Every patient deserves the GOLD STANDARD...

Transfusion Medicine Checklist

CAP Accreditation Program

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
www.cap.org

07.11.2011
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# Transfusion Medicine Checklist

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### SUMMARY OF CHECKLIST EDITION CHANGES

**Transfusion Medicine Checklist**  
07/11/2011 Edition

The following requirements have been added, revised, or deleted in this edition of the checklist, or in the two editions immediately previous to this one.

If this checklist was created for a reapplication, on-site inspection or self-evaluation it has been customized based on the laboratory's activity menu. The listing below is comprehensive; therefore some of the requirements included may not appear in the customized checklist. Such requirements are not applicable to the testing performed by the laboratory.

*Note: For revised checklist requirements, a comparison of the previous and current text may be found on the CAP website. Click on Laboratory Accreditation, Checklists, and then click the column marked Changes for the particular checklist of interest.*

#### NEW Checklist Requirements

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UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

To provide laboratories with a better means to engage in and meet their accreditation requirements, the CAP has enhanced the checklist content and updated its design. New components containing additional information for both the laboratory and inspectors include Subject Headers, Declarative Statements and Evidence of Compliance. See below for a definition of each new feature as an example of how they appear in the checklists.

Using Evidence of Compliance (EOC)

This component, which appears with several checklist requirements, is intended to:

1. Assist a laboratory in preparing for an inspection and managing ongoing compliance
2. Drive consistent understanding of requirements between the laboratory and the inspector
3. Provide specific examples of acceptable documentation (policies, procedures, records, reports, charts, etc.)

In addition to the Evidence of Compliance listed in the checklist, other types of documentation may be acceptable. Whenever a policy/procedure/process is referenced within a requirement, it is only repeated in the Evidence of Compliance if such statement adds clarity. All policies/procedures/processes covered in the CAP checklists must be documented. A separate policy is not needed for each item listed in EOC as it may be referenced in an overarching policy.
**HOW TO INSPECT USING R.O.A.D INSPECTION TECHNIQUES**
*(Read, Observe, Ask, Discover)*

CAP has streamlined the inspection approach used during onsite inspections and is now offering guidance to inspectors by providing assessment techniques to facilitate a more efficient, consistent, and effective inspection process. Specific inspector instructions are listed at the beginning of a grouping of related requirements.

Rather than reviewing each individual requirement, CAP inspectors are encouraged to focus on the Inspector Instructions for a grouping of related requirements. Once an area of concern has been identified through "Read," "Observe," "Ask," "Discover," or a combination thereof, inspectors are encouraged to "drill down" to more specific requirements, when necessary and review more details outlined in the Evidence of Compliance statements. If a requirement is non-compliant, circle the requirement number to later list on the Inspector Summation Report. Inspectors may also make notes in the margins of the checklist document.

Inspector Instructions and Icons used to evaluate a laboratory's performance now appear in several areas throughout the Inspector Checklists. Please note that all four R.O.A.D elements are not always applicable for each grouping, or sections of related requirements.

**Inspector Instructions:**

**READ**/review a sampling of laboratory documents. Information obtained from this review will be useful as you observe processes and engage in dialogue with the laboratory staff.

*(Example of the complimentary inspector instructions for Quality Management/Quality Control General Issues section appearing across checklists):*

- Sampling of QM/QC policies and procedures
- Incident/error log and corrective action

**OBSERVE** laboratory practices by looking at what the laboratory personnel are actually doing and note if practice deviates from the documented policies/procedures.

*(Example)*

- Observe the settings/QC range limits established in the laboratory LIS/HIS to ensure that the laboratory's stated ranges are accurately reflected

**ASK** open-ended, probing questions that start with phrases such as "tell me about..." or "what would you do if..." This approach can be a means to corroborate inspection findings that were examined by other techniques, such as Read & Observe. Ask follow-up questions for clarification. Include a variety of staff levels in your communication process.

*(Example)*

- As a staff member, what is your involvement with quality management?
- How do you detect and correct laboratory errors?

**DISCOVER** is a technique that can be used to "drill down" or further evaluate areas of concern uncovered by the inspector. "Follow the specimen" and "teach me" are two examples of Discovery. Utilizing this technique will allow for the discovery of pre-analytic, analytic, and post-analytic processes while reviewing multiple requirements simultaneously.

*(Example)*

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

An inspection of a laboratory section, or department will include the discipline-specific checklist(s), the Laboratory General Checklist, and the All Common Checklist.

In response to the ongoing request to reduce the redundancy within the Accreditation Checklists, the CAP accreditation program is introducing the All Common Checklist (COM).

The purpose of the All Common Checklist is to group together those requirements that were redundant in Laboratory General and the discipline-specific checklists. Therefore, the CAP centralized all requirements regarding: proficiency testing, procedure manuals, test method validations, and critical results into one checklist, the COM checklist.

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.

QUALITY MANAGEMENT AND QUALITY CONTROL

GENERAL ISSUES

Inspector Instructions:

- Sampling of QM/QC policies and procedures
- QM/QC program, including pre-analytic, analytic and post-analytic monitor records and corrective action when indicators do not meet threshold
- Incident/error log and corrective action
- Sampling of final disposition
- Blood/tissue supplier agreement
- Timely provision of blood agreement
- CBER notification policy
- Records of high school graduate high complexity test review by supervisor

- How do you evaluate data on the incident/error log? How do you determine appropriate corrective action?
- As a staff member, what is your involvement with quality management?
- How do you detect and correct laboratory errors?
- 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 documentation to determine if the steps taken follow the laboratory policy for corrective action
- Follow an incident identified on the incident/error log and follow actions including notification and resolution
**NEW** 07/11/2011

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 Register. 1999(Aug 19);[42CFR606.15(c]

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TRM.20000  Documented QM/QC Plan  Phase II

The transfusion medicine section has a written quality management/quality control (QM/QC) program.

**NOTE:** The QM/QC program in the transfusion medicine section must be clearly defined and documented. The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory’s systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective/preventive action based on data from its QM system.

All QM requirements in the Laboratory General Checklist pertain to the transfusion medicine section.

REFERENCES

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TRM.30000 Ongoing Record Evaluation

There is documentation of ongoing evaluation by the laboratory director or designee of all of the following.

1. Reactivity of reagents and their controls
2. Instrument function checks
3. Temperature records

NOTE: Quality control data must be reviewed and assessed at least at monthly intervals by the laboratory director or designee.

**REVISED** 07/11/2011

TRM.30400 Unusual Laboratory Results

There is a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner.

NOTE: One common method is review of results by a qualified person (technologist, supervisor, pathologist, laboratory director) before release from the laboratory, but there is no requirement for supervisory review of all reported data for single analyte tests that do not include interpretation. All tests that include an interpretation must be reviewed by the laboratory director or qualified designee before release from the laboratory. In computerized laboratories, there should be automatic "traps" for improbable results. The system for detecting clerical errors, significant analytical errors, and unusual laboratory results must provide for timely correction of errors, i.e. before results become available for clinical decision making. For confirmed errors detected after reporting, corrections must be promptly made and reported to the ordering physician or referring laboratory, as applicable.

