COLLEGE of AMERICAN PATHOLOGISTS

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Laboratory Department

Transfusion Medicine Checklist

CAP Accreditation Program

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Transfusion Medicine Checklist

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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. 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.

CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES
Transfusion Medicine Checklist
12/26/2024 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 inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements

Requirement	Effective Date
TRM.40705	12/26/2024

REVISED Checklist Requirements

Requirement	Effective Date
TRM.30900	12/26/2024
TRM.30950	08/24/2023
TRM.31400	12/26/2024
TRM.31900	08/24/2023
TRM.32250	08/24/2023
TRM.33300	08/24/2023
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TRM.44955	08/24/2023
TRM.44957	08/24/2023
TRM.45267	08/24/2023
TRM.45270	08/24/2023
TRM.47450	08/24/2023
TRM.50050	12/26/2024
TRM.50200	08/24/2023

DELETED/MOVED/MERGED Checklist Requirements
None

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.


Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

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

TRM.22000 LIS Transfusion Validation **Phase II**

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 the length of time the system is in use, plus two additional years.

TRM.30000 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

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

Evidence of Compliance:
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

TRM.30550 Misidentification and Mistransfusion Risk Monitoring **Phase II**

The facility monitors the risk of pretransfusion sample misidentification and other causes of mistransfusion and subjects the related processes 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

TRM.30575 Mistransfusion Risk Reduction **Phase II**

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

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.

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.

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)

TRM.30866 Service Agreement **Phase II**

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 **Phase II**

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:
- ✓ Records of supplier monitoring

***REVISED** 12/26/2024*

TRM.30900 Records of Deviation From SOP **Phase II**

The transfusion service medical director or physician 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 physician 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 physician 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.

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TRM.30950 Biologic Product Deviation Notifications **Phase II**

The laboratory notifies the appropriate agency when a biological product deviation occurs.

NOTE: For laboratories subject to US regulations, deviations may occur during compatibility testing, component preparation, labeling, storage, and distribution of units for transfusion. A biologic product deviation (BPD) is reportable to the Center for Biologics Evaluation and Research (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 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.

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

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

TRM.30970 Donor and Transfusion-Related Fatality Notifications **Phase II**

The laboratory notifies the appropriate agency when a donor-related fatality or transfusion-related fatality following transfusion of any component occurs.

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

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

Evidence of Compliance:

✓ Records of reportable events, if applicable

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).

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

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' instructions, 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.

Evidence of Compliance:

✓ Records of validation if instructions have been modified

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** 12/26/2024*

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 must be followed. Facilities must have written procedures to assess QC (eg, pattern of reactivity, typing of patient cells for the corresponding antigen, or antibody of known specificity reacting against panel cell(s)).

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.

***REVISED** 08/24/2023*

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. The requirement to check the timers on serologic centrifuges does not apply to digital timers.

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

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

TRM.32208 Collection/Processing Equipment **Phase II**

The laboratory assesses 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 must 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:
- ✓ 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.

*****REVISED** 08/24/2023***
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.

TYPE OF RECORD	RETENTION PERIOD
Donor Records	
• Blood/component donor information, consent and collection • Donor blood testing • Donor notification of significant findings • Component production • Look back investigation/disease reporting • Final unit disposition • Irradiation of cellular components • Acceptability of returned units into inventory	10 years
• Donor collection package inserts	10 years beyond donor unit disposition or expiration, whichever is longer
• Indefinitely and permanently deferred donors • Donors placed under surveillance (for recipient protection	Indefinitely

Patient Records	
• Transfusion administration records (TRM.41450) • Therapeutic phlebotomy/apheresis records • Final unit disposition	10 years
• Patient pre-transfusion testing results/interpretation • Immediate evaluation/interpretation of transfusion reactions • Evaluation/interpretation of delayed transfusion reactions • Emergency release of blood, including signature of requesting physician obtained before or after release	10 years
• Transfusion problems such as difficulty in blood typing, transfusion reactions, unexpected antibodies, and special transfusion requirements.	Indefinitely

Other Records	
• Employee signatures, initials, identification codes, and inclusive dates of employment • Identification of individuals performing each significant step in collection, processing, compatibility testing, and transportation of blood and blood components • Traceability of blood, blood components, and critical materials • Final inspection and verification of blood before issue • Container (eg, portable coolers) qualification/process validations	10 years
• Competency records • Training records • Orders and requests for blood/blood components • Blood supplier agreements	5 years

• Review and approval of new and revised policies and procedures • Discontinued policies and procedures	
• Computer system validation records • Records of changes to software, the test library, and major functions of laboratory information systems	Length of time the system is in use plus 2 additional years.

