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COMMISSION ON LABORATORY ACCREDITATION

Laboratory Accreditation Program

TRANSFUSION MEDICINE CHECKLIST

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TRANSFUSION MEDICINE

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SUMMARY OF CHANGES
TRANSFUSION MEDICINE Checklist
 9/27/2007 Edition

The following questions 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 questions included may not appear in the customized checklist. Such questions are not applicable to the testing performed by the laboratory.

Note: For revised checklist questions, 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 Questions

<u>Question</u>	<u>Effective Date</u>
TRM.05000	09/27/2007
TRM.32275	09/27/2007
TRM.40235	09/27/2007
TRM.40651	09/27/2007
TRM.42110	09/27/2007
TRM.42135	09/27/2007
TRM.44987	09/27/2007
TRM.45268	09/27/2007
TRM.30575	10/31/2006
TRM.30950	10/31/2006
TRM.43612	10/31/2006
TRM.44925	10/31/2006
TRM.45075	10/31/2006
TRM.45125	10/31/2006
TRM.45160	10/31/2006
TRM.45170	10/31/2006
TRM.45180	10/31/2006
TRM.45190	10/31/2006
TRM.46138	10/31/2006
TRM.47112	10/31/2006
TRM.13466	04/06/2006
TRM.16732	04/06/2006

REVISED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
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TRM.10150	09/27/2007
TRM.30575	09/27/2007
TRM.31220	09/27/2007
TRM.32250	09/27/2007
TRM.40900	09/27/2007
TRM.41300	09/27/2007
TRM.41850	09/27/2007
TRM.42450	09/27/2007
TRM.30550	10/31/2006
TRM.31400	10/31/2006
TRM.40600	10/31/2006
TRM.40650	10/31/2006
TRM.42192	10/31/2006
TRM.42250	10/31/2006
TRM.42300	10/31/2006
TRM.42350	10/31/2006
TRM.44525	10/31/2006
TRM.44537	10/31/2006
TRM.44970	10/31/2006
TRM.45050	10/31/2006
TRM.45268	10/31/2006
TRM.47000	10/31/2006
TRM.47600	10/31/2006
TRM.47820	10/31/2006
TRM.31000	04/06/2006

DELETED Checklist Questions

<u>Question</u>	<u>Effective Date</u>
TRM.10200	09/27/2007
TRM.32400	09/27/2007
TRM.32500	09/27/2007
TRM.32700	09/27/2007
TRM.33100	09/27/2007
TRM.43550	10/31/2006
TRM.44200	10/31/2006
TRM.45262	10/31/2006
TRM.45274	10/31/2006
TRM.45277	10/31/2006
TRM.45279	10/31/2006
TRM.45280	10/31/2006
TRM.45282	10/31/2006
TRM.45285	10/31/2006
TRM.30500	04/06/2006

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CONTINUING EDUCATION INFORMATION

Beginning January 2008, you may earn continuing education credits (CME/CE) by completing an online Inspection Preparation activity that includes review of this checklist.

Prior to reviewing the checklist, log on to the CAP Web site at www.cap.org <<http://www.cap.org>>>, click the Education Programs tab, then select Laboratory Accreditation Program (LAP) Education Activities, and Inspection Preparation for complete instructions and enrollment information.

IMPORTANT: The contents of the Laboratory General Checklist are applicable to the Transfusion Medicine section of the laboratory.

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

INSPECTION TECHNIQUES – KEY POINTS

I. READ – OBSERVE – ASK – the three methods of eliciting information during the inspection process. These three methods may be used throughout the day in no particular order. Plan the inspection in a way that allows adequate time for all three components.

READ = Review of Records and Documents

Document review verifies that procedures and manuals are complete, current, available to staff, accurate and reviewed, and describe good laboratory practice. Make notes of any questions you may have, or processes you would like to observe as you read the documentation.

