Every patient deserves the GOLD STANDARD ...
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ON-LINE CHECKLIST AVAILABILITY

Participants of the CAP accreditation programs may download the checklists from the CAP website (www.cap.org) by logging into e-LAB Solutions. 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.

SUMMARY OF CHECKLIST EDITION CHANGES

Transfusion Medicine Checklist

07/28/2015 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 listing of requirements below is from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.*

NEW Checklist Requirements

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REVISED Checklist Requirements

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INTRODUCTION

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

NOTE: Many of the requirements in this Checklist reflect United States regulatory requirements, particularly those of the US Food and Drug Administration (FDA). These requirements may not be applicable in other countries for purposes of CAP accreditation.

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 addressed by the checklist (e.g. transfusion service, donor service, apheresis service). Larger laboratories may have separate directors providing oversight for these services.

QUALITY MANAGEMENT AND QUALITY CONTROL

GENERAL ISSUES

Inspector Instructions:

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

- What do you do if QC for components is not acceptable?
- Has your laboratory implemented a risk-reduction system for mistransfusion? If not, how will you develop a plan to do so?
- How has your laboratory validated the LIS for blood banking?

- Select several occurrences in which component QC is not acceptable and follow records to determine if the steps taken follow the laboratory procedure for corrective action

TRM.22000  LIS Transfusion Validation  Phase II

The laboratory information system is 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 (e.g. electronic crossmatching and release of group specific products). Most laboratories utilize a series of screen captures to demonstrate the processes in the LIS. Records of system validation must be retained for at least two years beyond the service life of the system.

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

**REVISED** **04/21/2014**

TRM.30000 Monthly QC Review Phase II

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

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

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

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

TRM.30550 Misidentification Risk Phase II

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

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

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

REFERENCES

**REVISED** **07/28/2015**

TRM.30575 Misidentification Risk 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 collection of the pretransfusion testing sample, 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. The laboratory is expected to have implemented a plan to reduce these risks through implementation of a risk-reduction system. Among options that might be considered are: (1) 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); (2) Utilizing a mechanical barrier system or 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 may be used. The laboratory should participate in monitoring the effectiveness of the system that it implements.
The laboratory should also consider improvements in procedures and/or educational efforts as part of its program to reduce the risk of mistransfusion.

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

TRM.30700 QC Records Phase II
The records indicate that when components are prepared that do not meet the quality control requirements, corrective action is taken and records maintained.

REFERENCES

**REVISED** 07/28/2015
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 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.

REFERENCES

**REVISED** 07/28/2015
TRM.30850 Adequate Blood/Tissue Supply 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 should 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 (e.g. 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 (e.g. phone numbers) must be readily available to laboratory staff.

Evidence of Compliance:
✓ Copy of approved agreement (e.g. contract) with blood/tissue supplier(s)

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

NOTE: The agreement or policy should define the expectations for turnaround time, requests for patients with special transfusion needs (e.g. CMV negative, leukoreduced), notifications of delays in obtaining suitable products, and transportation of components and products. Agreements should be approved by the medical staff, transfusion service medical director, and hospital administration.

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

TRM.30882 Supplier Evaluation/Selection Process

The transfusion service laboratory has an effective mechanism for evaluating and selecting suppliers of critical materials and monitoring suppliers' ability to meet the laboratory's needs.

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

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

TRM.30900 Records of Deviation From SOP

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

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

REFERENCES

TRM.30950 CBER Notification

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

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

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

REFERENCES
1) US Food and Drug Administration Biologic Product Deviation Reporting [http://www.fda.gov/cber/biodev/biodev.htm](http://www.fda.gov/cber/biodev/biodev.htm)

REAGENTS AND CRITICAL MATERIALS

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

Inspector Instructions:

| READ | • Sampling of test procedures for reagent handling  
• Sampling of current reagent/critical material package inserts, for consistency with written procedures  
• Sampling of records of new reagent and critical material lot inspection and evaluation  
• Inventory log  
• Sampling of typing sera/reagent cell reactivity QC records |
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<td>OBSERVE</td>
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| ASK | • How do you store reagents and controls used in test procedures?  
• How do you evaluate new lots of critical materials?  
• How does your laboratory manage and control reagent inventory? |
| DISCOVER | • If there is an occurrence in which typing sera/reagent cell QC is not acceptable, follow records to determine if the steps taken follow the laboratory policy for corrective action |

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

TRM.31227 Package Inserts

Phase II

Current package inserts are available for the typing sera and other critical materials used by the laboratory.
NOTE: The laboratory must have a procedure that assures that the most current package insert is in use. When changes to the package insert are noted, the appropriate procedures must be updated as necessary.

TRM.31234  Reagent Handling  Phase II

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

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

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

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

TRM.31241  Reagent QC  Phase II

All new lots of reagents and critical materials (e.g. blood collection sets) are inspected and tested, as applicable, before use, with records of acceptance.

**REVISED** 07/28/2015

TRM.31250  Reagent Expiration Date  Phase II

All reagents are used within their indicated expiration date.

NOTE: Rare antisera may be used beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. The laboratory is expected to have in-date reagents for routine antibody panel testing.

For laboratories not subject to US regulations, expired reagents may be used only under the following circumstances: 1. The reagents are unique, rare or difficult to obtain; or 2. Delivery of new shipments of reagents is delayed through causes not under control of the laboratory. The laboratory must retain records of the performance of expired reagents in accordance with written laboratory policy.

Evidence of Compliance:
✓ Written policy for evaluating reagents that are used beyond their expiration date

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

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)

TRM.31400 Antisera/Reagent Red Cell QC Phase II

There are records of acceptable reactivity and specificity of typing sera and reagent cells on each day of use, including a check against known positive and negative cells or antisera, or manufacturer’s directions for daily quality control are followed.

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

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

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

REFERENCES

INSTRUMENTS AND EQUIPMENT

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

Inspector Instructions:

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

TRM.31900 Serologic Centrifuge Checks Phase II

Mechanical timers on serologic centrifuges, and the speed of the centrifuge, are checked for accuracy every 6 months.

NOTE: Most serologic centrifuges and timers do not require frequent recalibration. Accuracy of speed and timing must be checked initially and after adjustments, repairs, or implementation of new techniques. The frequency of such checks should be based on the historical stability of the centrifuge, but at least every 6 months. This requirement does not apply to digital timers.

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

REFERENCES
TRM.32200  Blood Volume Standardization

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 each day of use to ensure that the correct volume is being drawn.

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 each day of use to ensure that the correct volume is drawn.

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

REFERENCES

**REVISED** 07/28/2015

TRM.32208  Collection/Processing Equipment

There is a procedure to assess the conformance of blood, components or tissues when equipment used for collection or processing is found to be out of calibration and records maintained.

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

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

TRM.32216  Pipette Accuracy

There is a written procedure for the verification of pipette (fixed volume, adjustable and/or micropipettes) accuracy of calibration (gravimetric, colorimetric or other verification procedure) before being initially placed in service, and results recorded.

REFERENCES

**REVISED** 07/28/2015

TRM.32232  Pipette Accuracy
Pipettes used for quantitative dispensing are checked for accuracy and reproducibility at defined intervals (at least annually), and results recorded.

NOTE: Pipette checks must be performed following manufacturer's instructions, at minimum, and as defined in laboratory procedure.

For analytic instruments with integral automatic pipettors, the accuracy and precision of the pipetting system should be checked periodically, unless it is not practical for the end-user laboratory. Manufacturers' recommendations should be followed.

REFERENCES

RECORDS

The following routine records must be retained and available as required by applicable federal and local law; but, in no instance for fewer than 5 years after the records for processing have been completed, or 6 months after the latest expiration date for an individual component (whichever is later), in accordance with 21 CFR 606.160 and 42CFR493.1103 through 493.1105.

Inspector Instructions:

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

**REVISED** 04/21/2014
TRM.32250 Record Retention Phase II
Records are retained for an appropriate period.

NOTE: Records must be retained per the current CAP requirements, and in conformity with state and federal regulatory requirements. At the time of this Checklist edition, the requirements are as follows:

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

*Applies only to transfusion-related testing. General retention requirements (refer to Laboratory General checklist) apply to testing not related to transfusion.
### 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

- Indefinitely and permanently deferred donors
- Donors placed under surveillance (for recipient protection)

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### Patient Records

- Transfusion administration records (TRM.41450)
- Therapeutic phlebotomy/apheresis records
- Final unit disposition

- Patient pre-transfusion testing results/interpretation
- Immediate evaluation/interpretation of transfusion reactions
- Emergency release of blood, including signature of requesting physician obtained before or after release

- Transfusion problems such as transfusion reactions, unexpected antibodies, and special transfusion requirements.

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### Other Records

- Employee signatures, initials, and identification codes

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### Quality Control Records*

- Quality management reviews
- Proficiency testing records
- Inspections of blood/critical materials
- Instrument/equipment quality control and maintenance
- Irradiation dose delivery
- Control systems for patient testing
- Procedure review/procedure discontinued

- Control systems for donor testing
- Retyping of donor units

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<td>10 yrs beyond tissue's disposition or expiration, whichever is longer</td>
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### Tissue Records (including bone marrow and/or progenitor cells)

- Collection, transportation, processing, issuing, disposition
- Daily temperature monitoring

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TRM.32275 Component Records

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

TRM.32300 Receipt of Blood

Records include information about all blood received from outside sources.