Each procedure must include a listing of common situations that may cause analytically inaccurate results, together with a defined protocol for dealing with such analytic errors or interferences. This may require alternate testing methods; in some situations, it may not be possible to report results for some or all of the tests requested.

The intent of this requirement is NOT to require verification of all results outside the reference (normal) range.

Evidence of Compliance:

✓ Record of review of results OR records of consistent implementation of the error detection system(s) defined in the procedure AND
✓ Records of timely corrective action of identified errors

TRM.30550 Misidentification Risk

The facility has a documented 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 documenting appropriate review and follow-up of significant errors and patterns of errors in identification and other processed AND
✓ Records of investigation and appropriate corrective/preventive action (e.g. education of staff, changes in procedures, etc.) for significant errors/review of monitoring data for corrective action and process improvement, when appropriate
Misidentification Risk

Phase I

The facility has a plan to implement 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 participate in the development of a plan to reduce these risks through implementation of a risk-reduction system. Among options that might be considered are: (1) Documenting the ABO group of the intended recipient on a second sample collected at a separate phlebotomy (including documentation 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.

Supervisory Result Review

Phase II

In the absence of on-site supervisors, the results of tests performed by personnel are reviewed by the laboratory director, transfusion service medical director or general supervisor within 24 hours.

NOTE: The CAP does NOT require supervisory review of all test results before or after reporting to patient records. Rather, this requirement is intended to address only that situation defined under CLIA for "high complexity testing" performed by trained high school graduates qualified under 42CFR493.1489(b)(5) when a qualified general supervisor is not present.

Evidence of Compliance:
✓ Written policy defining the review process and personnel whose results require review AND
✓ Records of result review for specified personnel

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
TRM.30700 QC Records

The records indicate that when components are prepared that do not meet the quality control requirements, corrective action is taken and documented.

REFERENCES

TRM.30800 Disposition Documentation

There is a means to document the disposition of all blood components, derivatives, cellular therapy products, and tissues obtained, including the method of destruction or transfer of units unsuitable for transfusion or transplant.

NOTE: Documentation must show that all products obtained by the laboratory are accounted for and documented as destroyed or otherwise disposed of, including recovered plasma where appropriate. In this case, "record of disposition" refers to record of whether the product, component or tissue was released for transfusion, transfused, transplanted, or discarded.

REFERENCES

TRM.30850 Adequate Blood/Tissue Supply

There is an agreement or 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

TRM.30866 Service Agreement

There is an agreement or understanding 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 understanding 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  Phase II

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 defining evaluation, selection and monitoring criteria for suppliers AND
✓ Records of supplier monitoring

TRM.30900 Deviation From SOP Documentation  Phase II

There is a mechanism for the transfusion service medical director or designee to approve and document deviations from the standard operating procedures.

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

REFERENCES

TRM.30950 CBER Notification  Phase II

There is a policy requiring notification of the 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.
REAGENTS and CRITICAL MATERIALS

The verification of reagent performance is required and must be documented. Any of several methods may be appropriate, such as direct analysis with reference materials, parallel testing of old vs. new reagents, or checking against routine controls. The intent of the requirements is for new reagents to be checked by an appropriate method and the results recorded before being placed in service. Where individually packaged reagents/kits are used, there should be criteria established for monitoring reagent quality and stability, based on volume of usage and storage requirements. For example, processing of periodic “wet controls” to validate reagent quality and operator technique may be a component of such a system.

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

Inspector Instructions:

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

- Sampling of reagents (expiration date, labeling, storage)

- How do you store reagents and controls used in test procedures?
- How do you validate and document new reagent lots?
- What are your laboratory’s criteria for mixing components from one lot number of reagent kit with components from another lot number of kit?
- How does your laboratory manage and control reagent inventory?

- If there is an occurrence in which typing sera/reagent cell QC is not acceptable, follow documentation to determine if the steps taken follow the laboratory policy for corrective action
TRM.31220  Reagent Labeling  Phase II

Reagents and solutions are properly labeled, as applicable and appropriate, with the following elements.

1. Content and quantity, concentration or titer
2. Storage requirements
3. Date prepared or reconstituted by laboratory
4. Expiration date
5. Lot number, as applicable

NOTE: The above elements may be recorded in a log (paper or electronic), rather than on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc.

Evidence of Compliance:
✓ Written policy defining elements required for reagent labeling

REFERENCES

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, there is documented evaluation confirming 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 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 documentation of acceptance.
**REVISED**  07/11/2011
TRM.31250  Reagent Expiration Dates  Phase II

All reagents are used within their indicated expiration date.

NOTE: Rare reagents may be used beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. This exception is permitted by the FDA. This does NOT apply to reagents that are readily available. The laboratory should establish criteria defining which reagents are considered “rare.”

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 document validation of the performance of expired reagents in accordance with written laboratory policy.

Evidence of Compliance:
✓ Written policy for evaluating reagents that lack a manufacturer's expiration date

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24);7164 [42CFR493.1252(d)]
2) Food and Drug Administration. Guide to inspections of blood banks, 1994(Sep)

TRM.31350  Reagent Kit Components  Phase II

If there are multiple components of a reagent kit, the laboratory uses components of reagent kits only within the kit lot unless otherwise specified by the manufacturer.

Evidence of Compliance:
✓ Written documentation defining allowable exceptions for mixing kit components from different lots

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24);7164 [42CFR493.1252(d)]

**REVISED**  07/11/2011
TRM.31375  Inventory Control  Phase II

An appropriate inventory control system is in use to track the use of all lot numbers of critical materials received.

NOTE: Tracking must include date received, 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

Records document 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

**REVISED** 07/11/2011

Comparability of Instrument/Method Phase II

If the laboratory uses more than one instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for correlation of results.

NOTE: This requirement applies to tests performed on the same or different instrument makes/models or by different methods. This comparison must include all nonwaived instruments/methods. The laboratory director must establish a protocol for this check.

Quality control data may be used for this comparison for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number.

Otherwise, the use of human samples, rather than stabilized commercial controls, is preferred to avoid potential matrix effects. The use of pooled patient samples is acceptable since there is no change in matrix. In cases when availability or pre-analytical stability of patient/client specimens is a limiting factor, alternative protocols based on QC or reference materials may be necessary but the materials used should be validated (when applicable) to have the same response as fresh human samples for the instruments/methods involved.

This checklist requirement applies only to instruments/methods accredited under a single CAP number.

Evidence of Compliance:
✓ Written procedure for performing instrument/method correlation including criteria for acceptability AND
✓ Records of correlation studies reflecting performance at least twice per year with appropriate specimen types

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. Fed Register. 2003(Jan 24):5236 [42CFR493.1281(a)]
INSTRUMENTS AND EQUIPMENT

A variety of instruments and equipment are used to support the performance of analytical procedures. All instruments and equipment should be properly operated, maintained, serviced, and monitored to ensure that malfunctions of these instruments and equipment do not adversely affect the analytical results.