OBSERVE – ASK = Direct Observation and Asking Questions

Observing and asking questions accomplish the following:

1. Verifies that the actual practice matches the written policy or procedure
2. Ensures that the laboratory processes are appropriate for the testing performed

3. Ensures that outcomes for any problem areas, such as PT failures and issues/problems identified through the quality management process, have been adequately investigated and resolved
4. Ensures that previously cited deficiencies have been corrected

Use the following techniques:

- **Observe laboratory practices** – look at what the laboratory is actually doing. Compare the written policy/procedure to what you actually observe in the laboratory to ensure the written policy/procedure accurately reflects laboratory practice. Note if practice deviates from the documented policies/procedures.
- **Ask open ended, probing questions** – these are starting points that will allow you to obtain large amounts of information, and help you clarify your understanding of the documentation you've seen and observations you've made. This eliminates the need to ask every single checklist question, as the dialogue between you and the laboratory may address multiple checklist questions.
 - Ask open-ended questions that start with phrases such as “show me how...” or “tell me about ...” or “what would you do if...”. By asking questions that are open-ended, or by posing a hypothetical problem, you will avoid “cookbook” answers. For example, ask “Could you show me the specimen transport policy and show me how you ensure optimum specimen quality?” This will help you to determine how well the technical staff is trained, whether or not they are adhering to the lab's procedures and policies, and give you a feel for the general level of performance of the laboratory.
 - Ask follow-up questions for clarification. Generally, it is best not to ask the checklist questions verbatim. For example, instead of asking the checklist question “Is there documentation of corrective action when control results exceed defined tolerance limits?” ask, “What would you do if the SD or CV doubles one month?” A follow-up probing question could be, “What would you do if you could not identify an obvious cause for the change in SD or CV?”

II. Evaluate Selected Specimens and Tests in Detail

For the Laboratory General Checklist: Follow a specimen through the laboratory. By following a specimen from collection to test result, you can cover multiple checklist questions in the Laboratory General checklist: questions on the specimen collection manual; phlebotomy; verbal orders; identification of patients and specimens; accessioning; and result reporting, including appropriate reference ranges, retention of test records, maintaining confidentiality of patient data, and proper handling of critical results and revisions to reports.

For the individual laboratory sections: Consult the laboratory's activity menu and focus on tests that potentially have the greatest impact on patient care. Examples of such tests include HIV antibodies, hepatitis B surface antigen, urine drugs of abuse, quantitative beta-hCG, cultures of blood or CSF, acid-fast cultures, prothrombin time and INR reporting, and compatibility testing and unexpected antibody detection. Other potentially high-impact tests may be identified by looking at very high or low volume tests in the particular laboratory, or problems identified by reviewing the Variant Proficiency Testing Performance Report.

To evaluate preanalytic and postanalytic issues: Choose a representative specimen and “follow” the specimen through the laboratory or section of the laboratory, reviewing appropriate records in the preanalytic and postanalytic categories.

To evaluate analytic processes: Choose 2 or 3 analytes and perform a comprehensive review of records, including procedure manuals, quality control and proficiency testing records, instrument maintenance records and method performance validations for the last 2 years, selecting timeframes at the beginning, mid-point, and end of this timeframe. Compare instrument print-outs to patient reports and proficiency testing results to ensure accurate data entry. If problems are identified, choose additional tests or months to review.

III. Verify that proficiency testing problem have been resolved: From the inspector’s packet, review the Variant PT Performance Report that identifies, by analyte, all of the PT scores below 100%. Correlate any PT problems to QC or maintenance records from the same time period. Be thorough when reviewing these representative records, selecting data from the beginning, middle and end of the period since the last on-site inspection.

IV. Review correction of previous deficiencies: Review the list of deficiencies from the previous on-site inspection provided in the inspector’s packet. Ensure that they have been appropriately addressed.