Quality Control Records	
• Management reviews for the effectiveness of the quality system • Proficiency testing records • Irradiation dose delivery	5 years
• Control systems for donor testing • Retyping of donor units • Inspections of blood/critical materials • Instrument/equipment quality control and maintenance • Control systems for patient testing • Inspection of weld for completeness • Temperature monitoring (eg, graphs, logs) of refrigerators, freezers, and platelet incubators	10 years

Tissue Records (including cellular therapy products)	
• Collection, transportation, processing, issuing, and disposition • Obsolete labels	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:

✓ 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 **Phase II**

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.

*****REVISED** 08/24/2023***

TRM.33300 License/Registration of Laboratory **Phase II**

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: For laboratories subject to US regulations, 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.

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

PROCEDURES AND TESTS

IMMUNOHEMATOLOGICAL PROCEDURES

TRM.40050 Agglutination/Hemolysis Criteria **Phase II**

Criteria for agglutination and/or hemolysis are defined.

NOTE: Criteria must be defined to provide uniformity of interpretation of positive and negative agglutination and hemolysis results.

TRM.40100 Test Result Recording **Phase II**

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 **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; this does not imply that each operator must perform QC daily. Personnel must 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

TRM.40130 Alternative Control Procedures **Phase II**

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: 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:

- ✓ Records of alternative control procedures

TRM.40140 QC Confirmation of Acceptability **Phase II**

Personnel review control results for acceptability before reporting patient/client results.

Evidence of Compliance:

- ✓ Records of control result approval

TRM.40145 QC Corrective Action **Phase II**

The laboratory performs and records corrective action when control results exceed defined acceptability limits.

NOTE: The actions taken must be consistent with the laboratory's quality control program (GEN.30000). 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 (eg, trending for repeat failures, etc.).

Evidence of Compliance:

- ✓ Records of corrective action for unacceptable control results

TRM.40150 Anti-D Controls **Phase II**

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. The selection of controls used must be consistent with the manufacturer's instructions.

Evidence of Compliance:
- ✓ Records of anti-D control results

TRM.40200 Antiglobulin Test Controls - Anti-IgG or Polyspecific Reagents **Phase II**

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 Antiglobulin Test Controls - Anti-C3 Reagents **Phase II**

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

TRM.40215 ABO Typing on Solid Organ Donors **Phase I**

Laboratories participating in donor evaluation for solid organ transplantation follow 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.

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.

TRM.40230 Specimen Labeling for Pretransfusion Testing **Phase II**

All blood samples used for pretransfusion testing are labeled at the time of specimen collection 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 individual collecting the specimen.**

NOTE: Blood specimens collected for pretransfusion 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 individual who collected the blood specimen, such as initials or another identifier on the tube, or an electronic record.

Evidence of Compliance

- ✓ Properly labeled blood specimens **AND**
- ✓ Records identifying the individual collecting pretransfusion testing specimens

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 pretransfusion testing.

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

*****REVISED** 12/26/2024***

TRM.40300 Historical Record Check **Phase II**

ABO, Rh, and antibody screen test results are compared with 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. Acceptable ABO and Rh historical records for transfusion purposes are only those generated or entered by laboratory personnel into the health system's laboratory information system and performed by an accredited laboratory/certified by the relevant

government agency in its jurisdiction. 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:

- ✓ 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.

TRM.40500 Recipient Sample **Phase II**

The maximum interval during which a sample may be used before obtaining a new sample is defined.

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 three days in patients who have been transfused or pregnant within the past three months, or if relevant medical/ transfusion history is unknown or uncertain. The day of sample draw is day zero.

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:
- ✓ Logs or computer records with forward and reverse grouping

TRM.40600 Unexpected Antibody Screen **Phase II**

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:
- ✓ Logs or computer records indicating the reactions at the different phases of testing

TRM.40650 Serologic Crossmatch **Phase II**

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 no clinically significant antibodies are detected in the antibody screen and there are no records of previous clinically significant or unexplained 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:
- ✓ Logs or computer records of serologic crossmatches

TRM.40651 Autologous Unit Crossmatch **Phase I**

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 **Phase II**

For non-group O neonates receiving non-group O red blood cells, the neonate's serum/ plasma is screened 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:
- ✓ Logs or computer records with screening results

TRM.40655 DAT Algorithm **Phase II**

When a direct antiglobulin test (DAT) 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:
- ✓ Records for DAT consistent with procedure

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.