Evidence of Compliance:

✓ Written procedure defining the required information as stipulated by the laboratory AND
✓ Invoices, shipping records and/or logs for all incoming blood components

TRM.32350 Records QC

There is a written procedure to verify that copies of records are complete, legible, and contain the original content.

NOTE: This item applies to both electronic and paper records. Laboratories converting data onto another medium for storage and retention must have a procedure to verify the accuracy, legibility, and completeness of the records before original documents are discarded. This checklist item would apply to any situation in which the lab makes a copy of an original record.

TRM.32900 Bacteriologic Studies

Records include information about bacteriologic studies (when indicated).

Evidence of Compliance:

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

TRM.33200 Personnel Audit Trail

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

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

REFERENCES


TRM.33300 License/Registration of Laboratory

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

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

IMMUNOHEMATOLOGICAL PROCEDURES

Inspector Instructions:

- Sampling of blood type/antibody screen policies and procedures
- Sampling of QC policies and procedures
- Sampling of QC records
- Sampling of critical patient results/log

- Technologist performing testing (recording results at the time of testing)

- What is your laboratory’s course of action when ABO and Rh typing results are not in agreement with the patient’s historical record?
- How does your laboratory ensure that the direct antiglobulin test detects RBC-bound complement as well as IgG?
- How do you confirm negative antiglobulin tests?
- How do you determine when quality control is unacceptable and when corrective actions are needed?
- How do you document critical results? Who do you contact?

- Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory policy for corrective action

TRM.40050 Agglutination/Hemolysis Criteria

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

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

TRM.40100 Test Result Recording

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

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

TRM.40120 QC Handling

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

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

REFERENCES

TRM.40140 QC Confirmation of Acceptability Phase II

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

NOTE: It is implicit in quality control that patient test results will not be reported when controls do not yield acceptable results.

Evidence of Compliance:
✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
✓ Evidence of corrective action taken when QC results are not acceptable

REFERENCES

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.

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

TRM.40200 DAT Controls 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
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

**NEW** 07/28/2015
TRM.40215 ABO Typing on Solid Organ Donors

Laboratories participating in donor evaluation for solid organ transplantation have a written policy for ABO typing.

NOTE: A1 subgroup typing must not be performed in patients that have been transfused with red blood cells in the past three months.

COMPATIBILITY TESTING

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

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

| OBSERVE | • Collection of blood specimen used for compatibility testing (patient identification, specimen labeling) |

| ASK | • How do you verify patient identification when the patient is not able to verbally respond?
  • How is the phlebotomist identified who has collected the specimen for compatibility testing?
  • What do you do if the specimen label does not match the requisition exactly?
  • If applicable, how do you handle neonatal transfusions? What blood groups are transfused? |

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

TRM.40230 Compatibility Specimen Labeling

Phase II

All blood samples used for compatibility testing are labeled 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 phlebotomist.

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

Evidence of Compliance

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

REFERENCES

3) Sandler SG, Langeberg A, Carty K, Dohnalek LJ. Bar codes and radio-frequency technologies can increase safety and efficiency of blood transfusions. LabMedicine 2006;37:438-439

TRM.40235  Patient Identification  Phase II

The patient is asked to verbally verify his/her identity, whenever practical, at the time of specimen collection.

NOTE: When a translator is needed, verbal verification is not required if obtaining a translator would delay specimen collection.

TRM.40250  Specimen/Requisition Verification  Phase II

An appropriately trained member of the transfusion service confirms that all identifying data on the transfusion requisition is identical to the information on the specimen tube before compatibility testing.

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

TRM.40300  Historical Record Check  Phase II

ABO, Rh, and antibody screen test results are compared against results of the same tests recorded previously to detect discrepancies and identify patients requiring specially selected units.

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

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

TRM.40350  Typing Discrepancies - Investigation/Reconciliation  Phase II

There are records of the investigation and reconciliation of all cases in which the ABO and Rh typing results were not in accord with the patient's historical record.

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

TRM.40450  Donor Unit ABO/Rh Confirmation  Phase II

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

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

TRM.40500 Recipient Sample

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

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

TRM.40550 Forward/Reverse Typing

For each patient, red blood cells are tested with anti-A, anti-B, 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.

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

REFERENCES

TRM.40600 Unexpected Antibody Screen

The method used to screen for unexpected red cell alloantibodies includes incubation at 37°C, reagent red cells that are not pooled, and reading at the antiglobulin phase.

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

TRM.40650 Serologic Crossmatch

For allogeneic units, a serologic crossmatch is performed to detect serologic incompatibility.

NOTE: Under certain circumstances, a transfusion service may elect to omit the antiglobulin phase of the serologic crossmatch. The antiglobulin test may be omitted if the antibody screen is negative and there is no history of detection of unexpected antibodies. Nevertheless, a procedure to demonstrate ABO incompatibility, either a serologic crossmatch or a validated computer system, is required. The computer crossmatch may not be used if the patient has, or has had,
evidence of clinically significant alloantibodies. Typing, screening and crossmatching of neonates can be abbreviated if a specific procedure is available.

Evidence of Compliance:
✓ Written procedure for serologic crossmatch, including criteria for omitting the antiglobulin phase AND
✓ Written procedure for crossmatching for neonates, if applicable AND
✓ 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, there is a written procedure to screen the neonate’s serum/plasma for anti-A or anti-B if the donor unit and maternal blood ABO blood groups are not compatible.

NOTE: Methods used to detect anti-A or anti-B should include an antiglobulin phase.

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

TRM.40655  DAT Test System  Phase II
When a direct antiglobulin test is ordered by a patient’s physician, the test system allows detection of RBC-bound complement as well as IgG.

NOTE: This procedure is intended to detect patients with complement-mediated hemolysis which may occur in paroxysmal cold hemoglobinuria, autoimmune hemolytic anemia, or drug-induced hemolytic anemia. For the purpose of diagnosing hemolytic disease of the newborn, use of anti-C3 is not required.

Complement-mediated hemolysis may not be detected using an antiglobulin reagent containing only anti-IgG, because not all cases of complement-mediated hemolysis have detectable IgG coating the red blood cell. TRM.40200 and TRM.40210 also apply.

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

REFERENCES
COMPUTER CROSSMATCHES

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

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

Inspector Instructions:

- Sampling of computer crossmatch policies and procedures
- Sampling of confirmation of donor unit ABO/Rh records
- Sampling of records of the initial/revalidation of the electronic crossmatch system

- What method do you use to verify the recipient's ABO blood group?
- What computer alerts are generated when there are discrepancies?
- In what instances would an electronic crossmatch not be appropriate?

TRM.40670 ABO Verification Phase II

The recipient’s ABO blood group 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 may be inadequate unless the sample has been drawn using a mechanical barrier system or digital bedside patient identification system.

Evidence of Compliance:

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

TRM.40680 Donor Unit/Recipient Information Phase II

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

Evidence of Compliance:

✓ Written policy defining information to be stored in the information system

TRM.40690 Data Entry Verification Phase II

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

NOTE: When a serologic crossmatch is not performed, patient safety must be ensured by requiring verification of proper data entry before issuing blood or blood components. The computer system must alert the user of any discrepancies of donor unit labeling, blood group confirmatory test interpretation, and to the existence of any ABO incompatibility.
Evidence of Compliance:
✓ Written procedure for the verification of correct data entry prior to release of blood/blood components **AND**
✓ Records of verification of correct data entry **AND**
✓ Written description of computer system alerts used to prevent issuance of blood components when discrepancies exist

**SELECTION OF BLOOD AND COMPONENTS FOR TRANSFUSION**

Inspector Instructions:

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

**REVISED** 07/28/2015

TRM.40700 Selection of Blood Components Phase II

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

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

TRM.40710 Rh Negative Transfusion Recipients Phase II

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

**NOTE:** Rh-negative transfusion recipients shall receive Rh-negative Red Blood Cells and Whole Blood except with authorization of the transfusion service physician due to inventory shortages or other extraordinary circumstances. However, the policy of the laboratory may allow for transfusion of Rh-positive platelet units to Rh-negative recipients who are not at risk of future pregnancy. The procedure should include consideration of prophylaxis against Rh immunization in Rh-negative platelet recipients receiving an Rh-positive platelet unit.

REFERENCES
Transfusion Medicine Checklist

TRM.40720 Immunohematologic Conditions

There is a procedure for providing appropriate components in patients with immunohematologic conditions (clinically significant red cell antibodies, transplantation, etc.) and for transfusion of special blood components (red cell antigen-negative, irradiated, CMV-reduced risk, hemoglobin S-negative, etc.).

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

**REVISED** 07/28/2015

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

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

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

TRM.40760 Granulocytes And/Or Platelets Crossmatch-Compatible

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

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

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

TRM.40770 Life-Threatening Situations

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

NOTE: Written policies and procedures must be available to expedite testing for transfusion in a life-threatening situation. If an institution's procedure allows abbreviated testing in massive transfusion situations, records should indicate that the procedure was followed. Records must include the authorization by a qualified physician. (If approved by the institution and recorded in the laboratory’s procedures, the physician responsible for the transfusion service laboratory may accept this responsibility.) If an incompatibility is discovered on completion of an incomplete crossmatch, the responsible physician must be notified in a timely manner and this notification recorded.

Red blood cells released before testing has been completed must be conspicuously labeled as uncrossmatched on the tag or label. Records of completion of compatibility testing for units released uncrossmatched must be maintained.