LABORATORY SAFETY

The inspector should review relevant questions from the Safety section of the Laboratory General checklist, to assure that the transfusion medicine laboratory is in compliance. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

PROFICIENCY TESTING

Definitions:

Proficiency testing (PT) is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory’s results with those of other laboratories in the group and/or with an assigned value...(adapted from Clinical Laboratory Standards Institute Harmonized Terminology Database; available at <http://www.nccls.org/>).

Alternative assessment is defined as determination of laboratory testing performance by means other than PT--for example, split-sample testing, testing by a different method, etc.

College of American Pathologists (CAP) accredited laboratories must participate in the CAP Surveys, or a CAP-approved alternative proficiency testing program. This must include attempted enrollment in Surveys with graded analytes matching those for which the laboratory performs patient testing. Enrollment in CAP Surveys containing ungraded analytes is strongly encouraged.

****NEW****

09/27/2007

TRM.05000

Phase I

N/A YES NO

Does the laboratory's current CAP Activity Menu accurately reflect the testing performed?

NOTE: An accurate Activity Menu is required to properly assess a laboratory's compliance with proficiency testing requirements. The accuracy of the Activity Menu can be assessed by inquiry of responsible individuals, and by examination of the laboratory's test requisition(s), computer order screens, procedure manuals, or patient reports. All tests performed by the laboratory should be listed on the Activity Menu, and visa versa.

If tests are identified that are not included on the laboratory's test menu, the inspector should contact the CAP (800-323-4040) for instructions.

Please note that unusual or esoteric tests performed in the laboratory section may not be specifically listed on the laboratory's activity menu but may be identified on the activity menu as a miscellaneous code. Further information may be found with the laboratory's instrumentation list. Some activities are also included on the Master Activity Menu using more generic groupings or panels instead of listing the individual tests. The Master Activity Menu represents only those analytes that are directly measured. Calculations are not included.

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2004(Oct 1): 985 [42CFR493.51].

TRM.10000

Phase II

N/A YES NO

Does the laboratory participate in the appropriate required CAP Surveys or another proficiency testing (PT) program accepted by CAP for the patient testing performed?

NOTE: The list of analytes for which CAP requires proficiency testing is available on the CAP website [<http://www.cap.org/>] or by phoning 800-323-4040 (or 847-832-7000), option 1. A laboratory's participation in proficiency testing must include all analytes on this list for which it performs patient testing. Participation in proficiency testing may be through CAP Surveys or another proficiency testing provider accepted by CAP. Laboratories will not be penalized if they are unable to participate in an oversubscribed program. If unable to participate, however, the laboratory must implement an alternative assessment procedure for the affected analytes. For regulated analytes, if the CAP and CAP-accepted PT programs are oversubscribed, CMS requires the laboratory to attempt to enroll in another CMS-approved PT program.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801]; 2) Westgard JO, *et al*. Laboratory precision performance. State of the art versus operating specifications that assure the analytical quality required by Clinical Laboratory Improvement Amendments proficiency testing. *Arch Pathol Lab Med*. 1996;120:621-625; 3) NCCLS. *Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition*. NCCLS document GP22-A2 (ISBN 1-56238-552-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004; 4) College of American Pathologists, Commission on Laboratory Accreditation. Standards for laboratory accreditation; Standard III. Northfield, IL: CAP, 1999.

TRM.10050**Phase II****N/A YES NO**

For tests for which CAP does not require PT, does the laboratory at least semiannually 1) participate in external PT, or 2) exercise an alternative performance assessment system for determining the reliability of analytic testing?

NOTE: Other appropriate performance assessment procedures may include: split sample analysis with reference or other laboratories, split samples with an established in-house method, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such alternative performance assessment procedures, as applicable, in accordance with good clinical and scientific laboratory practice. Participation in ungraded/educational proficiency testing programs also satisfies this checklist question.

Semiannual alternative assessment must be performed on tests for which PT is not available.

The list of analytes for which CAP requires proficiency testing is available on the CAP website [<http://www.cap.org/>] or by phoning 800-323-4040 (or 847-832-7000), option 1.