***REVISED** 12/26/2024*

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

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).

Acceptable ABO and Rh historical records for transfusion purposes are only those generated or entered by laboratory personnel into the health system's laboratory information system and performed by an accredited laboratory/certified by the relevant government agency in its jurisdiction.

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

Evidence of Compliance:
- ✓ Work records of test results and/or search of records verifying ABO type

TRM.40680 Donor Unit/Recipient Information **Phase II**

The laboratory information system contains the donor identification 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.

TRM.40690 Data Entry Verification **Phase II**

If a serologic crossmatch is not performed, the laboratory verifies correct computer data entry before issuing blood or blood components, and the computer alerts users 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:

- ✓ 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

***REVISED** 12/26/2024*

TRM.40700 Selection of Blood Components **Phase II**

The laboratory has blood component selection criteria for the following:

- **ABO group-specific or compatible red blood cell-containing components**
- **ABO group-specific whole blood**
- **Group O whole blood with low anti-A/B titers if given to non-O patients**
- **Components containing plasma or platelets.**

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 or platelets is permitted due to blood supply and medical necessity, the laboratory has a written policy on their use.

***NEW** 12/26/2024*

TRM.40705 Use of Low-titer Group O Whole Blood **Phase II**

If low-titer group O whole blood is used, the laboratory follows written policies and procedures for its use.

NOTE: The following must be defined:

- *Indications for use*
- *Product specifications*
- *Administration instructions*
- *Indications to switch to component therapy and ABO type selection*
- *The limit on the number of units to be transfused for each patient during a bleeding event or within a time period.*

TRM.40710 Rh Negative Transfusion Recipients **Phase II**

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

***REVISED** 12/26/2024*

TRM.40720 Provisions for Special Components **Phase II**

The laboratory has processes 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 for deviations to written procedures may be made only with the approval of the physician responsible for the transfusion service, or physician designee (refer to TRM.47725).

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

The laboratory prevents or limits 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 **Phase II**

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:
✓ Records of crossmatches

TRM.40770 Life-Threatening Situations **Phase II**

The laboratory has adequate processes to investigate and handle 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

PERINATAL TESTING

TRM.40780 RhIG Candidates **Phase II**

The laboratory has a process to identify 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-certified 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 must 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.

TRM.40800 RhIG Dosage **Phase II**

Laboratories performing Rh immune globulin (RhIG) dosage calculations 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

TRANSFUSION 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.

TRM.40875 Transfusion Service Medical Director Responsibility **Phase I**

The responsibilities of the transfusion service medical director are defined, with records available of 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.

TRM.40900 Blood/Tissue Sign-Out **Phase II**

The process 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:

✓ Sign-out records for blood and tissue

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**

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

A final check is performed at the time of issuance to verify clerical identification and transfusion records for the following:

- **Identification of the recipient with two identifiers**
- **Donation identification 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:

✓ Records of checks at the time of issue

TRM.41000 Blood Administration Procedure **Phase II**

The blood administration procedure defines steps for 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.

TRM.41025 Transfusionist Training **Phase II**

Personnel involved in transfusion are trained initially and in-serviced at least annually, 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**

Evidence of Compliance:

✓ Records of training and in-service

TRM.41050 Handling of Blood Products **Phase II**

Written procedures are available for handling blood products 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 **Phase II**

A written policy is available 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.

TRM.41300 Donor and Recipient Information Verification **Phase II**

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**
- **Donation identification number (DIN) or pool 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:

✓ Records of donor/recipient information verification in the presence of the patient prior to transfusion

TRM.41450 Blood Administration Record **Phase II**

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**

TRM.41475 Post-Transfusion Observation **Phase II**

Patients who 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 **Phase II**

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

ADVERSE REACTION PROCEDURES

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

Criteria for the recognition of transfusion reactions and the clinical actions to be taken in the event of a suspected transfusion reaction are defined and readily available to clinical personnel in areas where patients are transfused.

TRM.41750 Reporting of Transfusion Reactions and Incidents **Phase II**

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

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.

