:
✓ Autologous donation records consistent with suitability criteria or with physician approval

REFERENCES

**ALLOGENEIC DONORS ONLY**

This section applies only for allogeneic whole blood or apheresis donations (ie, not self-donation or autologous), and is in addition to the requirements in the previous "All Donors (Allogeneic and Autologous)" section. The presence of certain items does not imply that the donor must be rejected because of a positive response, but rather that the information is recorded and that an evaluation of that specific problem ensues. If blood is not collected from allogeneic donors, omit this section.
Inspector Instructions:

- Sampling of allogeneic donor policies and procedures
- Educational material provided to donors
- Sampling of donor history, physical exam and screening test records
- Follow a donor record through all phases of collection. Further evaluate evidence of follow up for significant findings in donor history, physical examination or screening test results.

TRM.45273 Educational Material

**Potential allogeneic donors are given educational material explaining the risks of infections transmitted by transfusion.**

**NOTE:** Allogeneic donors must be given educational material informing them of the risks of relevant transfusion-transmitted infections, the activities that may place a person at risk of acquiring HIV and other infections, and that testing may not detect all infected persons. The donor screening questions must provide an opportunity to obtain an accurate and truthful history of possible infectious exposure.

**Evidence of Compliance:**
- Records indicating that donor received educational material

**REFERENCES**
1) Food and Drug Administration. Guidance for Industry. Revised recommendations for reducing the risk of immunodeficiency virus transmitted by blood and blood products. August 2020
2) Food and Drug Administration. General donor eligibility requirements. 2020(September 10):[21CFR630.10(b)].

TRM.45275 Parenteral Drug Use Inspection

**Records indicate that both arms of allogeneic donors are inspected for evidence of parenteral drug use.**

**NOTE:** Both arms of allogeneic donors must be inspected for evidence of parenteral drug use and to ensure the venipuncture site is free of any scars, lesions, or needle marks which may be indicative of self-injected drug use.

TRM.45276 Donation Time Intervals

**For allogeneic donations, the time interval between donations meets current requirements.**

**NOTE:** Allogeneic donors must be excluded if their last donation has not met the required interval between donations. Current exclusions include less than eight weeks since last whole blood donation, less than 16 weeks since two-unit red cell apheresis collection, and less than two days since last hemapheresis.

**Evidence of Compliance:**
- Written donor collection procedures with minimum collection intervals between donations defined

**REFERENCES**
TRM.46138  Allogeneic Donor Evaluation  Phase II

There are records indicating that allogeneic donors are evaluated in a manner consistent with FDA regulations and guidances.

NOTE: The Donor History Questionnaire (formerly, the Uniform Donor History Questionnaire), is one approved approach, but other methods using procedures approved by the FDA may be used. If the Donor History Questionnaire is utilized, blood collectors may append additional questions and/or apply more stringent requirements in donor selection.

Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations.

REFERENCES

DONOR BLOOD TESTING

This section applies to the primary testing of DONOR blood collected on site. If the laboratory performs infectious disease testing (eg, HBsAg, anti-HIV, RPR, etc.) in the Transfusion Medicine section of the laboratory, additional checklists (eg, Chemistry, Immunology, etc.) will be required to inspect this testing.

Inspector Instructions:

- Sampling of donor blood testing policies and procedures
- Sampling of donor blood testing records
- Sampling of infectious disease testing QC records
- Sampling of instrument function check records
- Deferred donation list

- How do you ensure that quarantined units are not inadvertently released?
- What is your process for identifying prior donations from donors who now test positive for infectious diseases? How are recipients of those components notified?

- Follow a quarantined unit from testing to final disposition. Determine if procedures ensure safeguards to prevent transfusion.

TRM.47000  Routine Typing  Phase II

The routine procedure includes tests with anti-A and anti-B, A_1 and B cells, anti-D, and if negative for anti-D, a test for weak D.

NOTE: Routine procedures must include at a minimum, forward and reverse A and B grouping, and a test for the D antigen. Negative-appearing D tests must be confirmed by a test for weak D.