COMMENTARY:

N/A

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):7184 [42CFR493.1236(c)(1)]; 2) Shahangian S, *et al*. A system to monitor a portion of the total testing process in medical clinics and laboratories. Feasibility of a split-specimen design. *Arch Pathol Lab Med*. 1998;122:503-511.

TRM.10100**Phase II****N/A YES NO**

Does the laboratory integrate all proficiency testing samples within the routine laboratory workload, and are those samples analyzed by personnel on all shifts who routinely test patient samples, using the same primary method systems as for patient/donor samples?

NOTE: Replicate analysis of proficiency testing samples is acceptable only if patient specimens are routinely analyzed in the same manner. With respect to morphologic examinations (identification of cell types and microorganisms; review of electrophoretic patterns, etc.), group review and consensus identifications are permitted only for unknown samples that would ordinarily be reviewed by more than one person in an actual patient sample.

If the laboratory uses multiple methods for an analyte, proficiency testing samples should be analyzed by the primary method. The educational purposes of proficiency testing are best served by a rotation that allows all technologists to be involved in the proficiency testing program. Proficiency testing records must be retained and can be an important part of the competency and continuing education documentation in the personnel files of the individuals. When external proficiency testing materials are not available, the semi-annual alternative performance assessment process should also be integrated within the routine workload, if practical.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7146 [42CFR493.801(b)]; 2) Shahangian S, *et al*. Toward optimal PT use. *Med Lab Observ*. 2000;32(4):32-43.

****REVISED**** 09/27/2007**TRM.10150****Phase II****N/A YES NO**

Is there ongoing evaluation of PT and alternative assessment results, with prompt corrective action taken for unacceptable results?

NOTE: Compliance with this item can be examined by selecting a sample of PT evaluation results and alternative assessment records. Special attention should be devoted to unacceptable results. Compliance requires that all of the following are true:

1. *There is documented evidence of ongoing review of all PT reports and alternative assessment results by the laboratory director or the director's designee. Reviews should be completed within one month of the date reports and results become available to the laboratory.*
2. *All "unacceptable" PT results and alternative assessment test result have been investigated.*
3. *Corrective action has been initiated for all unacceptable PT and alternative assessment results. Corrective action is appropriate to the nature and magnitude of the problem; it might consist of staff education, instrument recalibration, change in procedures, institution of new clerical checks, discontinuation of patient testing for the analyte or discipline in question, or other appropriate measures.*
4. *Primary records related to PT and alternative assessment testing are retained for two years (unless a longer retention period is required elsewhere in this checklist for specific analytes or disciplines). These include all instrument tapes, work cards, computer printouts, evaluation reports, evidence of review, and documentation of follow-up/corrective action.*

COMMENTARY:

N/A

REFERENCES: 1) Clinical and Laboratory Standards Institute (CLSI). *Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition*. CLSI document GP27-A2 (ISBN 1-56238-632-8). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2007; 2) Shahangian S, *et al*. Toward optimal PT use. *Med Lab Observ*. 2000;32(4):32-43; 3) Zaki Z, *et al*. Self-improvement by participant interpretation of proficiency testing data from events with 2 to 5 samples. *Clin Chem*. 2000;46:A70.

****NEW****

04/06/2006

TRM.13466

Phase II

N/A YES NO

Is there a policy that prohibits interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider?

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb

28):7146 [42CFR493.801(b)(3)]; 2) Bierig JR. Comparing PT results can put a lab’s CLIA license on the line. Northfield, IL: College of American Pathologists *CAP Today*. 2002;16(2):84-87.

****NEW**** **04/06/2006**

TRM.16732 Phase II N/A YES NO

Is there a policy that prohibits referral of proficiency testing specimens to another laboratory?