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

TRM.42000 Additional Transfusion Reaction Evaluation **Phase II**

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

*****REVISED** 12/26/2024***

TRM.42050 Transfusion Reaction Interpretation **Phase II**

The transfusion service medical director or physician designee interprets and reports the findings of an adverse reaction investigation 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 physician designee, must be placed in the patient's chart.

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

TRM.42060 Transfusion Reaction Monitoring **Phase II**

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

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

The laboratory notifies 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)

TRM.42110 TRALI **Phase II**

The laboratory has a process to recognize, investigate and reduce the risk of transfusion-related acute lung injury (TRALI).

Evidence of Compliance:

- ✓ Records from blood supplier regarding TRALI mitigation strategies for plasma, apheresis platelets and whole blood

***REVISED** 08/24/2023*

TRM.42120 Blood Component Recall and Quarantine **Phase II**

The laboratory identifies and quarantines 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: 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. The laboratory must have a process to ensure that all suspect components in current inventory are quarantined.

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

Evidence of Compliance:

- ✓ Records of actions taken for each notification

TRM.42135 Blood Supplier Notifications **Phase II**

The transfusion service manages quarantines, recalls, and market withdrawals issued by its blood suppliers.

Evidence of Compliance:

- ✓ Records of actions taken for each notification

***REVISED** 12/26/2024*

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

The transfusion service notifies and counsels recipients, or notifies their physician of record, or other authorized individual, about potentially infectious blood components, such as specified in regulations for HIV and HCV.

NOTE: Attempts are required to notify the recipient, recipient's physician of record, next of kin, or legal representative, consistent with national, federal, state (or provincial), and local regulations.

Evidence of Compliance:

- ✓ Records of attempts to notify the recipient, recipient's physician of record, or other authorized individual consistent with national, federal, state (or provincial), and local regulations

APHERESIS

DONOR APHERESIS

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

TRM.42213 Staff Training - Donor Apheresis **Phase II**

Personnel 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.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:
- ✓ Donor records with test results

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.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.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 **Phase II**

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

TRM.42240 Donation Interval **Phase II**

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 plateletpheresis 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 plateletpheresis should be at least seven days. There must be no more than 24 donations in 12 months.*
6. *If plateletpheresis 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:

- ✓ Donor records consistent with defined procedure

THERAPEUTIC APHERESIS

TRM.42245 Responsibility for Therapeutic Apheresis **Phase II**

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:

- ✓ Patient records/charts showing evidence of transfusion service director/designated physician oversight

TRM.42246 Therapeutic Apheresis Records **Phase II**

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**

TRM.42248 Patient Safety and Protection **Phase II**

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.

TRM.42255 Staff Training - Therapeutic Apheresis **Phase I**

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**

Requests for therapeutic apheresis are reviewed and approved in a timely manner.

NOTE: Policies 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.

TRM.42267 Informed Consent - Therapeutic Apheresis **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

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:
- ✓ Records of time-out verification for each procedure

TRM.42280 Adverse Reactions - Therapeutic Apheresis **Phase II**

There are defined processes for 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

TRM.42285 Therapeutic Phlebotomy Units for Transfusion **Phase II**

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:

- ✓ Records of patient/donors meeting the criteria for allogeneic donations

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:

- ✓ 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 must include proper patient identification, adequate training of laboratory staff, proper sterile technique, and appropriate volume to be removed.

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**

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

TRM.42310 Physician Order **Phase I**

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

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:

Component	Definition
Fresh Frozen Plasma (FFP)	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
Plasma Frozen Within 24 Hours After Phlebotomy	Plasma separated from whole blood and frozen between 8-24 hours after collection
FFP, Thawed	Fresh Frozen Plasma thawed between 30-37°C, then stored at 1-6°C for up to 24 hours
Plasma Frozen Within 24 Hours After Phlebotomy, Thawed	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
Thawed Plasma	“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

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.

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

Blood/blood components shipped outside of the facility are properly packaged 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 **Phase II**

The laboratory follows a validated process for accepting blood/blood components back into inventory after they have been issued.

NOTE: The process must include verification of the integrity and appearance of the blood/blood component and maintenance at appropriate temperatures.

The steps and criteria for acceptance of units back into inventory must be validated by the laboratory (such as the use of transport/portable containers).

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

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.

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

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:

- ✓ QC records for continuous temperature monitoring **OR** records of checks at defined frequency

TRM.42550 Storage Temperature Range Corrective Action **Phase II**

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

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 **Phase II**

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

***REVISED** 12/26/2024*

TRM.42750 Storage Unit Alarms **Phase II**

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 recorded.