Evidence of Compliance:
✓ Records of donor blood typing for each unit

REFERENCES
1) Domen RE. Policies and procedures related to weak D phenotype testing and Rh immune globulin administration. Results from supplementary questions to the comprehensive transfusion medicine survey of the College of American Pathologists. *Arch Pathol Lab Med.* 2000;124:1118-1121
Screen for Unexpected Antibodies - Allogeneic Donors

Testing includes a screen for unexpected antibodies to red cell antigens on all allogeneic donors.

Evidence of Compliance:
- Written procedure defining criteria for screening for unexpected antibodies AND
- Records of antibody screening for blood donations meeting defined criteria

Infectious Disease Testing

For laboratories subject to US regulations, all FDA-required or recommended infectious disease tests are performed on blood samples collected at the time of donation, or collected at least once in the prior 30 days for a directed donor for a single intended recipient. Reagents used are licensed or registered by the FDA and procedures are approved by the FDA.

NOTE 1: Tests required or recommended by the FDA are provided in the Code of Federal Regulations and FDA Guidelines, and are subject to change. In certain instances, the FDA may approve pathogen reduction methods as an alternative to testing. Current tests include the following: nucleic acid testing (NAT) for HIV-1, HCV, HBV, and WNv; serologic anti-HIV-1, anti-HIV-2, anti-HBc, anti-HCV, HBsAg, anti-HTLV-I, anti-HTLV-II and serologic tests for syphilis and Trypanosoma cruzi antibodies. T. cruzi testing should be done at least once in the lifetime of each donor. NAT testing for Babesia species may be required in selected states by the FDA.

NOTE 2: Autologous donations for the patient-donor's own use are not required to be tested for infectious disease markers unless the units could be used for allogeneic transfusions or will be transferred to another establishment:
- If the receiving establishment allows autologous donations to be used for allogeneic transfusion, all donations must be tested for infectious disease markers.
- If the receiving establishment does not allow autologous donations to be used for allogeneic transfusion, the laboratory must at a minimum test the first donation in each 30-day period.

Evidence of Compliance:
- Records of infectious disease testing for each unit

REFERENCES
1) Food and Drug Administration. General biological products standards. Testing requirements for relevant transfusion-transmitted infections; Test requirements. 2020 [Apr 1];71 [21CFR 610.40].

Infectious Disease Testing

For laboratories not subject to US regulations, blood donors are tested for human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), and syphilis on blood samples taken at the time of donation (or taken in the prior 30 days for a designated donor to a single recipient), using reagents and procedures that are in compliance with applicable regulations.

NOTE: Laboratories must also perform all other infectious disease tests required by their national, federal, state (or provincial), and local laws and regulations.

The World Health Organization (WHO) recommends mandatory blood donor testing for HIV-1, HIV-2 and HCV (HIV and HCV antibodies or antigen-antibody combinations), HBV (surface
antigen, HBsAg), and syphilis (treponemal antibodies). Nucleic acid testing is not required, but if feasible should be performed in countries with high incidences of HIV, HCV or HBV.

REFERENCES

TRM.47112 Off-Site Testing Agreement

If testing of donated units is performed by another facility, there is a written agreement for the performance of this testing that specifies adherence to the requirements of this checklist and a system to assure accurate receipt of test results with appropriate interpretation.

Evidence of Compliance:
✓ Written agreement with testing site, as applicable

TRM.47125 Supplemental Tests

FDA licensed, approved, or cleared supplemental tests, when available, are performed when a donor screening test is reactive.

NOTE: The FDA requires that a licensed, approved, or cleared supplemental test be performed whenever available for a reactive screening test. Supplemental tests are currently approved for syphilis, anti-HIV, Chagas, HTLV, and HBsAg neutralization.

Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations.

REFERENCES

TRM.47150 Infectious Disease Testing QC

The records of infectious disease testing indicate controls and standards react as expected and instrument function checks are appropriate.

NOTE: Review of the records must indicate proper function of all the components of the test before reporting results and releasing units from quarantine.

TRM.47200 Sample Mix-Up Precautions

There is a written procedure to track and minimize the risk of sample mix-up to ensure specimen integrity and identification.

NOTE: This can be accomplished in an automated fashion, or by manual procedures, but it must ensure that positive results are linked to the correct unit.