NOTE: Under CLIA-88 regulations, there is a strict prohibition against referring proficiency testing specimens to another laboratory. In other words, the laboratory may not refer a proficiency testing specimen to a laboratory with a different CLIA number (even if the second laboratory is in the same health care system).

COMMENTARY:

N/A

REFERENCE: Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28): [42CFR493.801(b)(4)].

QUALITY MANAGEMENT AND QUALITY CONTROL

GENERAL ISSUES

TRM.20000 Phase II N/A YES NO

Does the transfusion medicine section have 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 preanalytic, 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 questions in the Laboratory General Checklist pertain to the transfusion medicine section.

COMMENTARY:

N/A

REFERENCES: 1) Krempel G, Jarosz C. Transfusion medicine's role in hospital performance improvement. An administrator's view. *Arch Pathol Lab Med.* 1999;123:486-491; 2) Alving B, Alcorn K. How to improve transfusion medicine. A treating physician's perspective. *Arch Pathol Lab Med.* 1999;123:492-495; 3) Mancini ME. Performance improvement in transfusion medicine. What do nurses need and want? *Arch Pathol Lab Med.* 1999;123:496-502; 4) Kopko PM, Holland PV. Process improvement in transfusion medicine. One blood center's approach. *Arch Pathol Lab Med.* 1999;123:569-575; 5) Hanson M. The "P's and Q's" of quality systems. *Arch Pathol Lab Med.* 1999;123:576-579; 6) Sherman LA. Outcomes in transfusion. *Arch Pathol Lab Med.* 1999;123:599-602; 7) AuBuchon JP. Optimizing the cost-effectiveness of quality assurance in transfusion medicine. *Arch Pathol Lab Med.* 1999;123:603-606; 8) AuBuchon JP. The role of transfusion medicine physicians. A vanishing breed? *Arch Pathol Lab Med.* 1999;123:663-667; 9) Novis DA, *et al.* Quality indicators of blood utilization. Three College of American Pathologists Q-probes studies of 12, 288, 404 red blood cell units in 1639 hospitals. *Arch Pathol Lab Med.* 2002;126:150-156; 10) Novis DA, *et al.* Quality indicators of fresh frozen plasma and platelet utilization. Three College of American Pathologists Q-probes studies of 8 981 796 units of fresh frozen plasma and platelets in 1639 hospitals. *Arch Pathol Lab Med.* 2002;126:527-532; 11) Novis DA, *et al.* Operating room blood delivery turnaround time. A College of American Pathologists Q-Probes study of 12 647 units of blood components in 466 institutions. *Arch Pathol Lab Med.* 2002;126:909-914.

TRM.30000

Phase II

N/A YES NO

Is there documentation of ongoing evaluation by the laboratory director or designee of all of the following?

1. **Control results of routine procedures**
2. **Reactivity of reagents**
3. **Instrument function checks**
4. **Temperature records**

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

COMMENTARY:

N/A

TRM.30400**Phase II****N/A YES NO**

Is there a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results, in a timely manner?

NOTE: The laboratory must have a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results. One common method is review of results by a qualified person (technologist, supervisor, pathologist) before release from the laboratory, but there is no requirement for supervisory review of all reported data. The selective use of delta checks also may be useful in detecting clerical errors in consecutive samples from the same patient/client. 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 suspected errors detected by the end user after reporting, corrections must be promptly made if such errors are confirmed by the laboratory.

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.

COMMENTARY:

N/A

****REVISED**** 10/31/2006**TRM.30550****Phase II****N/A YES NO**

Does the facility have 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.

COMMENTARY:

N/A

REFERENCES: 1) Linden JV, *et al.* A report of 104 transfusion errors in New York State. *Transfusion*. 1992;32:601-6; 2) Dzik WH, *et al.* An international study of the performance of patient sample collection. *Vox Sanguinis* 2003;85:40-47; 3) Lumadue JA, *et al.* Adherence to a strict specimen-labeling policy decreases the incidence of erroneous blood grouping of blood bank specimens. *Transfusion* 1997;37:1169-72.