Examples of recording systems include:
- *Paper chart records*
- *Paper graphs*
- *Electronic records*
- *Event logs*

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

TRM.42850 Alarm Adjustment **Phase II**

Alarms are adjusted to be triggered before the temperature falls outside the 1 to 6℃ 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 **Phase II**

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**

The laboratory follows written procedures when there are temperature variances outside of acceptable storage 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**

The laboratory follows 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**

The laboratory defines and follows criteria for the proper labeling of components with all required information.

NOTE: The 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).

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.

TRM.43610 Red Blood Cell Unit Labeling with Historical Antigen Typing **Phase II**

The laboratory follows 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.

TRM.43625 Label Approval **Phase II**

The laboratory approves 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.

Evidence of Compliance:
- ✓ Records of label inspection and approval

TRM.43650 Component Handling **Phase II**

The laboratory maintains sterility of each component during component handling, including pooling and the use of sterile connecting devices.

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.

Evidence of Compliance:
- ✓ Records of component pooling **AND**
- ✓ Records of weld inspection, as applicable

TRM.43700 Pooled Components **Phase II**

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

TRM.43750 24 Hour Expiration **Phase II**

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:
- ✓ Component processing records showing modified expiration dates when appropriate

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

RED BLOOD CELLS WASHED

TRM.43850 Plasma Removal **Phase II**

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

RED BLOOD CELLS FROZEN

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 must be retained to permit prompt retrieval.

TRM.43950 RBC Freezing Method **Phase II**

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.

TRM.44000 Pre-Transfusion Testing **Phase II**

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

TRM.44100 Open System Preparation Usage **Phase II**

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

TRM.44150 Deglycerolization Requirements **Phase II**

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)

TRM.44250 Leukocyte-Reduced RBC Criteria **Phase II**

Records indicate that leukocyte-reduced Red Blood Cells contain less than 5 X 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.

PLASMA

TRM.44350 Frozen Plasma Collection/Storage **Phase II**

Plasma is separated from 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:
- ✓ 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℃ 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℃ and maintained at 1 to 6℃ 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℃ and maintained at 1 to 6°C, it is used within five days.

CRYOPRECIPITATE

TRM.44600 Cryoprecipitated AHF Preparation **Phase II**

Cryoprecipitated AHF is prepared to preserve fibrinogen and factor VIII activity using the following process:

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**

NOTE: If pathogen reduced cryoprecipitated fibrinogen complex is being prepared, it must be prepared according to manufacturer's instructions.

Evidence of Compliance:

- ✓ Records of temperature monitoring for the refrigerated centrifuge **AND**
- ✓ Records of component processing

PLATELETS

***REVISED** 12/26/2024*

TRM.44850 Platelet Preparation **Phase II**

Platelets are prepared within eight hours of the collection of whole blood that has not been cooled below 20℃; or, if prepared by apheresis methods, platelets are prepared according to the instrument manufacturer's instructions.

NOTE: For cold-stored platelets (CSP), the unit must be placed in storage at 1-6°C no later than four hours from the end of collection if an FDA-approved pathogen reduction device is not used. If a pathogen reduction device is used, CSPs must be placed at 1-6°C no later than four hours after completion of pathogen reduction.

NOTE: Conventional (room-temperature) 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.

TRM.44900 Platelet Component Acceptability Criteria — Phase II

Records indicate that platelet components have acceptable numbers of platelets and that acceptable pH levels have been maintained during storage.

NOTE: Platelet concentrates are required to have a minimum of 5.5 X 10^{10} platelets/unit and Apheresis Platelets are to have a minimum of 3 X 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.

TRM.44925 Platelet Count Verification — Phase I

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:

✓ Records of verification at defined frequency

TRM.44950 Platelet Component Storage — Phase II

Platelet components are stored under appropriate conditions and are transfused within the approved storage time for the particular container, collection method, and bacterial risk control 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.*

***REVISED** 08/24/2023*

TRM.44955 Bacterial Contamination in Platelets **Phase II**

The laboratory (or its blood supplier) ensures 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.

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

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 use of apheresis or whole blood platelets tested with an FDA-cleared/approved rapid test QC by the performing facility **OR**
- ✓ Records of culture of aliquots from individual WBD platelet units destined for pooling or apheresis platelets **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)

***REVISED** 08/24/2023*

TRM.44957 Bacterial Contamination in Platelets Notification **Phase II**

If the transfusion service laboratory performs testing to detect bacterial contamination of platelets, the laboratory handles and investigates platelet components that are suspected of having bacterial contamination, prohibiting release of the units for transfusion, notifying the blood supplier, and identifying 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.