Inspector Instructions:

- Sampling of instrument policies and procedures
- Sampling of temperature logs (refrigerator, freezer, water bath, heat block, ambient)
- Records of traceability to NIST standards
- Procedure for evaluating and approving the use of products that were collected or processed under compromised conditions
- Sampling of pipette/dilutor checks
- Sampling of instrument maintenance logs and repair records
- Sampling of semi-annual serologic centrifuge checks (mechanical timer and speed)
- Sampling of blood volume regulator QC records

What is your laboratory's course of action prior to using non-certified thermometers?

TRM.31500 NIST Thermometer

An appropriate thermometric standard device of known accuracy is available. (guaranteed by manufacturer to meet NIST standards.)

NOTE: Thermometers should be present on all temperature-controlled instruments and environments and checked daily. Thermometric standard devices should be recalibrated or recertified prior to the date of expiration of the guarantee of calibration.

Evidence of Compliance:
✓ Thermometer certificate of accuracy

TRM.31600 Non-Certified Thermometers

All non-certified thermometers in use, including blood-warmer thermometers, are checked before being placed in service, and at least annually thereafter, against an appropriate thermometric standard device.

Evidence of Compliance:
✓ Written procedure defining criteria for verification of non-certified thermometers AND
✓ Records of verification prior to being placed in service

TRM.31700 Calibrated Thermometers

Calibrated thermometers are present in all water baths, dry baths, heat blocks, refrigerators, and freezers used for blood components, reagents, samples, and platelet rotators/incubators.
NOTE: Thermometer location should ensure correct temperature in all areas. Thermocouple probes may be used as an alternative method for checking the temperature of dry baths or heat blocks.

**REVISED** 06/17/2010

TRM.31800 Temperature Checks Phase II

Temperatures are checked and recorded on each day of use, specifying the unit and location for all temperature dependent instruments and equipment.

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). Controlled-temperature devices used for storage of blood components must have temperatures recorded at least every 4 hours if the device does not continuously record temperature.

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 documented (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. The functionality of the system must be documented daily.

TRM.31900 Mechanical Timers 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.

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

REFERENCES

TRM.32000 Routine Maintenance Schedule Phase II

All instruments and equipment used by the transfusion service laboratory are clean, well maintained and calibrated properly.

NOTE: There must be a routine plan or maintenance schedule available for checking the critical operating characteristics of all the instruments in use on a regular, periodic basis. The procedure and schedule must be, at a minimum, as thorough and as frequent as specified by the manufacturer. The performance of all equipment must be validated on receipt. All service and repairs must be documented, and equipment must be appropriately re-qualified after repair.
TRM.32100  Maintenance Records  Phase II

Instrument maintenance, service and repair records (or copies) are promptly available to, and usable by, the technical staff operating the equipment.

NOTE: The effective utilization of instruments by the technical staff depends upon the prompt availability of maintenance, repair, and service documentation (copies acceptable). The laboratory personnel are responsible for the reliability and proper function of their instruments and must have access to the information.

TRM.32200  Blood Volume Standardization  Phase II

Equipment used to regulate volume of blood drawn from blood donors or individuals undergoing therapeutic phlebotomy is standardized with a container of known mass or volume before initial use and after repairs or adjustments, and checked 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 to showing standardization checks documented at defined frequency

REFERENCES

TRM.32208  Collection/Processing Equipment  Phase II

A process is in place to assess and document the conformance of blood, components or tissues when equipment used for collection or processing is found to be out of calibration.

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 defined process for dealing with such situations to determine whether the affected component(s) are or can be made to be suitable for their intended use. Such a plan must include the approval of the potentially compromised product by both the laboratory 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  Automatic Pipettes  Phase II

There is a documented procedure defining how automatic pipettes (fixed volume, adjustable and/or micropipettes) are checked for accuracy of calibration (gravimetric, colorimetric or other verification procedure) before being initially placed in service, and results documented.
Automatic pipettes used for quantitative dispensing are checked for accuracy and reproducibility at least annually, and the results recorded.

NOTE: Automatic pipettes used for quantitative dispensing must be checked for accuracy and reproducibility at least annually. Results of such checks must be documented. 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
6) Johnson B. Calibration to dye for: Artel’s new pipette calibration system. Scientist. 1999;13(12):14
**Immunohematology 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.*

<table>
<thead>
<tr>
<th>TYPE OF RECORD</th>
<th>RETENTION PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Donor Records</strong></td>
<td></td>
</tr>
<tr>
<td>• Blood/component donor information, consent and collection</td>
<td>10 years</td>
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<tr>
<td>• Donor blood testing</td>
<td></td>
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<tr>
<td>• Donor notification of significant findings</td>
<td></td>
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<tr>
<td>• Component production</td>
<td></td>
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<tr>
<td>• Look back investigation/disease reporting</td>
<td></td>
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<tr>
<td>• Final unit disposition</td>
<td></td>
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<tr>
<td>• Indefinitely and permanently deferred donors</td>
<td>Indefinitely</td>
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<tr>
<td>• Donors placed under surveillance (for recipient protection)</td>
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<tr>
<td><strong>Patient Records</strong></td>
<td></td>
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<tr>
<td>• Transfusion administration records (TRM.41450)</td>
<td>10 years</td>
</tr>
<tr>
<td>• Therapeutic phlebotomy/apheresis records</td>
<td></td>
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<tr>
<td>• Final unit disposition</td>
<td></td>
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<tr>
<td>• Patient pre-transfusion testing results/interpretation</td>
<td>10 years</td>
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<tr>
<td>• Immediate evaluation/interpretation of transfusion reactions</td>
<td></td>
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<tr>
<td>• Transfusion problems such as transfusion reactions, unexpected antibodies, and special transfusion requirements.</td>
<td>Indefinitely</td>
</tr>
<tr>
<td>• Employee signatures, initials, and identification codes</td>
<td>10 years</td>
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<tr>
<td>*<em>Quality Control Records</em></td>
<td></td>
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<tr>
<td>• Quality management reviews</td>
<td>5 years</td>
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<tr>
<td>• Proficiency testing records</td>
<td></td>
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<tr>
<td>• Inspections of blood/critical materials</td>
<td></td>
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<tr>
<td>• Instrument/equipment quality control and maintenance</td>
<td></td>
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<tr>
<td>• Irradiation dose delivery</td>
<td></td>
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<tr>
<td>• Control systems for patient testing</td>
<td></td>
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<tr>
<td>• Retyping of donor units</td>
<td></td>
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<tr>
<td>• Annual procedure review/procedure discontinued</td>
<td></td>
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<tr>
<td>Control systems for donor testing</td>
<td>10 years</td>
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<td>----------------------------------</td>
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<tr>
<td><strong>Tissue Records (including bone marrow and/or progenitor cells)</strong></td>
<td></td>
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<tr>
<td>Collection, transportation, processing, issuing, disposition</td>
<td>10 yrs beyond tissue's disposition or expiration, whichever is longer</td>
</tr>
<tr>
<td>Daily temperature monitoring</td>
<td>10 years</td>
</tr>
</tbody>
</table>

### TRM.32275 Component Records
**Phase II**

The records include documentation of each component from receipt/collection through processing, storage, and testing, to final disposition.

### TRM.32300 Receipt of Blood
**Phase II**

Records include information about all blood received from outside sources.

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

### TRM.32350 Records QC
**Phase II**

A process is in place 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 process in place 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
**Phase II**

Records include information about bacteriologic studies (when indicated).