****NEW**** 10/31/2006

****REVISED**** 09/27/2007

TRM.30575 Phase I N/A YES NO

Does the facility have 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. The use of a second manual banding system, while currently acceptable, is probably not as effective as the above two options. 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.

COMMENTARY:

N/A

REFERENCES: 1) WH Dzik, MF Murphy, G Andreu, MD *et al.* An international study of the performance of patient sample collection. *Vox Sanguinis* 2003;85:40-47; 2) Lumadue JA, Boyd JS, Ness PM. Adherence to a strict specimen-labeling policy decreases the incidence of erroneous blood grouping of blood bank specimens. *Transfusion* 1997;37:1169-72; 3) Wenz B, Burns ER. Improvement in transfusion safety using a new blood unit and patient identification system as part of safe transfusion practice. *Transfusion*. 1991;31:401-3; 4) Callum JL, Kaplan HS, Merkley LL *et al.* Reporting of near-miss events for transfusion medicine: improving transfusion safety. *Transfusion* 2001;41:1204-11.

"record of disposition" refers to record of whether the unit was released for transfusion, transfused, transplanted, or discarded.

COMMENTARY:

N/A

REFERENCE: Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, current edition:[21CFR606.160].

TRM.30850

Phase II

N/A YES NO

Is there 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 medical staff, 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.

COMMENTARY:

N/A

REFERENCE: Sazama K. The changing relationships in transfusion medicine. *Arch Pathol Lab Med.* 1999;123:668-671.

TRM.30866

Phase II

N/A YES NO

Is there 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 products. Agreements should be approved by the medical staff, transfusion service medical director, and hospital administration.

COMMENTARY:

N/A

TRM.30882 Phase II

N/A YES NO

Does the transfusion service laboratory have 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.

COMMENTARY:

N/A

TRM.30900 Phase II

N/A YES NO

Is there 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 physician 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 physician 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 stem hemorrhage.

COMMENTARY:

N/A

REFERENCES: 1) Lam H-TC, *et al.* Are retrospective peer-review transfusion monitoring systems effective in reducing red blood cell utilization? *Arch Pathol Lab Med.* 1996;120:810-816; 2) Shulman G, *et al.* Creating useful statistics to audit transfusion services. *Lab Med.* 1998;29:371-374.

****NEW******10/31/2006****TRM.30950****Phase I****N/A YES NO****Is there a policy requiring notification of the Centers for Biologics Evaluation and Research according to U.S. federal regulations when a biological product deviation occurs?**

NOTE: A manufacturer 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 21 CFR 606.171, 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. Manufacturing in a transfusion service may include compatibility testing, component preparation, labeling, storage, and distribution of units for transfusion. A BPDR is reportable to CBER if the transfusion service releases a blood product from its control and the error has the potential to effect the safety, potency or purity of the product, even if it is not administered to a patient.

COMMENTARY:

N/A

REFERENCES: 1) California Blood Bank Society “Does an unlicensed, unregistered transfusion service need to report Biological Product Deviations to the FDA?” http://www.cbbsweb.org/enf/2005/unreg_report_bpdfa.html; 2) US Food and Drug Administration Biologic Product Deviation Reporting <http://www.fda.gov/cber/biodev/biodev.htm>.

PROCEDURE MANUAL

The procedure manual should be used by personnel at the workbench and should include: test principle, clinical significance, specimen type, required reagents, test calibration, quality control, procedural steps, calculations, reference intervals, and interpretation of results. The manual should address relevant pre-analytic and post-analytic considerations, as well as the analytic activities of the laboratory. The specific style and format of procedure manuals are at the discretion of the laboratory director.

The inspection team should review the procedure manual in detail to understand the laboratory's standard operating procedures, ensure that all significant information and instructions are included, and that actual practice matches the contents of the procedure manuals.