Evidence of Compliance:
✓ Written procedure defining criteria for tracking samples

TRM.47250 Record Review

Testing records and records of release from quarantine are reviewed by a supervisory level individual or other designated individual prior to release of units for transfusion, and the reviews are recorded.
NOTE: There are records demonstrating compliance with the quarantine policies and assuring that incompletely tested units, or units that have reactive results, are not released for transfusion.

TRM.47300  Deferred Donor Units  Phase II

There is a written procedure to ensure that quarantined units, units from deferred donors and units on which testing is incomplete are not inappropriately released.

NOTE: Disposition of these units must be controlled and recorded.

Evidence of Compliance:
✓ Written procedure for releasing units from quarantine with processes to prevent inappropriate release

TRM.47320  Donation Tracking  Phase II

There is a written procedure for identifying previous donations from persons who now test reactive for viral marker screening tests and notifying consignees of components from those units, when applicable.

NOTE: In the US, the FDA requires that blood centers identify previous units collected from donors who are reactive in one or more tests for viral markers and recommends that, under certain conditions, consignees of components from these units be notified of a potential risk to recipients.

Evidence of Compliance:
✓ Written procedure for look-back and consignee notification for donors testing positive for viral marker screening AND
✓ Donor records

REFERENCES
2) FDA Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing Product Disposition, and Donor Deferral and Reentry, December 2017.

TRM.47350  Quarantine/Unit Disposal Procedure  Phase II

There are written procedures for unit quarantine and disposal, and records are retained.

NOTE: An effective procedure for unit quarantine and disposal is a necessity to prevent inappropriate release of units.

Evidence of Compliance:
✓ Written procedure for unit quarantine and disposal AND
✓ Donor records for quarantine and disposal

TRM.47400  Deferred Donor List  Phase II

The donor’s identity is checked against a list of deferred donors before the blood is distributed.

NOTE: Records must be retained to allow identification of deferred donors, so that blood and components from such individuals will not be distributed. When possible, checking this registry before donation is preferred.
Evidence of Compliance:
✓ Records of checks against deferral list prior to release

REFERENCES

TRM.47450 Result Review
Phase II

Records indicate that the transfusion service medical director reviews abnormal donor testing results and ensures donor notification in a timely manner.

NOTE: The transfusion service medical director must review abnormal donor testing results and ensure donor notification so appropriate counseling and treatment can be obtained. The FDA requires notification attempts to be completed within eight weeks.

The patient's physician must be notified for autologous donations.

Evidence of Compliance:
✓ Written procedure for result review and donor notification for abnormal donor testing results
AND
✓ Records of director review and notification for abnormal results

REFERENCES

TRM.47500 Post-Donation Information
Phase II

There is a written procedure for managing post-donation information about the donor’s suitability.

NOTE: Post-donation information from the donor or another source may affect the donor's eligibility and the safety of past or current products.

CELLULAR THERAPY

This section addresses the collection, transport, processing, storage and/or administration of cellular therapy products including hematopoietic progenitor cells (bone marrow, peripheral blood stem cells, and cord blood), immune effector cells, gene-modified cells and other cellular therapies.

Requirements for qualification and management of donors of allogeneic products are as for allogeneic blood donors. Record retention, quality management and quality control, and other requirements in this checklist, as well as in the Laboratory General and All Common Checklists, apply to cellular therapy products, as appropriate.

The term "transfusion service medical director" is used generically throughout the checklist to refer to the physician who has oversight responsibility for the different services (eg, transfusion service, donor service, apheresis service, cellular therapy services) addressed by the checklist requirements. Some laboratories may have separate directors providing oversight for these services; however, all directors must meet the required qualifications.
QUALITY MANAGEMENT AND GENERAL ISSUES

Inspector Instructions:

- Sampling of cellular therapy policies and procedures
- Sampling of records of unusual events with notification

- How do you ensure communication with physicians of patient treatment decisions?
- How do you monitor clinical outcomes?
- Have you validated your protocols?
- How do you label cellular therapy products?

- Select a component/product and track progression through ordering, patient consent, collection, processing and final disposition. Confirm that the identity of the individual performing each step is recorded.

TRM.47525 Personnel Responsibilities

The responsibilities of all parties in the collection, transport, processing, storage and administration of cellular therapy products are defined.

TRM.47575 Personnel Qualifications

The collection, processing, storage, and administration of cellular therapy products is overseen by qualified, licensed physician(s) having appropriate training and/or experience, who meets the qualifications defined in TRM.50050.