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

Evidence of Compliance:

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

PLATELETS LEUKOCYTE-REDUCED

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 8.3×10^5 WBCs, and for plateletpheresis units, less than 5×10^6 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.

IRRADIATED CELLULAR COMPONENTS

TRM.44970 Radiation Dose **Phase II**

If the facility irradiates blood and components, there is a process 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, semi-annually for Cobalt-60), or per manufacturer's recommendations for alternate sources of radiation) 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.

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.

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.44991 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.

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)

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.

TRM.45252 Donor Procedures **Phase II**

Written donor procedures are 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 **Phase II**

The laboratory ensures the 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.

TRM.45254 Training and Competency for Donor Collection Personnel **Phase II**

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

TRM.45255 Physician Availability and Emergency Services **Phase II**

The laboratory ensures that a qualified and licensed physician is available to answer donor suitability questions, and has a process to obtain emergency services for treatment of adverse donation reactions.

TRM.45256 Donor Demographics **Phase II**

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

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

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.

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

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

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 - Allogeneic and Autologous 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.*

TRM.45264 Donor Record **Phase II**

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

TRM.45265 Follow-Up **Phase II**

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

TRM.45266 Numeric Identification Agreement **Phase II**

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

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TRM.45267 Donor Arm Preparation **Phase II**

Donor arm preparation is performed using an FDA-approved method for skin disinfection prior to phlebotomy to reduce the risk of bacterial contamination of the donor unit.

NOTE: Written procedure must describe 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.

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

TRM.45268 First Volume Diverted From Collection for Platelets **Phase I**

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.

TRM.45269 Adverse Reactions - Donor Collection **Phase II**

There are defined processes 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

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

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.

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

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 laboratory follows a written policy approved by the transfusion service medical director for the safe collection of autologous blood under certain guidelines. If a patient does not meet the criteria defined in the guidelines, consent for collection is obtained from the transfusion service medical director or physician designee.

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

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.

TRM.45273 Educational Material **Phase II**

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

TRM.45275 Parenteral Drug Use Inspection **Phase II**

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 **Phase II**

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.

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.

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.

TRM.47000 Routine Typing **Phase II**

Routine donor blood typing 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

TRM.47050 Screen for Unexpected Antibodies - Allogeneic Donors **Phase II**

Allogeneic donor blood testing includes a screen for unexpected antibodies to red cell antigens.

Evidence of Compliance:
- ✓ Records of antibody screening for blood donations meeting defined criteria

TRM.47105 Infectious Disease Testing **Phase II**

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.

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

TRM.47112 Off-Site Testing Agreement **Phase II**

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 **Phase II**

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.

Evidence of Compliance:
- ✓ Records of supplemental testing, as applicable

TRM.47150 Infectious Disease Testing QC **Phase II**

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 **Phase II**

The laboratory has a process 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.

TRM.47250 Record Review **Phase II**

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**

The laboratory has a process to prevent inappropriate release of quarantined units, units from deferred donors, and units on which testing is incomplete.

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

TRM.47320 Donation Tracking **Phase II**

The laboratory has a process 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:
- ✓ Donor records

TRM.47350 Quarantine/Unit Disposal Procedure **Phase II**

The laboratory has a process 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:
- ✓ 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

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TRM.47450 Result Review **Phase II**

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.

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

Evidence of Compliance:
- ✓ Records of director review and notification for abnormal results

TRM.47500 Post-Donation Information **Phase II**

The laboratory has a process 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.

PERSONNEL

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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) be board certified in blood banking/transfusion medicine or 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.

Specific technical supervisor functions (listed in GEN.53400) may be delegated to an individual qualifying under 42CFR493.1449(d) with a minimum of a bachelor's degree in a chemical, biological, clinical or laboratory science, or medical technology from an accredited institution and at least four years of laboratory training or experience, or both, in immunohematology.

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

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

TRM.50150 Training and Competency for Critical Tasks **Phase II**

Transfusion service personnel responsible for performing critical tasks are trained and assessed for competency 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 (eg, issuing blood components, modification/manufacturing of blood products).

It is the laboratory director's responsibility to determine:

- *How competency is assessed*
- *Qualifications of the individuals 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

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

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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 and processing 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.