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

REFERENCES
PERINATAL TESTING

Inspector Instructions:

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

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

TRM.40780  RhIG Candidates  Phase II

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

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

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

REFERENCES

TRM.40790  Fetomaternal Hemorrhage Detection  Phase II

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

NOTE: A post-partum blood sample from identified Rh immune globulin candidates must be evaluated for fetomaternal hemorrhages. A standard method (Kleihauer-Braun-Betke or flow cytometry) should be used to calculate the appropriate dosage of Rh immune globulin, based on the estimated volume of fetal whole blood or red blood cells in the maternal circulation.
Evidence of Compliance:
✓ Written procedures for detection of fetomaternal hemorrhage AND
✓ Written procedures for quantification of fetal bleed, including calculations used to determine dose of Rh immune globulin AND
✓ Patient reports with screening results, quantification of fetal bleed and recommended dosage

REFERENCES

TRM.40800 RhIG Administration

There is a written procedure to ensure that Rh immune globulin is administered to 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 or the patient is known to be alloimmunized to the D antigen.

Evidence of Compliance:
✓ Written procedure for administration of RhIG AND
✓ Patient records confirming administration within the appropriate timeframe

TRM.40820 Historical Record Check

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

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

Evidence of Compliance:
✓ Written procedure for checking ABO/Rh and antibody screening results with historical results AND
✓ Records of historical checks
TRANSFUSION PROCEDURES

Inspector Instructions:

- Sampling of transfusion policies and procedures
- Sampling of transfusionist records of initial and annual training
- Sampling of patient records for recording of the required elements of administration and monitoring of transfusion of blood components
- If applicable, sampling of transfusion committee or blood utilization committee minutes demonstrating transfusion service medical director participation

- How do you examine blood products just prior to issue?
- What are the sign/symptoms of a transfusion reaction?
- What course of action would you take if you suspect a transfusion reaction?

- Observe a transfusion beginning with bedside patient identification, observation of label or tag with required information, use of additional fluids/drugs, monitoring by the transfusionist and records of blood administration.

TRM.40875 Transfusion Service Medical Director Responsibility

Phase I

There are records of the transfusion service medical director participation in:

1. The development of policies and procedures regarding recipient consent for transfusion/transplantation
2. Establishing criteria for transfusion
3. Reviewing cases not meeting transfusion audit criteria
4. Monitoring transfusion practices

NOTE: At a minimum, recipient consent procedures should communicate risks and benefits of transfusion and transplantation, as well as alternatives to transfusion; and the right of the adult patient to refuse transfusion. Procedures should include an opportunity for the transfusion/transplant recipient to ask questions. The transfusion service medical director must be involved in physician education and review of transfusion practices to ensure the appropriateness of use of blood components and the ability of the transfusion service to meet patient needs. The monitoring required to do this effectively can be met by various mechanisms, including reviewing cases not meeting transfusion audit criteria. Suggested monitors include the following: ordering practices, sample collection and usage (including discard of components), and compliance with institutional peer review recommendations. Data from the review and monitoring of transfusion practices should be used to modify blood administration policies and procedures, as necessary.

Evidence of Compliance:

✓ Written policy defining responsibilities of transfusion service medical director

REFERENCES

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

TRM.40900 Blood/Tissue Sign-Out

Phase II
The procedure for signing blood/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 should be trained and competent in prompt delivery.

TRM.40950  Clerical Identifiers  Phase II

Written procedures include instructions to verify clerical identification of blood (i.e. two patient identifiers, donor unit identification number or pool number), blood type of donor, and blood type of recipient before issuance.

REFERENCES

**REVISED** 07/28/2015

TRM.41000  Blood Administration Procedure  Phase II

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

NOTE: Because acute significant harm from transfusion frequently results from patient or blood component misidentification, from undetectable incompatibilities between the donor and recipient or inapparent defects (e.g. bacterial contamination), patients must be closely observed during and for a period of time after blood administration. Changes in vital signs or patient communication may signal an unintended adverse event.

REFERENCES

**REVISED** 07/28/2015

TRM.41025  Transfusionist Training  Phase II

Personnel involved in transfusion are trained in the identification of transfusion recipients and blood components, and in observation of recipients pretransfusion, during, and after transfusion, to include recognition and reporting of adverse transfusion events with records of in-service education at least annually.

NOTE: All personnel who administer blood components must be trained to identify transfusion recipients and components, and to closely observe patients during and for a period of time after blood administration.

Evidence of Compliance:
✓ Records of initial and annual training for all transfusionists

REFERENCES

TRM.41050  Handling of Blood Products  Phase II

There are written procedures for handling blood outside of the laboratory (avoidance of prolonged warming, need for filter, etc.).
NOTE: Such procedures should be used to train personnel who transport and/or transfuse blood, whether or not they are members of the transfusion medicine laboratory staff. The transfusion service should have appropriate procedures for transfusion offsite or at another institution, if applicable.

TRM.41150 Addition of Fluids/Drugs

There is a policy regarding the addition of drugs, or fluids other than 0.9% NaCl, to blood or blood components.

NOTE: Fluids other than 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.

**REVISED** 07/28/2015

TRM.41300 Bedside Identification

The recipient is always identified conclusively at the bedside with two patient identifiers by either two persons (e.g. by checking the wristband for name and hospital number), or by using bedside patient identification technology instead of a second person; and this information is matched to the unit of blood (or components) before transfusion.

Evidence of Compliance:
✓ Written procedure for blood administration that defines the requirements for verifying the identity of the patient and correlation with the information on the unit prior to transfusion.

REFERENCES

TRM.41350 Compatibility Label/Tag

A compatibility label or tag is securely attached to each unit before issuance, and it remains attached until completion of the transfusion.

NOTE: A label or tag must be securely attached to every unit before issuance and remain attached until the transfusion is completed. The label must include appropriate patient and donor identifiers and blood groups, and crossmatch testing interpretations.

REFERENCES

TRM.41450 Blood Administration Record

There is a record on the patient chart of the identity of the transfusionist, the blood component and unit number transfused, date and time of transfusion, evidence of patient monitoring pretransfusion, during and after transfusion, and any adverse effects.

REFERENCES

TRM.41475 Post-Transfusion Observation

Phase II
For patients receiving transfusions that will not be observed by medical personnel post-transfusion, instructions are provided to the patient regarding 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 (e.g. 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.

TRM.41525  Perioperative Blood Program  Phase II

The authority, responsibility, and accountability of the perioperative blood recovery and reinfusion program is defined.

Evidence of Compliance:
✓ Memorandum or policy describing the program

REFERENCES

TRM.41550  Intraoperative/Perioperative Safety and Efficacy  Phase II

The procedures for intraoperative and perioperative blood recovery ensure the safety and efficacy of the recovered blood components.

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

TRM.41600  Intraoperative/Perioperative Program Involvement  Phase II

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

NOTE: The intra- and perioperative collection and reinfusion procedures are part of the transfusion medicine procedures. The transfusion service medical director must be aware of, and participate in, the development of policies and procedures to help the institution ensure efficacy and patient safety.

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

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

**Inspector Instructions:**

| READ | • Sampling of transfusion reaction policies and procedures  
|      | • Sampling of initial and annual personnel training records for recognition of transfusion reactions  
|      | • Sampling of records of transfusion reaction work-ups, investigation, interpretation of findings, and reporting  
|      | • Sampling of records of blood supplier notification  
|      | • Sampling of records of actions taken when notified of quarantine, recall or market withdrawal  
|      | • Records of recipient notification and counseling when transfused with a potentially infectious blood product  
|      | • CBER fatality notification, if applicable |
| OBSERVE | • Donor/recipient transfusion reaction specimens (7 day retention, refrigerated, sealed) |
| ASK | • Are suspected transfusion reactions reported to the laboratory in a timely basis?  
|      | • What action do you take when you have been notified of a quarantine, recall or market withdrawal by your blood supplier? |
| DISCOVER | • Review the records of several transfusion reaction work-ups. Determine if the policies and procedures provide for thorough investigation and reporting. Determine if transfusion service medical director involvement is sufficient. |

**REVISED** 07/28/2015

**TRM.41650 Transfusion Reaction Recognition**

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

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

**Evidence of Compliance:**

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

**REFERENCES**

Policies require that transfusion reactions or incidents are reported immediately to the laboratory.

NOTE: Policies must require that all suspected transfusion reactions or incidents be reported immediately to the laboratory for evaluation. Investigation by the laboratory must be initiated as soon as possible to facilitate continuing care of the patient.

TRM.41770 System Failure

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

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

REFERENCES

TRM.41800 Post Transfusion Specimen Storage

Donor and recipient blood samples are appropriately stored for at least 7 days after transfusion for retesting, in the event of a transfusion reaction.

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

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

REFERENCES

TRM.41850 Transfusion Reaction Investigation

The immediate investigation of a potential 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: Rh typing of the post-reaction patient is not required. However, it is encouraged to add an additional level of patient verification. The direct antiglobulin test must allow detection of RBC-bound complement as well as IgG.

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

REFERENCES
TRM.42000 Transfusion Reaction Investigation Phase II

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

REFERENCES

TRM.42050 Transfusion Reaction Interpretation Phase II

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

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

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

REFERENCES

**REVISED** 07/28/2015

TRM.42100 Blood Supplier Notification Phase II

There is a written procedure for the notification of the facility providing blood and blood components when components are a suspected primary cause of an adverse reaction (e.g. transfusion-related acute lung injury, transfusion-related infection).