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

### TRM.33200 Personnel Audit Trail
**Phase II**

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

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

TRM.33300 License/Registration of Laboratory

Phase II

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

NOTE: If any blood components or cellular therapy products are collected or modified, even for only autologous collections, 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 should 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 documentation to determine if the steps taken follow the laboratory policy for corrective action
TRM.40050  Agglutination/Hemolysis Criteria  Phase II

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. (This is an excellent topic for competency assessment.)

TRM.40100  Test Result Recording  Phase II

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

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

TRM.40120  QC Handling  Phase II

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 run by the same personnel performing patient testing documented at defined frequency

REFERENCES

TRM.40140  QC Verification  Phase II

The results of controls are verified 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/procedure 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

**REVISED** 06/17/2010
Anti-D Controls

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

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

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

DAT Controls

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

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

Evidence of Compliance:
✓ Patient records/worksheet documenting confirmation of 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:
✓ Patient records/worksheet documenting confirmation of negative antiglobulin tests

COMPATIBILITY TESTING

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

Inspector Instructions:
- Sampling of compatibility testing policies and procedures
- Sampling of historical record checks
**Transfusion Medicine Checklist**

**07.11.2011**

- Sampling of confirmation of donor unit ABO/Rh records
- Sampling of worksheets/computer records with forward and reverse grouping, autologous and allogenic serologic crossmatches

- **READ**

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

- **OBSERVE**

- How do you verify the patient's identification when they are 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 to requisition exactly?
- If applicable, how do you handle neonatal transfusions? What blood groups are transfused?

- **ASK?**

- 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

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**REVISED** 07/11/2011

**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. Initials or other identifier of the phlebotomist.

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

**Evidence of Compliance**

✓ Written procedure defining labeling requirements of specimens for compatibility testing

**REFERENCES**

TRM.40235  Patient Identification

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

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

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

Records are available that document 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 Units ABO/Rh Confirmation

Records are available that document 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.
The documentation 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 CLIA-certified laboratory, with confirmation of the unit’s ABO/Rh type.

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

TRM.40500 Recipient Sample
Phase II

There is a 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.

TRM.40550 Forward/Reverse Typing
Phase II

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

TRM.40600 Unexpected Antibody Screen
Phase II

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 documenting the reactions at the different phases of testing

TRM.40650 Major Serologic Crossmatch
Phase II

For allogeneic units, a major serological 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 major serological 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 protocol 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  Non-Group O Neonate Transfusion  Phase II

For non-group O neonates receiving non-group O red blood cells, there is a process in place 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 non-group O antibody screening for neonates AND
✓ Logs or computer records with screening results

**REVISED**  06/17/2010

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.

**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?

**Evidence of Compliance:**
- Written procedure defining method for verification of ABO AND
- Work records documenting testing and/or search of records verifying ABO type

**TRM.40670 ABO Verification**

The recipient’s ABO blood group has been verified by repeat testing of the same sample, a different sample, or by performing a historical search of laboratory records.

*NOTE:* Verification of the patient’s ABO blood group must be performed by repeat testing of the same sample, a different sample, or a historical search of laboratory records for that patient. 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 documenting testing and/or search of records verifying ABO type

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

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

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

**TRM.40690 Data Entry Verification**

If a serologic crossmatch is not performed, there is a method 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 defining method for verification of ABO AND
- ✓ Work records documenting testing and/or search of records verifying ABO type
✓ Written policy requiring verification of correct data entry prior to release of blood/blood components AND
✓ Records for verification of correct data entry AND
✓ Documentation 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 process for emergency release requests?
- What is your course of action when an incompatibility has been discovered with an emergency release?

**TRM.40700 Whole Blood/Red Cells/Plasma**

**Phase II**

All recipients receive ABO group-specific whole blood, ABO group-specific or compatible red blood cell components, or ABO group-compatible plasma 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. This means that all recipients must receive ABO group-specific whole blood, ABO group-specific or compatible red blood cell components, and/or ABO compatible plasma.

**TRM.40710 Rh Transfusion**

**Phase II**

The transfusion service has a policy 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 policy should include a specific protocol for consideration of prophylaxis against Rh immunization in Rh-negative platelet recipients receiving an Rh-positive platelet unit.

**REFERENCES**

TRM.40720  Immunohematologic Conditions  Phase II

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.

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TRM.40740  ABO-Incompatible Donor Plasma - Infants  Phase II

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

NOTE: For infant recipients, donor 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.

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TRM.40760  Granulocytes And/Or Platelets Crossmatch- Compatible  Phase II

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

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

Evidence of Compliance:
✓ 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

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TRM.40770  Life-Threatening Situations  Phase II

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 documented authorization of a qualified physician.

NOTE: Policies and procedures must be available to expedite testing for transfusion in a life-threatening situation. If an institution's policy allows abbreviated testing in massive transfusion situations, records should indicate that the policy was followed. Documentation must include the authorization by a qualified physician. (If approved by the institution and documented 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 documented.

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

Evidence of Compliance:
✓ Records of emergency release authorization by a qualified physician
TRANSFUSION MEDICINE CHECKLIST
07.11.2011

REFERENCES

PERINATAL TESTING

Inspector Instructions:

- Rh immune globulin release policy
- How do you ensure that all Rh-negative women receive protection against Rh immune globulin?
- How do you evaluate for fetomaternal hemorrhage in those candidates for Rh immune globulin?
- What process is 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 processes for testing, dosing and time interval for administration are adequate.

TRM.40780 RhIG Candidates

There is a system to identify all potential Rh immune globulin candidates.

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 documented test result from any CLIA-licensed 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 policy or procedure defining the method for identification of RhIG candidates

REFERENCES

TRM.40790 Fetomaternal Hemorrhage Detection

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 Phase II

There is a mechanism 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 policy for administration of RhIG AND
✓ Patient records confirming administration within the appropriate timeframe

TRM.40820 ABO/Rh Historical Check Phase II

There is a method 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 such verifications of the sample's identity and the test results are strongly recommended.

TRANSFUSION PROCEDURES

Inspector Instructions:
- Sampling of transfusion policies and procedures
- Sampling of transfusionist records of initial and annual training
- Sampling of patient records for administration and monitoring of transfusion processes
- If applicable, sampling of transfusion committee or blood utilization committee minutes demonstrating medical director participation
Transfusion Medicine Checklist
07.11.2011

- How do you examine blood products just prior to issue?
- What are the signs/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 documentation of blood administration.

**REVISED** 07/11/2011
TRM.40875 Medical Director Responsibility - Policy Setting

Phase I

There is documentation that the transfusion service medical director participates in:

1. The development of policies, processes, 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 processes should be used to modify blood administration policies, 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  

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

**REFERENCES**

**TRM.41000  Transfusion Protocol**  
Phase II  

There is a procedure for blood administration, including positive identification 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**

**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 during and after transfusion, with 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

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

There are documented 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**  
Phase II  

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 they are FDA-approved for that purpose or documentation exists that no harm will result to the component or patient.