TRM.47625 System of Communication

An appropriate communications system is in place between the laboratory and treating physicians for communicating decisions on patient treatment.

NOTE: The system must address the ordering of procedures, collection protocols to be followed, end points and objectives of the collection procedures, storage including cryopreservation, and thawing and administration of cellular therapy products.

TRM.47675 Adverse Reaction Reporting

There is a written policy for reporting adverse reactions to the person responsible for investigating the occurrence.

Evidence of Compliance:

✓ Written policy defining criteria for reporting adverse reactions AND
✓ Records of unusual events with notification
There are records that all deviations (planned and unplanned) from standard operating procedures have been approved by the transfusion service medical director or, as appropriate, the recipient's physician.

NOTE: Planned deviations must be approved prior to implementation.

Examples of planned/unplanned deviations:
- Planned: Collection from a donor with a low hemoglobin or with a relevant travel history
- Unplanned: Apheresis collection personnel failed to record vital signs for an hour of the collection or intravenous access is lost and the collection must be aborted

Evidence of Compliance:
- Written policy for planned and unplanned deviations AND
- Records of deviation notification

**REVISED** 09/22/2021
TRM.47775 Clinical Outcomes

The laboratory monitors and reviews the clinical outcomes associated with the cellular therapy products it provides, such as determining the time to engraftment after infusion of hematopoietic progenitor cells (HPC).

NOTE: The transfusion service medical director responsible for cellular therapy services must be involved in the review of the data and assessment of outcome to monitor the quality of the laboratory service. In situations where there is a failure to engraft or a problem relating to product quality, there are records of investigation and corrective action, as appropriate.

For HPC products, time to engraftment following cellular therapy product infusion is measured by absolute neutrophil and platelet counts.

TRM.47825 New/Changed Protocol Validation

The laboratory has written procedures to validate new protocols, including significant changes to existing protocols.

TRM.47875 Requisition

Written orders are obtained from the patient’s physician for the collection, processing, storage and administration of cellular therapy products; or, if appropriate, the processing, storage and/or administration of the cellular therapy product is conducted according to an approved investigational study in which the subject/patient is enrolled.

TRM.47925 Process Tracking

Records identify the person performing each significant step in the collection, processing and administration of cellular therapy products.

NOTE: For collections performed at other facilities, there is a process to obtain the identity of the collection personnel, if requested.

TRM.47975 Product Labeling

The laboratory assigns a unique alphanumeric identifier to each cellular therapy product collected, processed and/or stored, including aliquots, and labeled with the International Society of Blood Transfusion (ISBT) terminology, with maintenance and tracking of this identifier throughout receipt, storage, issuing of the product, and disposition.
NOTE: All steps of cellular therapy labeling must be defined in the procedure manual and conform to ISBT labeling. The laboratory must have a valid system to receive and manage all cellular products that come into inventory, including those labeled with legacy labeling systems such as the 1985 Uniform Labeling (Codabar) Guidance System.

**TRM.47985 Labeling Systems**  
**Phase II**

Standard operating procedures define appropriate and complete labeling systems for all cellular products, aliquots and other samples.

NOTE: Units testing positive for infectious disease markers or having an at-risk medical history must be labeled as a “Biohazard”. Cellular therapy products must be clearly labeled or tagged “Do Not Irradiate” if transported outside the control of cellular therapy laboratory personnel.

The labeling of products must be consistent with the current Circular of Information for and the use of cellular therapy products.

**COLLECTION**

**Inspector Instructions:**

- Sampling of cellular therapy collection policies and procedures
- Sampling of records of pre-collection donor testing
- Sampling of records of product assessment
- Sampling of donor eligibility records

**TRM.47995 Donor Qualifications**  
**Phase II**

There are written procedures to evaluate the acceptability of cellular therapy product donors.

NOTE: The transfusion service medical director responsible for HPC services and transplant physicians should establish the qualifications for cellular therapy product donation. Approval from the donor’s physician must be obtained prior to donation. Evaluation should include history and physical examination to protect donors from risks of the collection process, and to assess the risk of disease transmission. Donors not meeting the established criteria must be approved by the HPC medical director and transplant physician. For allogeneic donation, there is a written procedure to verify that HLA typing for major histocompatibility antigens has been performed on both the donor and the patient by (for US laboratories) a CLIA-certified laboratory.