Evidence of Compliance:
✓ Records of blood supplier notifications

REFERENCES

**REVISED** 07/28/2015

TRM.42110 TRALI Phase II

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

NOTE: The laboratory should track the frequency of TRALI.

Evidence of Compliance:
✓ Written transfusion service procedure to investigate suspected TRALI cases AND
✓ Records from blood supplier regarding TRALI mitigation strategies for plasma, apheresis platelets and whole blood

REFERENCES

TRM.42120 Infectious Disease Identification/Quarantine Phase II
There is a procedure to identify and quarantine suspect components in inventory when notice is received about donors who now test reactive for an infectious disease.

**NOTE:** Because the FDA requires blood suppliers to notify transfusion facilities when certain donors are found to have seroconverted since the previous donation, there must be a procedure to ensure that all suspect components in current inventory are quarantined.

**Evidence of Compliance:**
- Records of actions taken for each notification

**REFERENCES**

**TRM.42135 Blood Supplier Notifications**

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

**Evidence of Compliance:**
- Records of actions taken for each notification

**REFERENCES**

**TRM.42150 Adverse Effects of Transfusion**

The transfusion service medical director has established procedures for evaluation of adverse effects of transfusion, including follow-up for transfusion-transmitted diseases and delayed transfusion reactions.

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

**REFERENCES**

**TRM.42170 Post Transfusion Counseling**

The transfusion service has a detailed procedure consistent with local, state, and national regulations/guidances for notification and counseling of recipients who have been transfused with a potentially infectious blood component.

**Evidence of Compliance:**
- Records of recipient notifications and counseling, as applicable

**REFERENCES**
1) CMS. Condition of participation: laboratory services Washington, DC: US Government Printing Office, 2011(42CFR482.27(b)
3) Guidance for industry: Nucleic acid testing (NAT) for human immunodeficiency virus type 1 (HIV-1) and hepatitis C virus (HCV): testing, product disposition, and donor deferral and reentry. Rockville, MD, Food and Drug Administration, May 2010
4) Guidance for industry: “Lookback” for hepatitis C virus (HCV); product quarantine, consignee notification, further testing, product disposition, and notification of transfusion recipients based on donor test results indication infection with HCV. Rockville, MD, Food and Drug Administration, December 2010
5) Guidance and rules may be found at [http://www.fda.gov/BiologicsBloodVaccines/default.htm](http://www.fda.gov/BiologicsBloodVaccines/default.htm)
There is a policy requiring notification of the appropriate agency when a transfusion-related fatality occurs following transfusion of any component.

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

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

REFERENCES
2) Notifying FDA of Fatalities Related to Blood Donation or Transfusion. September, 2003 CBER

APHERESIS

DONOR APHERESIS

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

Inspector Instructions:

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

- Apheresis components (labeling)

TRM.42212 Donor Safety and Protection Phase II

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

NOTE: Standard in-line clot filters (170-260 microns) must be used to prevent clots from being infused in the donor. The equipment used must be appropriately maintained and monitored.

TRM.42213 Staff Training Phase II

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

Evidence of Compliance:
✓ Records of education and training of personnel involved in apheresis
**REVISED** 04/21/2014
TRM.42214 Donor Eligibility Phase II

A policy defining donor apheresis eligibility criteria is available.

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

**Evidence of Compliance:**
- Donor eligibility criteria for each apheresis procedure performed (e.g. RBC apheresis, platelet apheresis, plasmapheresis) AND
- Records of donor evaluation prior to the procedure

**REFERENCES**

TRM.42215 Extended Donor Evaluation Phase II

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

**NOTE:** Additional testing may be required to evaluate donors in serial apheresis programs. Such additional measures may include total serum protein (no less than 6 g/dL), protein electrophoresis, serum immunoglobulin quantification, and platelet concentration before cytapheresis.

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

**REFERENCES**
4) FDA Memorandum, March 10, 1995, “Revision of FDA Memorandum of August 27, 1982: Requirements for Infrequent Plasmapheresis Donors”

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

**REVISED** 04/21/2014
TRM.42222 Donor Informed Consent Phase II

An informed consent explaining the risks and benefits of apheresis donation is reviewed and signed by the donor prior to donation.

**NOTE:** The donor must have the opportunity to ask questions and sign a document indicating consent to the procedure.
Evidence of Compliance:
✓ Copy of the consent form

REFERENCES

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

TRM.42224 Adverse Reaction  Phase I
There is a written procedure for the recognition, treatment, tracking, and trending of adverse donor reactions to apheresis.

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

TRM.42230 Volume Limits  Phase II
During apheresis, the total volume deficit is limited to no greater than 15% of the donor's estimated blood volume, or 10.5 mL/kg or procedures are in place to compensate for greater volume deficit in small volume donors.

NOTE: The laboratory should 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.

Evidence of Compliance:
✓ Written procedure defining 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 2 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 8 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 8 weeks. If the loss is equal to or greater than 300 mL, the donor must be deferred for 16 weeks (112 days).
4. The interval between plateletpheresis donations must be at least 2 days, no more than twice in a 7 day period, and no more than 24 times in 12 months.
5. 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 (1 unit per 8 weeks).
6. If plateletpheresis is performed more frequently than once every four weeks, the donor platelet count must be no less than 150,000/µL before the procedure or at the conclusion of the previous procedure.
7. If plasmapheresis is performed more frequently than once every 4 weeks, the FDA guidelines must be followed.

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

REFERENCES
2) Donor history questionnaire: http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/approvedproducts/licensedproductsblas.htm

THERAPEUTIC APHERESIS

Inspector Instructions:

READ
• Sampling of therapeutic apheresis policies and procedures
• Sampling of therapeutic apheresis patient records, including initial device placement
• Sampling of physician evaluation records and informed consents
• Sampling of personnel records of education and training

ASK
• If you use venous access devices, how do you verify the placement?
• What information is confirmed in a "time-out"?
• To what degree is the transfusion service medical director involved in the apheresis procedure?

TRM.42245 Responsibility for Therapeutic Apheresis

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

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

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

REFERENCES

TRM.42246  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. Drugs used
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: Standard in-line filters (170-260 microns) must be used to prevent clots from being infused in the patient. The equipment must be appropriately maintained and monitored.

TRM.42255  Staff Training  Phase I

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

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.

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

TRM.42260  Evaluation and Approval for Therapeutic Apheresis  Phase I

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

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

TRM.42265  Patient Suitability  Phase I

A qualified physician is responsible for evaluating the suitability of apheresis patients, including indications for the procedure, therapeutic goals, selection of replacement solutions, and criteria.
NOTE: Therapeutic apheresis should be performed using an evidence-based approach.

REFERENCES
1) J Clin Apher 22:3; 106-175 (2007)

TRM.42267 Patient Informed Consent

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

NOTE: The risks of apheresis must be explained by a knowledgeable, responsible person according to approved policies and procedures. The patient must have the opportunity to ask questions, and should be encouraged to sign a document indicating agreement.

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

REFERENCES

TRM.42270 Venous Access Verification

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

NOTE: Inappropriate placements have been reported to be the cause of severe complications including fatalities.

TRM.42275 Time-Out

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

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

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

TRM.42280 Adverse Reaction

Phase II
The standard operating procedure(s) describes 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 should provide information on monitoring for and treatment of potential complications including the loss of consciousness, hypocalcemia, hypotension, allergic reactions, air embolus, and hemolysis
THERAPEUTIC PHLEBOTOMIES

Inspector Instructions:

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

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

TRM.42285  Therapeutic Phlebotomies 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, the collecting establishment has received a variance from the FDA.

Evidence of Compliance:
✓ Written procedure for using blood collected for therapeutic phlebotomy for allogeneic donation including inclusion criteria AND
✓ Records demonstrating donor criteria for allogeneic donation

REFERENCES
1) FDA Guidance: Variance for Collection of Blood from Individuals with Hereditary Hemochromatosis (HH), August 2001 CBER

TRM.42290  Therapeutic Phlebotomy Responsibility  Phase II

If therapeutic phlebotomies are performed by laboratory staff, a qualified physician has accepted medical responsibility for the procedures.

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

Evidence of Compliance:
✓ Written policy defining responsibility for therapeutic phlebotomy procedures AND
✓ Patient records/charts showing evidence of qualified physician review

TRM.42295  Patient Protection  Phase II

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

NOTE: The procedures should include proper patient identification, adequate training of laboratory staff, proper sterile technique, and appropriate volume to be removed.
TRM.42300  Record Retention  Phase II

Records are maintained of all the following elements.

1. Order for therapeutic phlebotomy by patient’s physician
2. Patient identification (two identifiers required)
3. Patient diagnosis
4. Type of procedure performed
5. Nature and volume of components removed and replaced
6. Patient data and criteria for measuring patient response, as available
7. Adverse reactions, with medications administered
8. Record of 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.

NOTE: Therapeutic phlebotomy is a primary therapeutic option for patients with hemochromatosis, and useful resources are available at http://www.irondisorders.org.

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

REFERENCES
1) Tavill SA, Diagnosis and Management of Hemochromatosis. Hepatology 33:5;1321-1328

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 (e.g. surgery, nursing and dialysis units).