TRM.41300  Bedside Identification  Phase II

The recipient is always identified conclusively at the bedside 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 process for verifying the identity of the patient and checking it with the information on the unit prior to transfusion

REFERENCES

TRM.41350  Compatibility Label/Tag  Phase II

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  Phase II

There is documentation 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 before, 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

If a blood warming system is used during transfusion, it is FDA-cleared, and equipped with special features to alert the user to proper transfusion conditions.

NOTE: A blood warming system must be FDA-cleared, properly maintained, equipped with features to alert the user to proper transfusion conditions (e.g. a visible thermometer and audible alarm), so that use of the system does not result in damage to the blood component being warmed.

TRM.41525  Perioperative Blood Program

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  Perioperative Safety and Efficacy

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  Medical Director Involvement

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:

- 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

● Donor/recipient transfusion reaction specimens (7 day retention, refrigerated, sealed)

● 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?

● Review the documentation of several transfusion reaction work-ups. Determine if the policies and procedures provide for thorough investigation and reporting. Determine if medical director involvement is sufficient.

TRM.41650 Transfusion Reaction Recognition/Education Phase II
Criteria for the recognition of transfusion reactions are documented, and there is documentation of at least annual in-service education on the recognition of such reactions.

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

REFERENCES

TRM.41700 Transfusion Reaction Response Phase II
There are documented procedures describing actions to be taken in the event of a transfusion reaction.

REFERENCES

TRM.41750 Transfusion Reaction/Incident Reporting Phase II
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 medical director of the transfusion service is involved in the investigation and resolution of the issue.  
Evidence of Compliance: ✓ Records of 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

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  
The transfusion service medical director has established a documented protocol
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 is interpreted by the transfusion service medical director or designee, and reported in a timely and effective manner.

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

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

REFERENCES

TRM.42100 Blood Supplier Notification Phase II

There is a mechanism to notify 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

TRM.42110 TRALI Phase I

The laboratory has developed a plan to reduce the risk of transfusion-related acute lung injury (TRALI).

NOTE: The laboratory should track the frequency of TRALI.

Evidence of Compliance:
✓ Written policy for measures used to reduce the risk of TRALI OR records of communication with blood supplier on steps being taken to reduce the risk of TRALI

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  Phase I

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  Phase II

The transfusion service medical director has established protocols 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  Phase II

The transfusion service has a detailed procedure consistent with CMS and FDA 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
There is a policy requiring notification of the Centers for Biologics Evaluation and Research according to US federal regulations when a transfusion-related fatality occurs following transfusion of any component.

**NOTE:** Current reporting requirements mandate notification of the CBER Director 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

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**APHERESIS**

**GENERAL CONSIDERATIONS**

**Inspector Instructions:**
- Sampling of apheresis policies and procedures
- Sampling of apheresis patient records for all necessary elements
- Sampling of physician evaluation records and informed consents
- Sampling of personnel training records
- What information does the physician provide to the patient prior to apheresis?

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**Donor/Patient Protection**

The procedures for apheresis provide adequate protection for the patient/donor.

**NOTE:** The procedures should include positive patient/donor identification, adequate training of staff, and an appropriate physician's order reflecting an evidence-based approach to therapeutic apheresis, if applicable.

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**Evaluating Donor/Patient Suitability**

A qualified physician is responsible for evaluating the suitability of apheresis donors/patients, ensuring that an explanation of risks of the procedure is provided, and obtaining an informed consent.

**NOTE:** The risks of apheresis must be explained by a knowledgeable, responsible person...
according to policies and procedures established by the blood bank medical director. The donor/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/donor prior to procedure

REFERENCES

TRM.42197 Staff Training

All personnel performing apheresis procedures are trained in the recognition of procedural complications, adverse reactions and donor/patient care.

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

TRM.42205 Patient Safety

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

NOTE: Appropriate filters must be used to prevent clots from being reinfused in the donor/patient.

TRM.42210 Apheresis Records

Complete records are kept of each apheresis procedure including the following elements.

1. Donor/patient identity
2. Results of pertinent laboratory tests
3. Anticoagulants used
4. Volume of component(s)
5. Drugs used
6. Lot numbers of disposables and replacement fluids used
7. Reactions, if any
8. Treatment for reaction

DONOR APHERESIS

Inspector Instructions:
- Sampling of donor apheresis policies and procedures
- Sampling of donor apheresis procedure records and test results
- Apheresis components (labeling)
• Who is the physician available for consultation when apheresis is performed?

TRM.42215 Extended Donor Evaluation
Phase I

Additional criteria (beyond routine donor screening tests) are used to evaluate donors, appropriate for their apheresis procedure.

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 procedure defining criteria for extended testing of donors AND
✓ Donor records with test results

REFERENCES

TRM.42220 Plateletpheresis Donor Deferral
Phase II

Plateletpheresis donors are deferred for an appropriate time if they have taken medications known to irreversibly damage platelet function (e.g. aspirin) or that inhibit platelet function and have a prolonged half-life.

NOTE: Plateletpheresis donors must be deferred from platelet donation if they have taken medications known to irreversibly damage platelet function (e.g. aspirin-containing medication) or that inhibit platelet function and have a prolonged half-life. As single-donor plateletpheresis collections may be given as the sole means of platelet support, it is important to avoid donors whose platelets may be functionally impaired as a result of exposure to any of these medications. Such donors may donate whole blood, but are precluded as the sole source of platelets. The length of the temporary deferral depends on the medication, its mechanism of action, and its half-life.

Evidence of Compliance:
✓ Records of deferral

TRM.42225 Physician Availability
Phase II

A physician experienced in donor apheresis is available for prompt consultation when apheresis is performed.

REFERENCES
TRM.42230 Volume Limits Phase I

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.

NOTE: The laboratory should ensure that the donor blood volume deficit during apheresis is controlled. An intravascular volume deficit greater than 15% of blood volume will increase the risk of significant donor reaction secondary to hypovolemia.

TRM.42235 Apheresis Component Labeling Phase II

The apheresis components are properly labeled (unique identifier, ABO and Rh type for cellular components, time and date of expiration, and sedimenting agent if any).

Evidence of Compliance:
✓ Written procedure defining labeling requirements

TRM.42240 Donation Interval Phase II

For 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
1) Apheresis donation interval for double red cells: FDA algorithm for double RBCs: CBER

THERAPEUTIC APHERESIS
**Inspector Instructions:**

- Sampling of therapeutic apheresis policies and procedures
- Sampling of therapeutic apheresis patient records, including initial device placement
- Sampling of personnel records of education and training

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

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**TRM.42245  Medical Director/Desigee Responsibility  Phase II**

There is documentation that the transfusion service medical director or designee has accepted medical responsibility for apheresis procedures.

**NOTE:** The transfusion service medical director or designee must accept responsibility for the patient undergoing this apheresis. This involvement is in addition to responsibility for overall management of the therapeutic apheresis program, including quality assurance measures. At a minimum, such responsibility for a procedure would include 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 any adverse event. If the institution contracts with an outside service for apheresis, the medical director must determine that the outside service assures efficacy and patient safety.

**Evidence of Compliance:**

✓ Written policy defining medical director/designee responsibility for apheresis procedures

AND

✓ Patient records documenting medical director/designee involvement before, during and after the apheresis

**REFERENCES**

1) [http://apheresis.org/asfa_guidelines](http://apheresis.org/asfa_guidelines)

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**TRM.42246  Record Retention  Phase II**

Records are maintained of all the following elements.