**REFERENCES**


**TRM.48010 Consent**  
**Phase II**

Signed consent for collection is obtained prior to the collection procedure.

**TRM.48020 Donor Evaluation**  
**Phase II**

Autologous and allogeneic donors are evaluated prior to the collection procedure by a qualified individual, as specified by the transfusion service medical director.

**Evidence of Compliance:**

✓ Records of donor evaluation prior to collection procedures
**NEW** 06/04/2020  
TRM.48060  Pre-Collection Testing  
Phase II

The laboratory performs a complete blood count, including platelet count from each cellular therapy donor within 24 hours prior to the collection.

Evidence of Compliance:
✓ Records of donor testing prior to collection

**NEW/REVISED** 09/22/2021  
TRM.48070  Assessment of Cellular Product  
Phase II

The laboratory has a process for assessing the quality of each cellular therapy product collected to confirm product safety, viability, and integrity, and records are retained.

NOTE: When the manipulation process of cellular products results in an altered final cell population, the laboratory must evaluate the viable target cell population before and after the manipulation using a validated assay (where applicable).

Evidence of Compliance:
✓ Written process for assessing the quality of the cellular product collected AND  
✓ Records of cellular product assessment meeting predetermined specifications

**NEW** 06/04/2020  
TRM.48090  Donor Eligibility Status - Allogeneic Donors  
Phase II

The collection facility provides the records for each allogeneic cellular donor’s eligibility to the processing facility.

NOTE: The eligibility record must accompany the product at all times. Determination of eligibility is based on screening and testing according to applicable laws and regulations.

Evidence of Compliance:
✓ Policy for communicating cellular therapy donor eligibility AND  
✓ Records of cellular therapy donor eligibility status

REFERENCES

REAGENTS, SUPPLIES, AND EQUIPMENT

Inspector Instructions:

- Sampling of critical reagent, supply and equipment logs
- Sampling of records of LN2 monitoring
- Sampling of alarm checks
- Sampling of maintenance records
- Records of staff training on alarm response
- Sampling of storage unit temperature logs

- Liquid nitrogen storage unit visual inspection (sweating, cracks, rusting) and process to monitor LN2 level
- Active alarm system(s) in place for all liquid nitrogen storage units
• What is your back-up if your instrument fails?

• Identify a product that has been issued to a patient. Trace back to all reagents, supplies and equipment used in collection, processing and storage. Review associated temperature charts and liquid nitrogen records.

TRM.48120  Record Retention - Critical Reagents, Supplies and Equipment  Phase II

Records of all critical reagents, supplies, and equipment used in collection and processing, including lot numbers and expiration dates, are retained and traceable for each product.

NOTE: The record retention requirements of TRM.32250 apply, but the time period for retention begins with final disposition of the cellular therapy product.

Evidence of Compliance:
✓ Written policy defining the tracking of critical reagents, supplies and equipment used for each product AND
✓ Records such as reagent log, patient record or worksheets allowing for tracking of the required information

TRM.48130  Approved Reagents  Phase II

Reagents and supplies used in the collection, processing, cryopreservation, and administration of cellular therapy products are approved for human use.

NOTE: The use of reagents or supplies that are not approved must be either approved by the institution's Institutional Review Board as part of a trial, covered under an investigational new drug or device exemption, or previously validated in the scientific literature. For laboratories subject to US regulations, this approval comes from the FDA.

TRM.48140  Liquid Nitrogen Levels  Phase II

The laboratory has a written procedure to monitor and maintain adequate liquid nitrogen (LN2) levels in frozen storage units.

Evidence of Compliance:
✓ Written procedure defining method for monitoring LN2 levels AND
✓ Records of daily monitoring of LN2 levels

TRM.48180  Liquid Nitrogen Storage Unit Alarms  Phase II

All liquid nitrogen storage units are monitored 24 hours/day and are equipped with an alarm (in laboratory or remote) that is tested according to the manufacturer's recommended interval, or at least quarterly if not specified by the manufacturer, with results recorded.