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

**Inspector Instructions:**

- Sampling of blood component storage and handling policies and procedures
- Sampling of storage unit temperature logs (4 weeks of recordings), including remote storage, as applicable
- Sampling of records of corrective action when storage unit temperatures fall outside of the defined range
- Sampling of blood component records of inspection

- Refrigerator storage unit (organization, sufficient space, separation of units), including remote storage, as applicable
- Sampling of blood/blood components (labeling with all required elements, assigned expiration date)

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

**TRM.42350 Refrigerator Size**

*Phase II*

The blood storage refrigerator is large enough to meet the needs of the facility.

*NOTE:* Adequate refrigerated storage space is needed for proper storage and organization of blood. Insufficient storage space can compromise the organization of the units of blood 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 such as 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, immediately before use and at defined intervals, and records are maintained 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. In addition to the inspection, products must be checked for abnormal appearance and expiration date at defined intervals and immediately before use. For blood and blood components, inspection should include observation for bag integrity, hemolysis, and clots. Comparison of bag and segment color should be performed for red blood cell units as an aid in detecting bacterially-contaminated units.

REFERENCES

TRM.42460 Blood/Blood Component Shipping  Phase II

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

**REVISED** 07/28/2015

TRM.42470 Acceptance Back Into Inventory  Phase II

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

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

The steps and criteria defined in the procedure for acceptance of units back into inventory, such as the "30 minutes" rule, must be validated by the laboratory.

REFERENCES

**REVISED** 04/21/2014

TRM.42480 Expiration Dates  Phase II

The assigned expiration dates for storage of all blood components comply with the following list and the manufacturer’s recommendations.

1. FFP and Plasma frozen within 24 hours after phlebotomy- 1 year from date of collection of source blood (-18°C or colder)

2. Platelets - 5 days from time of collection of source blood, provided labeling recommends storage at 20-24°C with continuous agitation, or as specified in the directions for use for the blood collecting, processing, and storage system and, for laboratories subject to US regulations, the system must be approved by CBER; 4 hours if pooled (open system or 5 days following collection of oldest unit in the pool using an FDA-cleared closed system)

3. ACD and CPD RBCs -
• 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing
• 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing

4. CPDA-1 RBCs
• 35 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing
• 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing

5. RBCs Deglycerolized - 24 hours after washing, provided labeling recommends storage between 1 and 6 °C, or as specified in the directions for use for the blood collecting, processing, and storage system and, for laboratories subject to US regulations, the system must be approved by CBER

6. RBCs Frozen - 10 years from date of collection of source blood, provided labeling recommends storage at -65 °C or colder, or as specified in the directions for use for the blood collecting, processing, and storage system and, for laboratories subject to US regulations, the system must be approved by CBER

7. ACD and CPD Whole Blood - 21 days from date of collection, provided labeling recommends storage between 1 and 6 °C

8. Cryoprecipitate - 12 months from date of collection when stored at -18 °C or colder; 4 hours after thawing, if pooled or 6 hours after thawing, if single or pooled using a sterile connection device, when stored at 20-24 °C

NOTE: For laboratories not subject to US regulations, expiration dates must conform to local and national requirements for all approved component storage systems in use.

REFERENCES

TRM.42500 Blood/Component Storage Monitoring

For blood/blood component storage units (e.g. refrigerators, freezers, and platelet incubators) that lack continuous automated temperature recording, the temperatures are recorded at least every 4 hours.

NOTE: This checklist requirement applies to all blood component storage areas in the facility, including those located outside of the transfusion service (e.g. in surgery, nursing and dialysis units).

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.

The two acceptable ways of recording temperatures are: 1) recording the numerical temperature, or 2) placing a mark on a graph that corresponds to a numerical temperature (either manually, or using a graphical recording device). The identity of the individual recording the temperature(s) must be recorded (recording the initials of the individual is adequate).

The use of automated (including remote) temperature monitoring systems is acceptable, providing that laboratory personnel have ongoing immediate access to the temperature data, so that appropriate corrective action can be taken if a temperature is out of the acceptable range. There must be records showing daily functionality of the system.
Evidence of Compliance:
 ✓ Written procedure defining criteria and frequency for evaluation of blood/component storage units to include maintenance of temperature under all conditions AND
 ✓ QC records for continuous temperature monitoring OR records of checks at defined frequency

REFERENCES

**REVISED** 07/28/2015
TRM.42550 Storage Temperature Range Corrective Action  Phase II
If the proper storage temperature range is not maintained (inspector will check 4 weeks of recordings), there is evidence that timely corrective action has been taken, to include records of the disposition of any affected components.

TRM.42600 Consistent Temperature  Phase II
There are records that all large refrigeration units maintain the proper temperature throughout the unit.

NOTE: On all large refrigeration units, thermometers must be placed in several areas, or multiple point readings taken on a periodic basis to ensure that a 1-6°C temperature is maintained throughout. 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.

**REVISED** 07/28/2015
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. The correct placement for the temperature sensor is controversial. Some experts recommend leaving the sensor exposed to air, some recommend enclosing it in liquid, and some recommend enclosing it in an aluminum block.

TRM.42700 Emergency Power Supply  Phase II
The blood/blood components and tissue refrigerator(s) and freezer(s) have an emergency power supply.

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 and recorded at least quarterly.

NOTE: The laboratory should be able to demonstrate how the alarm system works and that there is a process to ensure a timely response to an alarm, including remote alarms.
Alarm Sensors To Trigger Action Needed

Alarms are adjusted to be triggered before the temperature falls outside the 1-6 °C acceptable temperature range for refrigerators, or outside the acceptable range for freezers 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. 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

Power Failure Back-Up

The alarms will continue to function if the power is interrupted.

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

Storage Temperature Variances

There are written procedures to follow if there are variances in the storage temperature limits.

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

Component Processing/Storage

There are written procedures for the processing and storage (including expiration, quarantine criteria, additives, pooling, etc.) of all components prepared and stored in the laboratory.

Component Labeling

For each component, the label specifies all of the required information, and requirements for proper labeling of components are defined.

NOTE: Required information may be offered separately in an approved “circular of information,” provided that the component label refers to the circular. All steps of blood component labeling must be defined in the procedure manual. There are two acceptable labeling systems in the
US: the 1985 Uniform Labeling Guideline and ISBT 128. The latter is recommended; if the laboratory does not use ISBT 128 routinely, it should have a plan for transitioning to the system. The laboratory must have a valid system to receive and manage all blood components that come into inventory, including those labeled with ISBT 128.

REFERENCES

TRM.43625  Label Approval  Phase II
There is a written procedure to approve the content and use of all new blood product labels including inspection for acceptable label content.

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

TRM.43650  Component Handling  Phase II
For each component, there are written procedures for maintaining sterility, including pooling and the use of sterile connecting devices, and there is evidence that these procedures are followed.

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

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

TRM.43700  Pooled Components  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

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

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

TRM.43800 RBC Hematocrit Limit

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

Inspector Instructions:

• RBC washing policy or procedure

TRM.43850 Plasma Removal

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

RED BLOOD CELLS FROZEN

Inspector Instructions:

• Red cell cryopreservation policy or procedure
• Sampling of temperature records
• Sampling of inventory records

TRM.43900 RBC Storage

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

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

REFERENCES
Red Blood Cells are frozen by an approved method.

NOTE: RBC should be frozen within six days of collection if anticoagulated with CPD or CPDA-1 or promptly after rejuvenation. For laboratories in the US, all methods and solutions must be approved by the FDA.

REFERENCES
1) Technical Manual, AABB, Methods 6.7 and 6.8, pg 741-745. [Mearyman and Valeri high-glycerol methods]

TRM.44000 Pre-Transfusion Testing

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

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

RED BLOOD CELLS DEGLYCEROLIZED

Inspector Instructions:

- RBC deglycerolization policy or procedure
- Sampling of inventory records

TRM.44100 Open System Preparation Usage

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

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

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

REFERENCES

TRM.44150 Deglycerolization Requirements

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

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

Inspector Instructions:

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

TRM.44250  Leukocyte-Reduced RBC Criteria  Phase II

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

NOTE: The method of preparation of leukocyte-reduced Red Blood Cells must be shown to retain at least 85% of the original red cells and to reduce the leukocyte concentration to less than the maximum amount prescribed by the FDA. Units with lower leukocyte concentrations are associated with decreased febrile transfusion reactions, reduced alloimmunization potential, reduced cytomegalovirus transmission, and other benefits. Quality control must be performed on 4 units per month, or 1% of total units prepared per month, whichever is greater.

REFERENCES

FRESH FROZEN PLASMA

Inspector Instructions:

- FFP policy or procedure
- Sampling of temperature monitoring records

- Sampling of thawed FFP components (relabeled)

TRM.44350  Plasma Collection/Storage  Phase II

The plasma is separated from the whole blood and placed at -18°C or lower within 8 hours of collection if the anticoagulant is CPD, CP2D, or CPDA-1.

NOTE: Fresh Frozen Plasma must be separated within 8 hours of collection when using CPD, CP2D, or CPDA-1 as the anticoagulant. Plasma may be separated from whole blood as long as 24 hours after collection and frozen at -18°C or lower, but it may not be labeled “Fresh Frozen” Plasma -- it is called “Plasma, Frozen Within 24 Hours of Collection.” Freezers need not be
operated at their lowest possible temperature, since some plastic plasma containers held at temperatures lower than -25°C may exhibit increased breakage rates upon handling.

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

TRM.44400  Plasma Freezer Monitoring  Phase II

The temperature required for proper storage in freezers is maintained and recorded.