1. Order for apheresis by patient’s physician
2. Patient identification (two identifiers required)
3. Patient diagnosis
4. Type of apheresis procedure
5. Blood fraction and volume of components removed and replacement fluid(s) type and volume
6. Patient data and criteria for measuring patient response, as available
7. Adverse reactions, with medications administered
8. Patient monitoring
9. Informed consent
TRM.42255  Personnel Qualifications  

**Medical personnel performing and/or supervising therapeutic apheresis are qualified by education and training.**

*NOTE: The personnel involved in provision of therapeutic apheresis, including operators and supervising physicians, shall be appropriately qualified. Examples of appropriate qualification have been established by the American Society for Apheresis (ASFA.) These guidelines were published [J Clin Apher 22:3;181-182(2007)] and are available at [http://www.apheresis.org/asfa_guidelines/index.cfm](http://www.apheresis.org/asfa_guidelines/index.cfm).*

**Evidence of Compliance:**

✓ Record of education and training of personnel involved in therapeutic apheresis

**REFERENCES**


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TRM.42260  Evaluation/Approval for Therapeutic Apheresis  

**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  Therapeutic Apheresis Request Review  

**There is a process to evaluate requests for therapeutic apheresis, including indications, therapeutic goals, selection of replacement solutions, and criteria for discontinuation of therapy.**

**REFERENCES**

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

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TRM.42270  Device Placement Verification  

**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.*

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TRM.42275  Time-Out  

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

1. Two patient identifiers
2. Planned procedure, as stated on consent
3. Written physician’s order
4. Availability of a qualified physician to respond if an adverse event occurs

*NOTE: The Joint Commission (TJC) requires the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery. The "time-out," or immediate preoperative pause, must occur in the location where the procedure is to be done with active participation of the appropriate members of the team. Procedures that involve one person also require time-out, though do not require involvement of additional personnel. See [http://www.jointcommission.org/PatientSafety/UniversalProtocol](http://www.jointcommission.org/PatientSafety/UniversalProtocol)/(as of 2007/12/03)*
Evidence of Compliance:
✓ Written apheresis procedure with steps to verify information **AND**
✓ Records of time-out verification for each procedure

REFERENCES

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**THERAPEUTIC PHLEBOTOMIES**

**TRM.42280  Adverse Reaction  Phase I**

The standard operating procedure describes evaluation of the therapeutic 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 such as hypocalcemia, hypotension, allergic and anaphylactic reactions, air embolus, respiratory distress, cardiac arrest etc.

**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?

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**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 and 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](http://www.fda.gov/CBER)

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**TRM.42290  Director/Designee Responsibility  Phase II**

If therapeutic phlebotomies are performed by blood bank staff, a qualified physician has accepted medical responsibility for the procedures.
NOTE: If therapeutic phlebotomies are performed by blood bank staff, the transfusion service medical director or 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 medical director/designee responsibility for therapeutic phlebotomy procedures AND
✓ Patient records/charts documenting director/designee review

TRM.42295 Patient Protection Phase I
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. Documented 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. Several practice guidelines have been published (e.g. Tavill SA, Diagnosis and Management of Hemochromatosis. Hepatology 33:5;1321-1328) and useful resources are available at http://www.cdc.gov/ncbddd/hemochromatosis/treatment.htm and 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.
Indications For Therapeutic Phlebotomy Review

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 medical director/designee 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, if possible
- Sampling of records of corrective action when storage unit temperature fall outside the defined range
- Sampling of blood component records of inspection
- Refrigerator storage unit (organization, sufficient space, separation of units), including remote storage, if possible
- Sampling of blood/blood components (labeling with all FDA-required elements, assigned expiration date)
- How are blood components received/shipped from the facility?
- How long can the blood component be out of the storage unit and then received back into
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

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

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

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

For blood/blood components shipped outside of the facility, procedures have been defined for proper packaging to prevent damage and control storage temperatures.

TRM.42470 Acceptance Back Into Inventory

There is a documented process in place for accepting blood/blood components back into
inventory after they have been issued.

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

REFERENCES

TRM.42480 Expiration Dates Phase II

The assigned expiration dates for all blood components comply with 21CFR 610.53 and the manufacturer’s recommendations.

NOTE: The expiration date requirements for blood components must comply with FDA requirements. Exceptions must be granted by the FDA and be documented by the laboratory.

REFERENCES

**REVISED** 06/17/2010

TRM.42500 Temperature-Dependent Equipment Phase II

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: All blood and components must be stored at an appropriate temperature to maintain viability and function. The storage of these blood and components 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 documented 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 documented (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. The functionality of the system must be documented daily.

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

REFERENCES
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, as well as documentation of the disposition of any affected components.

NOTE: Components must be maintained at the required storage temperature and documentation must exist of corrective action taken if the temperature range has not been continuously maintained. Such records must document the disposition of affected components.

Consistent Temperature  Phase II  

There is evidence 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 documentation 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.

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, the temperature sensor probe should be in liquid with heat transfer characteristics similar to blood, and a volume similar to the smallest units stored. 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. Placement of the sensor in liquid with heat transfer characteristics similar to blood is recommended but other procedures are also acceptable.

Emergency Power Supply  Phase II  

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

Storage Unit Alarms  Phase II  

There is an audible alarm for each component storage unit, the alarm continuously monitored 24 hours per day (in laboratory or remote), and the response system to an alarm has been validated.

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

Evidence of Compliance:  
✓ Written procedure defining criteria for monitoring alarms AND  
✓ Records of response time to the alarm

Alarm System Checks  Phase II  

Alarm systems are checked at specified periodic intervals (for both low and high settings)
and results recorded.

**TRM.42850  Alarm Sensors To Trigger Action Needed**  
**Phase II**

*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

**TRM.42900  Power Failure Back-Up**  
**Phase II**

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

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

**TRM.42950  Storage Temperature Variances**  
**Phase II**

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

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

**TRM.43500  Component Processing/Storage**  
**Phase II**

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

**REFERENCES**


**TRM.43600  Component Labeling**  
**Phase II**

*For each component, the label specifies all of the FDA 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

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

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

TRM.43650 Component Handling

For each component, there are defined 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 documented after each weld. If the integrity of the weld is incomplete, the unit must be considered an open system and the expiration date on the product label must be modified accordingly.

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

TRM.43700 Pooled Components

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

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

RED BLOOD CELLS

Inspector Instructions:
• RBC processing policy or procedure
• Sampling of RBC component processing and QC records
TRM.43750  24 Hour Expiration  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

REFERENCES
1) FDA CFR table for product dating periods, 21 CFR 610.53 (c):
http://a257.g.akamaitech.net/7/257/2422/01apr20051500/edocket.access.gpo.gov/cfr_2005/aprqtr/pdf/21cfr610.53.pdf

TRM.43800  RBC Hematocrit Limit  Phase II

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

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

Evidence of Compliance:
✓ Records of component QC documented at defined frequency

RED BLOOD CELLS WASHED

Inspector Instructions:
- RBC washing policy or procedure

TRM.43850  Plasma Removal  Phase II

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  Phase II

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

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

REFERENCES

TRM.43950  FDA-Approved Method  Phase I

Red Blood Cells are frozen by an FDA-approved method.