****REVISED**** **04/06/2006**

TRM.31000

Phase II

N/A YES NO

Is a complete procedure manual available at the workbench or in the work area?

NOTE 1: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed or electronic procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly documented.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

- a. A complete manual is available for reference*
- b. The card file or similar system corresponds to the complete manual and is subject to document control*

NOTE 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures must be available to laboratory personnel when the electronic versions are inaccessible (e.g., during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers. All procedures, in either electronic or paper form, must be readily available for review by the inspector at the time of the CAP inspection.

Electronic versions of procedures must be subjected to proper document control (i.e., only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of annual review). Documentation of review of electronic procedures may be accomplished by including statements such as "reviewed by [name of reviewer] on [date of review]" in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.

COMMENTARY:

N/A

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 [42CFR493.1251]; 2) van Leeuwen AM. 6 Steps to building an efficiency tool. *Advance/Laboratory*. 1999;8(6):88-91; 3) Borkowski A, *et al*. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol*. 2001;14:1-5; 4) Clinical and Laboratory Standards Institute (CLSI). *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition*. CLSI document GP2-A5 (ISBN 1-56238-600-X). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

TRM.31150**Phase II****N/A YES NO**

Is there documentation of at least annual review of all policies and procedures by the current laboratory director or designee?

NOTE: The director must ensure that the collection of policies and technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

COMMENTARY:

N/A

REFERENCES: 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 1992(Feb 28):7173 [42CFR493.1407(e)(13)]; 2) Borkowski A, *et al*. Intranet-based quality improvement documentation at the Veterans Affairs Maryland health care system. *Mod. Pathol*. 2001;14:1-5.

TRM.31155**Phase II****N/A YES NO**

Does the director (or a designee who meets CAP director qualifications) review and approve all new policies and procedures, as well as substantial changes to existing documents, before implementation?

NOTE: Current practice must match the policy and procedure documents.

COMMENTARY:

N/A

N/A

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 questions 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).

****REVISED**** **09/27/2007**

TRM.31220 **Phase II** **N/A YES NO**

Are reagents and solutions 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. The inspector will describe specific issues of non-compliance in the Inspector's Summation Report.

COMMENTARY:

N/A

TRM.31241

Phase II

N/A YES NO

Are all new lots of reagents and critical materials (e.g., blood collection sets) inspected and tested, as applicable, before use, with documentation of acceptance?

COMMENTARY:

N/A

TRM.31250

Phase II

N/A YES NO

Are all reagents 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."

COMMENTARY:

N/A

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); 3) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Equipment. Supplies and reagents. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.65(e)].

TRM.31350

Phase II

N/A YES NO

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

COMMENTARY:

N/A

REFERENCE: 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)].

TRM.31375**Phase II****N/A YES NO**

Is an appropriate inventory control system in use to track the use of all lot numbers of critical materials received?

NOTE: Tracking must include date received, placed into use, discarded or returned to the supplier.

COMMENTARY:

N/A

****REVISED****

10/31/2006

TRM.31400**Phase II****N/A YES NO**

Do 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 are manufacturer's directions for daily quality control 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.

COMMENTARY:

N/A

REFERENCE: 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):7171 [42CFR493.1217].

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. The inspection team should review the procedures for instrument-equipment operations, maintenance, and monitoring records to ensure that these devices are properly used.

TRM.31500 Phase II N/A YES NO

Is an appropriate thermometric standard device of known accuracy available? (NIST-certified or 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.

COMMENTARY:

N/A

TRM.31600 Phase II N/A YES NO

Are all non-certified thermometers in use, including blood-warmer thermometers, checked before being placed in service, and periodically thereafter, against an appropriate thermometric standard device?

COMMENTARY:

N/A

TRM.31700 Phase II N/A YES NO

Are calibrated thermometers 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.

COMMENTARY:

N/A

TRM.31800**Phase II****N/A YES NO**

Are temperatures checked and recorded on each day of use, specifying the unit and location for all temperature dependent instruments and equipment?