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

TRM.44450  FFP/Cryoprecipitate Thawing  Phase II

Frozen plasma components or cryoprecipitate are thawed at 30-37°C with protection against water contamination of outlet ports.

NOTE: If a microwave oven is used, data must be available showing acceptable preservation of labile coagulation factors and temperature maintained at less than or equal to 37°C and, for laboratories subject to US regulations, must be FDA-cleared/approved as a Class III medical device (pre-market approval). 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 30-37°C and maintained at 1-6°C for 1 to 5 days, it is relabeled as "Thawed Plasma".

TRM.44537  Thawed Cryoprecipitate-Reduced Plasma Usage  Phase II

If cryoprecipitate-reduced plasma is thawed between 30-37°C and maintained at 1-6°C, it is used within 5 days.

REFERENCES

CRYOPRECIPITATE

Inspector Instructions:
- Cryoprecipitate policy or procedure
- Sampling of records of component processing

TRM.44600  Cryoprecipitated AHF Preparation  Phase II

Cryoprecipitated AHF is prepared to preserve fibrinogen and factor VIII activity:

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

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

PLATELETS

Inspector Instructions:

READ

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

ASK

- How have you validated/revalidated your platelet count method?
- What system are you using to detect bacteria in platelet components?

TRM.44850 Platelet Preparation Phase II

Platelets are prepared within 8 hours of the collection of whole blood that has NOT been cooled below 20°C or, if prepared by apheresis methods, they are prepared according to the instrument manufacturer’s instructions.

NOTE: Platelets must be separated within 8 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 (20-24°C) with agitation. However, whole blood may be held for a longer period at room temperature prior to separation of components, not to exceed 24 hours, provided that safety and efficacy of the components are recorded. Storage at lower temperatures may result in reduced platelet survival. Apheresis platelets must be prepared according to the instructions of the manufacturer.

REFERENCES

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

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

REFERENCES

TRM.44950  Platelet Component Storage  Phase II

Platelet components are stored at 20-24 °C with appropriate agitation and transfused within the approved storage time for the particular container and collection method used.

NOTE: Storage of Platelets above 24 °C may result in undesirable metabolic changes. Platelet storage below 20 °C, even for brief periods, may cause irreversible declines in platelet function. Platelet bags currently approved and used for 5-day storage maintain adequate platelet viability and function for up to 7 days. However, concerns that contaminating bacteria may proliferate to dangerous levels during prolonged storage have reduced the allowable dating period to 5 days. Agitation during storage is necessary to ensure optimal gas exchange and maintenance of pH. Data in the literature suggest that platelets may be stored up to 24 hours without agitation. However, platelet bag manufacturer instructions must be followed if more stringent.

REFERENCES

TRM.44955  Bacterial Contamination in Platelets  Phase II

The laboratory (or its blood supplier) uses an FDA-cleared/approved or equivalent system to detect the presence of bacteria in all platelet components.
NOTE: The enhanced sensitivity requirement reflects the availability of multiple FDA-cleared/ approved quality control strategies; insensitive methods including pH, glucose and microscopy are no longer acceptable. Equivalent system is defined as a system that has been validated to demonstrate comparable or improved sensitivity in CFU/mL. If this testing is performed by the supplier of platelet components, the laboratory can satisfy this checklist requirement by having a written agreement with the supplier to be notified of supply units suspected of containing bacteria.

Evidence of Compliance:
✓ Individual units of WBD platelets or pools of up to 6 units of such platelets that have been tested by an FDA-cleared/approved method OR use of pre-pooled WBD platelets tested with an FDA-cleared/approved culture-based QC test by the supplier OR use of apheresis platelets tested with an FDA-cleared/approved culture-based QC test by the supplier OR culture of aliquots from individual WBD platelet units destined for pooling OR methods that are not FDA-cleared/approved but have been validated to be of equivalent clinical sensitivity to an FDA-cleared/approved assay

REFERENCES

PLATELETS LEUKOCYTE-REDUCED

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

TRM.44960 Method of Preparation

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

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

REFERENCES
1) Lutz P, Dzik WH. Large-volume hemocytometer chamber for accurate counting of white cells (WBCs) in WBC-reduced platelets; validation and application for quality control of WBC-reduced platelets prepared by apheresis and filtration. Transfusion. 1993;33:409-412
IRRADIATED CELLULAR COMPONENTS

Inspector Instructions:

- Irradiated component policy or procedure
- Sampling of records of component processing QC
- Sampling of indicator system QC records
- Sampling of maintenance records
- Certificate or letter of compliance with US NRC

- How do you ensure that your equipment meets the standards of the US Nuclear Regulatory Commission?

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

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TRM.44970 Radiation Dose

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

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

REFERENCES

TRM.44977 Blood Component Labeling And Expiration Dates

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.

Evidence of Compliance:
✓ Written procedure for labeling irradiated units

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**REVISED** 07/28/2015

TRM.44984 Maintenance Schedule
There is a schedule of maintenance and function checks for all blood irradiation equipment including timer checks, back-up timer checks, turntable inspection, and radiation leakage testing, and records maintained.

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TRM.44987 US NRC Requirements Phase II

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

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

REFERENCES


TRM.44991 Irradiated Blood/Blood Component Records Phase II

Records are maintained for blood and blood component irradiation 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.

HEMATOPOIETIC PROGENITOR CELLS

This section addresses the collection, transport, processing, storage and administration of cellular therapy products including hematopoietic progenitor cells (bone marrow, peripheral blood stem cells, and cord blood). Requirements for qualification and management of donors of allogeneic products are as for allogeneic blood donors. Record retention, quality assurance, and other requirements in this checklist apply to cellular therapy products, as appropriate.

QUALITY MANAGEMENT AND GENERAL ISSUES

Inspector Instructions:

- Sampling of cellular therapy policies and procedures
- Sampling of records of unusual events with notification
- How do you ensure communication with physicians of patient treatment decisions?
- How do you monitor clinical outcomes?
- Have you validated your protocols?
- How do you label cellular therapy products?
Select a component/product and track progression through ordering, patient consent, collection, processing and final disposition. Confirm that the identity of the individual performing each step is recorded.

**TRM.44992  Personnel Responsibilities  Phase II**

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

**REFERENCES**

1) Harris DT. Experience in autologous and allogeneic cord blood banking. *J Hematother.* 1996;5:123-128
5) *ibid.* Records and reports. Laboratory records. US Government Printing Office, 1999(Apr 1):[21CFR211.194(a)]

**TRM.44993  Personnel Qualifications  Phase II**

The collection, processing, storage, and administration of cellular therapy products is overseen by qualified, licensed physician(s) having appropriate training and/or experience.

**TRM.44994  System of Communication  Phase II**

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

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

**TRM.44995  Unusual Events Reporting  Phase II**

There is a written procedure for reporting unusual events to the person responsible for investigating the occurrence.

**Evidence of Compliance:**

✓ Written policy defining criteria for reporting unusual events AND
✓ Records of unusual events with notification

**TRM.44996  Deviations from SOP  Phase II**

There are records that all deviations from standard operating procedures have been approved by the transfusion service medical director or, as appropriate, the recipient's physician.

**TRM.44997  Clinical Outcomes  Phase II**

The laboratory monitors and reviews the clinical outcomes associated with the cellular therapy products it provides, such as determining the time to engraftment after infusion of hematopoietic progenitor cells.
NOTE: If the laboratory does not collect the data, the transfusion service medical director must be involved in the review of the data and assessment of outcome to monitor the quality of the laboratory service. In situations where there is a failure to engraft or a problem relating to product quality, there are records of investigation and corrective action, as appropriate.

TRM.44998 New/Changed Protocol Validation  Phase II

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

TRM.44999 Requisition  Phase II

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

TRM.45000 Process Tracking  Phase II

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

TRM.45001 Product Labeling  Phase II

The laboratory assigns a unique alphanumeric identifier to each cellular therapy product collected, processed and/or stored, including aliquots, with maintenance and tracking of this identifier throughout receipt, storage, issuing of the product, and disposition.

TRM.45002 Labeling Systems  Phase II

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

NOTE: Units intended for autologous administration only must be so designated on their label. Units for allogeneic administration must not receive final and complete labeling until all requirements, including infectious disease testing, have been satisfactorily completed. Units testing positive for infectious disease markers or having an at-risk medical history must be labeled as a “Biohazard”. Hematopoietic progenitor cell (HPC) products must be clearly labeled or tagged “Do Not Irradiate” if transported outside the control of cellular therapy laboratory personnel.

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

COLLECTION

Inspector Instructions:

● Sampling of cellular therapy collection policies and procedures
TRM.45003  Donor Qualifications  Phase II

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

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

TRM.45004  Consent  Phase II

Signed consent is obtained.

TRM.45005  Donor Evaluation  Phase II

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

Evidence of Compliance:
✓ Records of donor evaluation prior to collection procedures

REAGENTS, SUPPLIES, AND EQUIPMENT

Inspector Instructions:

- Sampling of critical reagent, supply and equipment logs
- Sampling of records of LN2 monitoring
- Sampling of alarm checks
- Sampling of maintenance records

- What is your back-up if your instrument fails?

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

TRM.45006  Record Retention  Phase II

Records of all critical reagents, supplies, and equipment used in collection and processing, including lot numbers and expiration dates, are maintained and traceable for each product.
NOTE: The record retention requirements of TRM.32250 apply, but the time period for retention begins with final disposition of the cellular therapy product.