NOTE: RBC should be frozen within 6 days of collection for CPD and CPDA-1 or promptly after rejuvenation with an FDA-approved solution.

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  Phase II

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

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

RED BLOOD CELLS DEGLYCEROLIZED

Inspector Instructions:
- RBC deglycerolization policy or procedure
- Sampling of inventory records

TRM.44100  Open System Preparation Usage  Phase II

Reconstituted deglycerolized Red Blood Cells that have been prepared with an open system are used within 24 hours or as approved by the FDA.

NOTE: The FDA also permits post-thaw storage for up to 14 days in a functionally closed, approved system.

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

REFERENCES
1) Valeri CR et al. A multicenter study of in vitro and in vivo values in human RBCs frozen with 40-percent (wt/vol) glycerol and stored after deglycerolization for 15 days at 4 °C in AS-3: assessment of RBC processing in the ACP 215. Transfusion, 2001;41:933-9
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

Leukocyte-Reduced RBC Criteria

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

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

**Phase II**

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

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

TRM.44450  FFP/Cryoprecipitate Thawing Requirement

**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, it must be FDA-cleared as a Class III medical device (premarket approval), or data must be available showing acceptable preservation of labile coagulation factors and temperature maintained at less than or equal to 37°C. 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 I**

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.44550  Cryoprecipitate AHF Preparation  Phase II

When preparing Cryoprecipitated AHF, Fresh Frozen Plasma is thawed at temperatures between 1-6°C.

Evidence of Compliance:
✓ Written procedure for preparation of cryoprecipitate AND
✓ Records of component processing

TRM.44600  Cryoprecipitate AHF Preparation  Phase II

When preparing Cryoprecipitated AHF, the thawed unit is immediately centrifuged at 1-6°C to separate the plasma from the cold insoluble material.

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

TRM.44650  Cryoprecipitate AHF Preparation  Phase II

The concentrated Cryoprecipitated AHF is refrozen within 1 hour.

Evidence of Compliance:
✓ Written procedure for preparation of cryoprecipitate AND
✓ Records of component processing

PLATELETS

Inspector Instructions:

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

- How have you validated/revalidated your platelet count method?
- What system are you using to detect bacteria in platelet components?
**REVISED** 06/17/2010
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 adequately documented. Storage at lower temperatures may result in reduced platelet survival. Apheresis platelets must be prepared according to the instructions of the manufacturer.

REFERENCES

**REVISED** 06/17/2010
TRM.44900 Platelet Component Acceptability Criteria  Phase II

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

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

REFERENCES

TRM.44925 Platelet Count Validated Method  Phase I

Platelet counts on platelet components are determined, when required, using a method that has been validated 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 1-2,000,000/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 validated 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 validation of the instrument for accuracy of platelet concentrations in the expected range AND
✓ Record of validation/revalidation documented at defined frequency

REFERENCES
Platelet components are stored at 20-24 °C with appropriate agitation and transfused within the FDA-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
3) Moroff G, George VM. The maintenance of platelet properties upon limited discontinuation of agitation during storage. Transfusion. 1999;30:427-430

**REVISED** 07/11/2011
TRM.44955 Bacterial Contamination in Platelets

The laboratory (or its blood supplier) uses an FDA-cleared 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 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 an 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-approved/cleared method
✓ Use of pre-pooled WBD platelets tested with an FDA-approved/cleared culture-based QC test by the supplier
✓ Use of apheresis platelets tested with an FDA-approved/cleared culture-based QC test by the supplier
✓ Culture of aliquots from individual WBD platelet units destined for pooling
✓ Methods that are not FDA-cleared but have been validated to be of equivalent clinical sensitivity to an FDA-cleared/approved assay

REFERENCES
1) Brecher ME, Means N, Jere CS, Heath D, Rothenberg S, Stutzman LC. Evaluation of an automated culture system for detecting

PLATELETS LEUKOCYTE-REDUCED

Inspector Instructions:

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

TRM.44960 Method of Preparation

Phase II

The method of preparation ensures acceptable leukocyte-reduction and platelet concentration in the final component, as prescribed by the FDA.

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.
TRM.44970 Radiation Dose Phase II

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

NOTE: All equipment used for blood irradiation should be validated by measuring the amount of radiation delivered by the product upon installation and after mechanical maintenance, especially those involving the specimen handling apparatus such as the turntable. There should be periodic documentation (annually for Cesium137 and semi-annually for Cobalt60) that the procedure delivers a minimum of 2500 cGy targeted to the midplane of the canister if a free-standing irradiator is used, or to the central midplane of an irradiation field if a radiotherapy instrument is used. The minimum dose at any point in the canister or irradiation field should be 1500 cGy. The procedure should define the maximum number of units of blood or blood components that can be irradiated in a batch. There should be a quality control program for the indicator system in use.

REFERENCES

TRM.44977 Blood Component Labeling And Expiration Dates Phase I

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

TRM.44984 Maintenance Schedule Phase II

There is a maintenance schedule for all blood irradiation equipment including timer checks, back-up timer checks, turntable inspection, and radiation leakage testing and documentation shows that the maintenance is performed.

TRM.44987 US NRC Requirements Phase I

There is documentation that the laboratory has met the requirements of the US Nuclear Regulatory Commission for blood irradiation devices.

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.

REFERENCES
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.

BONE MARROW AND/OR 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 documented.

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

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

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

There is a mechanism 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

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

TRM.44997 Clinical Outcomes

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

NOTE: If the laboratory does not collect the data, the 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, documentation of investigation and corrective action, as appropriate, must be present in the laboratory's records.

TRM.44998 New/Changed Protocol Validation

The laboratory has a process in place to validate new protocols, including significant changes to existing protocols.

NOTE: Validation data may include literature and reference review, prospective testing prior to implementation of procedures, and retrospective reviews to verify the reproducibility of the process. Validations must address prevention of microbial contamination during processing, where applicable. The director must be involved in determining the type of validations needed
and the review of validation data. Validation studies must be documented.

<table>
<thead>
<tr>
<th>TRM.44999</th>
<th>Requisition</th>
<th>Phase II</th>
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<tbody>
<tr>
<td>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.</td>
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<tr>
<th>TRM.45000</th>
<th>Process Tracking</th>
<th>Phase II</th>
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<tbody>
<tr>
<td>Laboratory records identify the person performing each significant step in the collection, processing and administration of cellular therapy products.</td>
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<tr>
<th>TRM.45001</th>
<th>Product Labeling</th>
<th>Phase II</th>
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<tr>
<td>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.</td>
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<tr>
<th>TRM.45002</th>
<th>Labeling Systems</th>
<th>Phase II</th>
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| 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. |

**REFERENCES**

**Collection**

**Inspector Instructions:**
- Sampling of cellular therapy collection policies and procedures

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**Collection Inspector Instructions:**

- Sampling of cellular therapy collection policies and procedures
TRM.45003 Donor Qualifications

Procedures are in place to evaluate the acceptability of cellular therapy product donors.