NOTE: The laboratory must be able to demonstrate how the alarm system works and that there is a process to ensure a timely response to an alarm, including remote alarms.
Evidence of Compliance:
✓ Records of alarm checks at defined frequency

TRM.48190  Critical Equipment Back-Up  Phase II
The laboratory has back-up capability for all critical instrumentation and storage devices.

TRM.48210  Laminar Flow Hood Maintenance  Phase II
Records show that the laminar flow hood is regularly cleaned, decontaminated and certified as appropriate.

PROCESSING

Inspector Instructions:

- Sampling of processing policies and procedures
- Sampling of processing and QC/culture records
- Sampling of records of ABO/Rh compatibility

- What is your course of action when a product is culture positive?

TRM.48220  Aseptic Techniques  Phase II
Aseptic techniques are employed in the collection, processing and administration of cellular therapy products prepared by the laboratory.

NOTE: Products must be handled using aseptic techniques, processed with minimum delay and maintained at appropriate storage temperatures. Processing of the cellular therapy product should be performed under appropriate environmental conditions to minimize the risk of microbial contamination (eg, biosafety cabinets, if not using a closed system).

TRM.48230  Microbial Content  Phase II
All products intended for administration are cultured for microbial content at appropriate time(s).

NOTE: There are records of review of positive culture results by the transfusion service medical director, including investigation and corrective action, as required

Evidence of Compliance:
✓ Written procedure defining criteria and timelines for culturing

TRM.48240  Physician Notification  Phase II
There is a written procedure to notify the patient’s physician of any positive microbial culture results or other problems with the cellular therapy product that could affect its suitability for administration.
NOTE: This requirement is not intended to preclude the use of components testing positive for bacterial contaminants. It is the responsibility of the transfusion service medical director and patient's physician to determine if the cellular therapy product is suitable for use.

Evidence of Compliance:
✓ Records of physician notification

TRM.48250 Processing Record Review Phase II
For each product processed, detailed records are retained and there is evidence that they are reviewed by the transfusion service medical director or designee in a timely manner (at least prior to administration).

TRM.48260 Allogeneic ABO/Rh Mismatch Phase II
For allogeneic donations, there is a written procedure for the processing of products where there is an ABO/Rh mismatch between the donor and the recipient.

CRYOPRESERVATION AND STORAGE

Inspector Instructions:
- Sampling of cryopreservation and storage policies and procedures
- Sampling of cryopreservation records
- Sampling of consent forms

TRM.48270 Cryopreservation Record Review Phase II
Cellular therapy product cryopreservation records, including freezing charts, when applicable, are reviewed by the transfusion service medical director or designee.

NOTE: If the laboratory uses a controlled rate freezer, the freezing chart for each cryopreservation must be reviewed for appropriate heat of fusion, cooling rate and unexpected peaks in temperature.

TRM.48280 Product Exposure To Cryoprotectant Agents Phase II
The cryopreservation procedure includes steps to minimize the exposure of the product to the cryoprotectant agents (e.g., DMSO) used during the freezing process.

NOTE: As DMSO is potentially toxic to cells at temperatures above 0°C, the processing and freezing procedure must involve steps to minimize the exposure of the stem cell component to DMSO.

TRM.48290 Informed Consent for Disposal Phase II
There is a written policy that addresses informed consent for collection, processing, length of storage, and conditions to be met for final disposition of the cellular therapy product.

NOTE: A pre-collection written agreement between the storage facility and the designated recipient and/or donor defining the length of storage of cellular therapy products and their long...
term disposition must be obtained. There must be records of efforts taken to contact the patient and the patient's physician prior to discarding the components.

**NEW** 09/22/2021

TRM.48295  Cord Blood Processing  Phase II

**Cord blood products are appropriately prepared prior to administration.**

**NOTE:** Cord blood units that have not been red cell reduced prior to being cryopreserved must be washed using methods to ensure the removal of the plasma.