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

TRM.45007 Approved Reagents  Phase II

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

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

TRM.45008 Liquid Nitrogen Levels  Phase II

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

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

TRM.45009 Storage Unit Alarms  Phase II

All storage units are monitored 24 hours/day and are equipped with an alarm (in laboratory or remote) that is tested at least quarterly for its ability to alert responsible staff at all times.

NOTE: The laboratory should be able to demonstrate how the alarm system works and that there is a process to ensure a timely response to an alarm, including remote alarms.

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

TRM.45010 Critical Equipment Back-Up  Phase II

The laboratory has back-up capability for all critical instrumentation and storage devices.

TRM.45011 Laminar Flow Hood Maintenance  Phase II

Records show that the laminar flow hood is regularly cleaned, decontaminated and certified as appropriate.
PROCESSING

Inspector Instructions:

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

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

TRM.45012 Aseptic Techniques

Aseptic techniques are employed in the collection, processing and administration of cellular therapy products prepared by the laboratory.

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

TRM.45013 Microbial Content

All products intended for administration are cultured for microbial content at appropriate time(s).

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

Evidence of Compliance:

✓ Written procedure defining criteria and timelines for culturing

TRM.45014 Physician Notification

There is a written procedure to notify the patient's physician of any positive microbial culture results or other problems with the cellular therapy product that could affect its suitability for administration.

NOTE: This requirement is not intended to preclude the use of components testing positive for bacterial contaminants. It is the responsibility of the transfusion service medical director and patient's physician to determine if the cellular therapy product is suitable for use.

Evidence of Compliance:

✓ Records of physician notification

TRM.45015 ABO/Rh Crosscheck

Phase II
An ABO/Rh typing is performed for each hematopoietic progenitor product processed, and the type is compared with the donor’s and/or recipient’s historical records, as appropriate.

Evidence of Compliance:
✓ Written procedure for ABO/Rh typing of each product and verification with historical type AND
✓ Records of product typing and ABO/Rh verification

TRM.45016 Processing Record Review Phase II

For each product processed, detailed records are maintained and there is evidence that they are reviewed by the transfusion service medical director or designee in a timely manner (at least prior to administration).

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TRM.45017 Allogeneic ABO/Rh Mismatch Phase II

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

CRYOPRESERVATION AND STORAGE

Inspector Instructions:

- Sampling of cryopreservation and storage policies and procedures
- Sampling of cryopreservation records
- Sampling of consent forms

TRM.45018 Cryopreservation Record Review Phase II

Cellular therapy product cryopreservation records, including freezing charts, when applicable, are reviewed by the transfusion service medical director or designee.

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

REFERENCES

TRM.45019 Product Exposure To Cryoprotectant Agents Phase II

The cryopreservation procedure includes steps to minimize the exposure of the product to the cryoprotectant agents (e.g. DMSO) used during the freezing process.

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

TRM.45020 Informed Consent Phase II
Informed consent for collection, processing and storage addresses length of storage and conditions to be met for final disposition of the cellular therapy product.

NOTE: There must be consent forms that cover the length of storage of cellular therapy products and their long term disposition. Efforts must be made to contact the patient and the patient’s physician prior to discarding the components and records maintained.

TRM.45021  Cord Blood Storage  Phase II

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

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

TRM.45022  Quarantined Cellular Therapy Products  Phase II

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

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

REINFUSION/ADMINISTRATION

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

TRM.45023  Administration/Reinfusion Adverse Reactions  Phase II

Adverse reactions unique to administration/reinfusion of cellular therapy products are recorded and evaluated.

NOTE: The transfusion service medical director is responsible for setting criteria for the detection of adverse reactions to cellular therapy products, as well as the evaluation and reporting of adverse reactions. The checklist requirements on Blood Component Administration and Adverse Reaction Procedures apply.

STORAGE AND ISSUE OF TISSUES

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

- Sampling of tissue storage policies and procedures
- Source facility registration/license
- Sampling of tissue storage records

- How are you informed of an adverse reaction to implanted tissue?

- Follow the records of receipt of tissue from donor facility through preparation, issuing, acceptance and disposition. Confirm that procedures and records ensure adequate tracing of all tissues.

TRM.45050  Tissue Program  Phase II

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

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

Evidence of Compliance:
✓ Written policy defining the responsibilities for the tissue-handling program AND
✓ QM records documenting hospital-wide involvement

REFERENCES
2) Haimowitz MD. Practical issues in tissue banking. *Am J Clin Pathol.* 1997;107(suppl 1):S75-S81

TRM.45075  Source Facility Criteria  Phase II

All source facilities are registered or licensed as required by state and federal regulations.

TRM.45100  Tissue Records  Phase II

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

REFERENCES
2) Haimowitz MD. Practical issues in tissue banking. *Am J Clin Pathol.* 1997;107(suppl 1):S75-S81
5) Ibid. Records and reports. Laboratory records. US Government Printing Office, 1999(Apr 1)[21CFR211.194(a)]

TRM.45125  Donor Infections/Adverse Events Investigation  Phase II

There are procedures for investigating donor infections or adverse events after tissues are received and implanted.
NOTE: Possible tissue-transmitted infections and other adverse events must be investigated and reported to the tissue source facility when appropriate.

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

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

TRM.45150  Tissue Storage Conditions

The procedure manual defines the necessary storage conditions of the different tissues handled, all required records and policies, and a procedure for return of each tissue type to storage, as appropriate, after issuance for use.

REFERENCES
2) Haimowitz MD. Practical issues in tissue banking. Am J Clin Pathol. 1997;107(suppl 1):S75-S81

TRM.45160  Specimen Handling/Storage

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

TRM.45165  Blood Vessel Storage

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

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

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

REFERENCES
1) OPTN Policies 5.10 (deceased donors) and 12.7.10 (living donors)--Vessel Recovery, Transplant, and Storage. Available at http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp

TRM.45170  Specimen Tracking

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

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

TRM.45180 Issue Usage Cards  Phase I
There is a written procedure for completing and returning issue usage cards to the source facility.

TRM.45190 Record Retention  Phase II
Procedures and records are retained for at least 10 years, or longer if required by state or federal regulations.

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

TRM.45200 Tissue Storage Temperature  Phase II
The records show that tissues were stored at the required temperatures.

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

REFERENCES
2) Haimowitz MD. Practical issues in tissue banking. Am J Clin Pathol. 1997;107(suppl 1):S75-S81

TRM.45250 Donor/Recipient Tracking Records  Phase II
Records allow for the identification of the donor and the recipient of each tissue handled, as well as tracking from donor to recipient and vice-versa.

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

REFERENCES
2) Haimowitz MD. Practical issues in tissue banking. Am J Clin Pathol. 1997;107(suppl 1):S75-S81

BLOOD/COMPONENT DONOR SELECTION AND COLLECTION

This section applies to both autologous (self) donations and donations for others (allogeneic, including apheresis donations)

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

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

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

ALL DONORS (ALLOGENEIC AND AUTOLOGOUS)

Inspector Instructions:

READ

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

OBSERVE

- Donor arm preparation, if possible

ASK

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

DISCOVER

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

TRM.45251 Regulatory Documents

Phase I

For US laboratories, the following documents are readily available (paper or electronic), and there is evidence of their use in policy and procedure development.

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

REFERENCES
1) FDA Guidelines: http://www.fda.gov/cber/guidelines.htm

TRM.45252 Donor Procedures

Phase II

Procedures for donor identification, selection, physical examination, arm preparation, phlebotomy, handling of collected units, and treatment/prevention of donor reactions are current, appropriate, and detailed in a manual.
TRM.45253  Donor Privacy/Confidentiality  

**Phase II**

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

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

TRM.45254  Personnel Qualifications  

**Phase II**

**Persons responsible for the donor selection process, predonation examination, and phlebotomy are qualified, trained and competent for these tasks.**

**Evidence of Compliance:**

✓ Records of training and competency assessment

TRM.45255  Physician Availability  

**Phase II**

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

**REFERENCES**


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 17 years old. Consent from a parent or guardian must be obtained if a donor is less than 17 years old, unless State law specifies a different age for donor consent. Furthermore, date of birth is a standard donor identification tool. The donor's address is required for notification of abnormal test results and deferral.

**Evidence of Compliance:**

✓ Donor selection records consistent with defined inclusion criteria

**REFERENCES**


TRM.45257  Inclusion Requirements  

**Phase II**

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

**NOTE:** Donor physiologic measurements must meet inclusion criteria. Usual inclusion criteria include:

1. **Body temperature** less than or equal to 37.5° C (99.5° F)
2. **Pulse** between 50-100 beats/minute without pathologic arrhythmia
3. **Diastolic blood pressure** less than or equal to 100 mm Hg
4. **Systolic blood pressure** less than or equal to 180 mm Hg

**Deviations from these values requires medical 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: Blood collection volumes up to 10.5 mL/kg body weight are permitted. Certain apheresis procedures may require different minimum weights.

REFERENCES

TRM.45259  Inclusion Requirements
Phase II

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

NOTE: Donor blood hemoglobin concentration or hematocrit must be measured before donation. Allogeneic donors must have a hemoglobin concentration no less than 12.5 g/dL, or a hematocrit no less than 38%. For autologous donors only, the transfusion service medical director may establish less stringent erythrocyte mass measurement criteria. For certain apheresis collection procedures (e.g. collection of two units of Red Blood Cells), the FDA has established a specific algorithm for donor acceptance.