NOTE: The apheresis 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 apheresis medical director and transplant physician. For allogeneic donation, a process must be in place 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

Appropriate consent is obtained.

TRM.45005 Donor Evaluation

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

Evidence of Compliance:
✓ Records with documented 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

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 FDA-Approved Reagents Phase II
Reagents and supplies used in the collection, processing, cryopreservation, and administration of cellular therapy products are approved by FDA for human use.

NOTE: The use of reagents or supplies that are not FDA-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.

TRM.45008 Liquid Nitrogen Levels Phase II
The laboratory has a method 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 equipped with an alarm (either remote or in the laboratory) that is tested at least quarterly for its ability to alert responsible staff at all times.

Evidence of Compliance:
✓ Records of alarm checks documented 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
There is documentation that the laminar flow hood is regularly cleaned, decontaminated and certified as appropriate.

Processing

Inspector Instructions:
Transfusion Medicine Checklist

- 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: Positive culture results must be reviewed by the laboratory medical director. Appropriate investigation and corrective action, if required, must be documented.

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

TRM.45014 Physician Notification

A policy is in place 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 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

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 Director/Designee Review**

Phase II

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

**TRM.45017 Allogeneic ABO/Rh Mismatch**

Phase II

For allogeneic donations, a process is in place to address how to process 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 Processing Record Review**

Phase II

Cellular therapy product cryopreservation records, including freezing charts, when applicable, are reviewed by the laboratory 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 to contact the patient and the patient’s physician must be made and documented prior to discarding the components.

TRM.45021 Cord Blood Storage

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

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

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

NOTE: The 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. Determine that processes 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.

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

TRM.45100 Tissue Records Phase II
There is documentation available for each tissue stored of the infectious disease testing and type of processing performed.

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 I
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. TJC hospital accreditation requires 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 from source facility recalls indicating action taken

TRM.45150 Tissue Storage Conditions Phase II

The procedure manual defines the necessary storage conditions of the different tissues handled, all required records and policies, and a protocol 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 Phase I

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

TRM.45170 Specimen Tracking Phase I

There are procedures for documenting the receipt, product identifiers, 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 system for completing and returning issue usage cards to the source facility.

TRM.45190 Record Retention Phase I

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

NOTE: TJC hospital accreditation requires 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 blood bank 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:  
- Sampling of donor policies and procedures  
- Sampling of donor history, physical exam and screening test records  
- Sampling of personnel training and competency records
Transfusion Medicine Checklist

- Donor arm preparation, if possible

- 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?

Follow a donor record through all phase 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](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  
**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

**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.**

TRM.45256 Donor Demographics

**Donor demographics include date of birth and address.**

**NOTE:** All donor demographics must include a birthdate. In the US, allogeneic donors should generally be at least 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

**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

**The laboratory has documented 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
1) FDA algorithm for double RBCs: Guidance for Industry: Recommendations for Collecting Red Blood Cells

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 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
1) REFERENCE: FDA algorithm for double RBCs: Guidance for Industry: Recommendations for Collecting Red Blood Cells

TRM.45260 Instrument QC
Phase II

The method used to determine donor hemoglobin concentration or hematocrit is monitored to ensure correct results.

Evidence of Compliance:
✓ QC records documented at defined frequency

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

TRM.45264 Donor Record
Phase II

The donor history, physical examination, and screening test results are recorded (paper or electronic).
TRM.45265  Follow-Up  Phase II
There is evidence of follow-up for significant findings in donor history, physical examination and screening test results.

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

TRM.45267  Donor Arm Preparation  Phase II
A documented procedure using sterile, prepackaged materials is followed for donor arm preparation that reduces 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. The FDA recognizes several methods for arm preparation.

REFERENCES

TRM.45268  First Volume Diverted From WB Platelets  Phase I
The first volume of the phlebotomy from which a platelet component is 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  Phase II
There is a documented 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
TRM.45270 Directed Donation Requirements Phase II
There is a process 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 evidence of request by the donor/patient’s physician.

TRM.45272 Autologous Donation Guidelines Phase I
The 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 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 allogenic 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 phase of collection. Further evaluate evidence of follow up for significant findings in donor history, physical examination or screening test results.
Transfusion Medicine Checklist

TRM.45273 Educational Material

**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 documenting 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 Greutzfeldt-Jakob Disease (CJD) and variant Greutzfeldt-Jakob Disease (vCJD) by blood and blood products. January 2002

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TRM.45275 Parenteral Drug Use Inspection

**There is documentation 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.

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TRM.45276 Donation Time Intervals

**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

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TRM.46138 Allogeneic Donor Evaluation

**There is documentation 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**


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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 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 processes 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
### Infectious Disease Testing

**Phase II**

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), performed 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: a serologic test for syphilis, anti-HIV-1, anti-HIV-2, anti-HBc, anti-HCV, HBsAg, anti-HTLV-I, and anti-HTLV-II. HIV-1 NAT should be used in place of HIV-1 p24 antigen testing. HCV and WNV NAT are recommended also.

For situations where only autologous blood will be transfused, the autologous units need not be tested for infectious disease markers unless they are being considered for allogeneic use or being transferred to another facility.

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

**REFERENCES**
2) HIV and HCV NAT: Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples, ADD 2005 WNV guidance

### 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

### Supplemental Tests

**Phase II**

FDA-approved supplemental tests are performed whenever indicated.

**NOTE:** The FDA requires that an FDA-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**

### Infectious Disease Testing QC

**Phase II**

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

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

### Sample Mix-Up Precautions

**Phase II**

There is a system 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 documented.

NOTE: There must be a mechanism for auditing 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 mechanism 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 documented by manual or computer systems.

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 there is a defined mechanism for 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 describing the process for look-back and notification for donors testing positive for viral marker screening AND
✓ Donor records

REFERENCES
7) Draft guidance, HIV and HCV NAT and lookback: Draft Guidance for Industry: Nucleic Acid Testing (NAT) for HIV-1 and HCV

TRM.47350 Quarantine/Unit Disposal Procedure

There is evidence that standard operating procedures provide for appropriate quarantine
and unit disposal steps, and these procedures are followed.

NOTE: An effective procedure for quarantine and unit 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

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 documenting check against deferral list prior to release

REFERENCES

TRM.47450 Result Review

There is evidence that the donor service medical director reviews abnormal donor testing results and ensures donor notification in a timely manner.

NOTE: The donor 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:
**REVISED** 07/11/2011

TRM.50000  Personnel - Technical Operations  Phase II

The person in charge of the technical operations of the transfusion medicine section of the laboratory has education equivalent to an MT(ASCP) and at least 4 years experience (one of which is in transfusion medicine) under a qualified laboratory director.

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

TRM.50050  Medical Director/Technical Supervisor  Phase II

The medical director (technical supervisor) of the transfusion medicine section is qualified under CLIA.

NOTE: The medical director (technical supervisor) of the transfusion medicine section 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.

Evidence of Compliance:
✓ Records of technical supervisor 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 medical director of the transfusion service is involved in development of all policies and procedures related to transfusion.

Evidence of Compliance:
✓ Records of director review of transfusion-related policies and procedures AND/OR meeting minutes documenting participation in 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.