TRM.48300  Cord Blood Storage  Phase II

**Cord blood products are stored with integrally attached segments to allow verification of their contents.**

Evidence of Compliance:
✓  Written procedure defining criteria for cord blood storage and verification of content

TRM.48310  Quarantined Cellular Therapy Products  Phase II

**All quarantined cellular therapy products, including products untested or testing positive for infectious disease markers, are stored in a manner to prevent inadvertent administration of the product and to minimize the risk of cross contamination of other products.**

Evidence of Compliance:
✓  Written procedure defining criteria for storage of quarantined cellular therapy products

**NEW** 09/22/2021

TRM.48315  Cellular Therapy Product Inventory Control System  Phase II

The laboratory has an inventory control system for each cellular therapy component stored that includes the following (as applicable):

- Identification of the recipient with two identifiers
- Donor unit identification number
- Storage device identifier
- Location of product within the storage unit
- Date of collection

Evidence of Compliance:
✓  Records of cellular therapy inventory control logs (paper or electronic)

ADMINISTRATION

Inspector Instructions:

- Cellular therapy adverse reaction policy or procedure
- Sampling of adverse reaction records and evaluation

TRM.48320  Administration Adverse Reactions  Phase II
Adverse reactions unique to administration of cellular therapy products are recorded and evaluated.

NOTE: The transfusion service medical director is responsible for setting criteria for the detection of adverse reactions to cellular therapy products, as well as the evaluation and reporting of adverse reactions.

PERSONNEL

Inspector Instructions:

- Records of education and experience
- Sampling of policies/procedures for transfusion service medical director review

**REVISED** 09/22/2021  
TRM.50050  Transfusion Service Medical Director (Technical Supervisor) Qualifications  
Phase II

The transfusion service medical director (technical supervisor) is qualified.

NOTE: The transfusion service medical director (technical supervisor) must be an MD or DO, licensed to practice medicine or osteopathy in the jurisdiction in which the laboratory is located, and either 1) possess qualifications required for board certification in clinical pathology or 2) have at least one year training or experience in immunohematology.

In Department of Defense laboratories, technical supervisors for the subspecialty of immunohematology must meet the qualifications defined in the Clinical Laboratory Improvement Program (CLIP) Procedures. A qualified medical director must perform duties requiring medical expertise.

The transfusion service medical director has oversight responsibility for the different services addressed by the checklist (eg, transfusion, donor, apheresis, cellular therapy). Some laboratories may have separate directors providing oversight for these services; however, all directors must meet these qualifications.

Evidence of Compliance:

✓ Records of transfusion service medical director (technical supervisor) qualifications including diploma, transcript(s), equivalency evaluation, current license (if required) AND

✓ Records of work history in related field

REFERENCES


TRM.50100  Director Involvement  
Phase II

The transfusion service medical director is involved in development of all policies and procedures related to transfusion.

Evidence of Compliance:

✓ Records of transfusion service medical director review of transfusion-related policies and procedures AND/OR meeting minutes of institutional transfusion committee meetings where policies and procedures are developed/approved
Transfusion Medicine Checklist

**NEW** 06/04/2020
TRM.50150  Training and Competency for Critical Tasks  Phase II

Transfusion service personnel responsible for performing critical tasks are trained and assessed at least annually.

NOTE: A critical task is defined as any non-testing function performed in the transfusion service that can affect patient safety or the quality of the service performed (e.g., issuing blood components, modification/manufacturing of blood products).

It is the laboratory director’s responsibility to determine:
- How competency is assessed
- Qualifications of the individual's assessing competency.

Requirements for training and competency of personnel performing patient testing are found in the Laboratory General Checklist, Personnel section. Training of blood transporters is described in TRM.40900.

Evidence of Compliance:
✓ Records of training and annual competency for critical tasks performed

REFERENCES

PHYSICAL FACILITIES

Sufficient space and utilities need to be provided for the overall workload of the transfusion medicine section, and to meet all safety requirements

Inspector Instructions:

- Space, storage and collection areas are all sufficient

- Is the work area sufficient for you to perform your duties safely and accurately?

**NEW** 09/22/2021
TRM.50200  Adequate Space  Phase I

The laboratory has adequate space in the following areas:
- Blood donor collection
- Apheresis/therapeutic apheresis/therapeutic phlebotomy
- Cellular therapy collection areas
- Blood/blood component and cellular therapy product storage and reagent equipment areas (refrigerators and freezers, platelet rotators, liquid nitrogen).

NOTE: There must be sufficient space of appropriate design to provide donors with privacy such that they feel comfortable divulging details of their health history. In addition, there must
be sufficient space in the phlebotomy area to accomplish the necessary functions and to allow access of additional or emergency personnel in case of an untoward event.