Evidence of Compliance:
✓ Donor screening records

REFERENCES

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TRM.45260  Instrument QC
Phase II

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

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

TRM.45261  Health Interview
Phase II

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

NOTE: Allogeneic donors should be healthy, and free of acute or symptomatic significant disease. Donors with diseases of the heart, liver, or lungs or a history of cancer or abnormal bleeding tendency should be excluded, unless determined to be suitable to donate by a transfusion medicine service physician.

Evidence of Compliance:
✓ Donor screening records

TRM.45263  Signed Consent Form
Phase II

An informed consent form is signed by the donor.
REFERENCES
3) Shaz BH, Demmons DG, Hillyer CD. Critical evaluation of informed consent forms for adult and minor aged whole blood donation used by United States blood centers. Transfusion 2009;49:1136-1145

TRM.45264 Donor Record
The donor history, physical examination, and screening test results are recorded (paper or electronic).

TRM.45265 Follow-Up
There is evidence of follow-up for significant findings in donor history, physical examination and screening test results.

TRM.45266 Numeric Identification Agreement
There is a written procedure to ensure that the numeric identification on pilot tubes, bags and related donor records are in agreement.

TRM.45267 Donor Arm Preparation
A written procedure requiring the use of sterile, prepackaged materials is followed for donor arm preparation to reduce the risk of bacterial contamination of the donor unit.

NOTE: The specific procedure used may vary but should include directions for the chemicals to be used, the time and manner that each is applied and the EXACT sequence of the steps taken so that bacterial contamination from removable surface microorganisms is minimized. Donor arm preparation should be monitored to assure that the laboratory's procedure is followed.

Although a variety of skin preparation techniques are available, the application of tincture of iodine following use of isopropyl alcohol is most effective in reducing commensal skin organisms, an important source of bacterial contamination of platelet units. Some donors may have allergies that preclude the application of topical iodine; alternative, effective measures may be used in such cases according to the institution’s standard operating procedures; the use of chlorhexidine is preferred. For laboratories subject to US regulations, the FDA recognizes several methods for arm preparation.

REFERENCES

TRM.45268 First Volume Diverted From WB Platelets
The first volume of the phlebotomy from which a platelet component will be derived is diverted from the whole blood or component collection.

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

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

TRM.45269 Adverse Reactions
There is a written procedure for recognition, treatment, tracking, and trending of adverse donor reactions, and personnel collecting donor units are appropriately trained.
Evidence of Compliance:
✓ Record of training for adverse reactions AND
✓ Records of donor reactions, including data on trending AND
✓ Procedure for recognizing and treating adverse reactions

TRM.45270 Directed Donation Requirements

Phase II
There is a written procedure to ensure that all directed donations between blood relatives are irradiated.

NOTE: The blood relationship of directed donors to recipients must be determined to ensure that components are irradiated to minimize the risk of graft versus host disease.

Evidence of Compliance:
✓ Written procedure for special handling of donations from directed donors

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

TRM.45271 Physician Request - Autologous Collection

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

TRM.45272 Autologous Donation Guidelines

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

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

REFERENCES

ALLOGENEIC DONORS ONLY

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

Inspector Instructions:

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

TRM.45273  Educational Material  Phase II

Potential allogeneic donors are given educational material explaining the risks of infectious diseases transmitted by transfusion.

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

Evidence of Compliance:
✓ Records indicating that donor received educational material

REFERENCES
2) Food and Drug Administration. Guidelines regarding exclusion of donors with a history of CJD or incarceration, 1995 (Jun)
4) Food and Drug Administration. Guidance for industry. Revised preventive measures to reduce possible risk of transmission of Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products. January 2002

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 whole blood donations, the time interval between donations meets current requirements.

NOTE: Allogeneic whole blood donors must be excluded if their last donation has not met the required interval between donations. Current exclusions include less than 8 weeks since last whole blood donation, less than 16 weeks since two-unit red cell apheresis collection, and less than 2 days since last hemapheresis.

Evidence of Compliance:
✓ Written donor collection procedures with minimum collection internals between donations defined

TRM.46138  Allogeneic Donor Evaluation  Phase II

There are records that allogeneic donors are evaluated in a manner consistent with the uniform Donor History Questionnaire.

NOTE: Blood collectors may append additional questions and/or apply more stringent requirements in donor selection.
REFERENCES

DONOR BLOOD TESTING

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

Inspector Instructions:

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

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

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

TRM.47000 Routine Typing Phase II

The routine procedure includes tests with anti-A and anti-B, A1 and B cells, anti-D, and if negative for anti-D, a test for weak D.

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

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

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

TRM.47050 Screen For Unexpected Antibodies Phase II

Testing includes a screen for unexpected antibodies on all donors with history of prior transfusions or pregnancy.

NOTE: This requirement applies to allogeneic and autologous donors.

Evidence of Compliance:
✓ Written procedure defining criteria for screening for unexpected antibodies AND
✓ Records of antibody screening for blood donations meeting defined criteria
TRM.47100  Infectious Disease Testing  Phase II

For laboratories subject to US regulations, all FDA-required or recommended infectious disease tests are performed 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 that are licensed or registered by the FDA and using procedures defined and approved by the FDA.

NOTE: Tests currently required or recommended by the FDA are: anti-HIV-1, anti-HIV-2, anti-HBc, anti-HCV, HBsAg, anti-HTLV-I, anti-HTLV-II and serologic tests for syphilis and Trypanosoma cruzi antibodies. (T. cruzi testing should be done at least once in the lifetime of each donor.) Nucleic acid testing (NAT) for HIV-1, HCV and WNV NAT is also recommended. Autologous units for the patient-donor's own use need not be tested for infectious disease markers unless they are being considered for allogeneic use or will be transferred to another facility.

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

REFERENCES

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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 local and federal authorities.

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

REFERENCES

TRM.47112  Off-Site Testing Agreement  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-cleared/approved supplemental tests are performed whenever indicated.
NOTE: The FDA requires that an FDA-cleared/approved supplemental test be performed whenever available for a reactive screening test. Supplemental tests are currently approved for syphilis, anti-HIV, HIV-1 antigen neutralization, and HBsAg neutralization.

REFERENCES

TRM.47150 Infectious Disease Testing QC

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

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

TRM.47200 Sample Mix-Up Precautions

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

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

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

TRM.47250 Record Review

Testing records and records of release from quarantine are reviewed by a supervisory level individual or other designated individual, and these reviews are recorded.

NOTE: There are records of audits for 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

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

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

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

TRM.47320 Donation Tracking

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

NOTE: In the US, the FDA requires that blood centers identify previous units collected from donors who are reactive in one or more tests for viral markers and recommends that, under certain conditions, consignees of components from these units be notified of a potential risk to recipients.
Evidence of Compliance:
✓ Written procedure for look-back and notification for donors testing positive for viral marker screening AND
✓ Donor records

REFERENCES
5) Proposed rule for HCV 1.0, Fed Register, 2000(Nov 16):65:69377

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TRM.47350 Quarantine/Unit Disposal Procedure Phase II

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

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

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

TRM.47400 Deferred Donor List Phase II

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

NOTE: Records must be maintained to allow identification of deferred donors, so that blood and components from such individuals will not be distributed. When possible, checking this registry before donation is preferred.

Evidence of Compliance:
✓ Records of checks against deferral list prior to release

REFERENCES

TRM.47450 Result Review Phase II

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

NOTE: The transfusion service medical director must review abnormal donor testing results and ensure donor notification so appropriate counseling and treatment can be obtained. The FDA requires patient and physician notification attempts to be completed within 8 weeks.

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

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

TRM.47500 Post-Donation Information

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

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

PERSONNEL

Inspector Instructions:

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

TRM.50000 Bench Testing Supervision

The person in charge of the bench testing/section supervisor of the transfusion medicine section of the laboratory has education equivalent to an associate’s degree (or beyond) in a chemical, physical or biological science or medical technology and at least 4 years experience (one of which is in transfusion medicine) under a qualified section director.

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, current license (if required) and work history in related field

TRM.50050 Transfusion Service Medical Director/Section Director

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

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

For laboratories not subject to US regulations, the person in charge of technical operations must: 1) hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution, AND 2) have 4 or more years of fulltime general laboratory training and experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties OR be certified by a board approved or recognized in the jurisdiction where the laboratory is located.

Evidence of Compliance:
✓ Records of transfusion service medical director/section director qualifications including degree or transcript, certification/registration, current license (if required) and work history in related field

REFERENCES
TRM.50100 Director Involvement Phase II

The transfusion service medical director of the transfusion service 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

PHYSICAL FACILITIES

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

Inspector Instructions:

- Space, storage and collection areas are all sufficient
- Is the work area sufficient for you to perform your duties safely and accurately?

TRM.60000 Adequate Space Phase I

There is adequate space for blood collection from donors.

NOTE: Adequate space should be provided for blood collection from donors. There must be sufficient space of appropriate design to provide donors with the feeling of privacy such that they will 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.

TRM.60400 Adequate Space Phase I

There is adequate space for blood storage refrigerators and freezers, reagent refrigerators, and platelet rotators.

TRM.60600 Adequate Space Phase I

There is adequate space for donor apheresis.

NOTE: There must be sufficient space in the phlebotomy area to accomplish the necessary functions and to allow access for additional or emergency personnel in case of an untoward event.

TRM.60700 Adequate Space Phase I
There is adequate space for therapeutic apheresis.