NOTE: This checklist question 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.

COMMENTARY:

N/A

TRM.31900**Phase II****N/A YES NO**

Are mechanical timers on serologic centrifuges, and the speed of the centrifuge, checked for accuracy every 6 months?

NOTE: Most serologic centrifuges and timers do not require frequent recalibration. However, 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.

COMMENTARY:

N/A

REFERENCE: Food and Drug Administration. Current good manufacturing practice for blood and blood components. Equipment. Washington, DC: US Government Printing Office, 2000(Apr 1):[21CFR606.60(b)].

TRM.32000**Phase II****N/A YES NO**

Are all instruments and equipment used by the transfusion service laboratory 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.

COMMENTARY:

N/A

TRM.32100 Phase II N/A YES NO

Are instrument maintenance, service and repair records (or copies) 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.

COMMENTARY:

N/A

TRM.32200 Phase II N/A YES NO

Is equipment used to regulate volume of blood drawn from blood donors or individuals undergoing therapeutic phlebotomy 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.

COMMENTARY:

N/A

REFERENCES: 1) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Equipment. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.60]; 2) *ibid*. Equipment. Supplies and reagents. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.100].

TRM.32208**Phase II****N/A YES NO**

Is a process 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.

COMMENTARY:

N/A

TRM.32216**Phase II****N/A YES NO**

Is there 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 are results documented?

COMMENTARY:

N/A

REFERENCES: 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab*. 1994;12(7):8-9; 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab*. 1994;12(9):16-17; 3) Perrier S, *et al*. Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem*. 1995;41:S183; 4) Bray W. Software for the gravimetric calibration testing of pipets. *Am Clin Lab*. Oct 1995 (available on the Internet at http://www.labrtrronics.com/pt_art.htm); 5) Kroll MH, *et al* (eds). *Laboratory Instrumentation Evaluation, Verification & Maintenance Manual*. 5th ed. Northfield, IL: College of American Pathologists. 1999;126-127; 6) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist*. 1999;13(12):14; 7) Connors M, Curtis R. Pipetting error: a real problem with a simple solution. Parts I and II. *Am Lab News*. 1999;31(13):20-22; 8) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med*. 2000;31:478-479.

TRM.32232**Phase II****N/A YES NO**

Are automatic pipettes used for quantitative dispensing checked for accuracy and reproducibility at specified, periodic intervals, and are the results recorded?

NOTE: Automatic pipettes used for quantitative dispensing must be checked for accuracy and reproducibility at specified, periodic intervals, depending upon the laboratory's intensity of pipette usage. 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.

COMMENTARY:

N/A

REFERENCES: 1) Curtis RH. Performance verification of manual action pipets. Part I. *Am Clin Lab.* 1994;12(7):8-9; 2) Curtis RH. Performance verification of manual action pipets. Part II. *Am Clin Lab.* 1994;12(9):16-17; 3) Perrier S, *et al.* Micro-pipette calibration using a ratiometric photometer-reagent system as compared to the gravimetric method. *Clin Chem.* 1995;41:S183; 4) Bray W. Software for the gravimetric calibration testing of pipets. *Am Clin Lab.* Oct 1995 (available on the Internet at http://www.labrtronics.com/pt_art.htm); 5) Kroll MH, *et al* (eds). *Laboratory Instrumentation Evaluation, Verification & Maintenance Manual.* 5th ed. Northfield, IL: College of American Pathologists. 1999;126-127; 6) Johnson B. Calibration to dye for: Artel's new pipette calibration system. *Scientist.* 1999;13(12):14; 7) Connors M, Curtis R. Pipetting error: a real problem with a simple solution. Parts I and II. *Am Lab News.* 1999;31(13):20-22; 8) Skeen GA, Ashwood ER. Using spectrophotometry to evaluate volumetric devices. *Lab Med.* 2000;31:478-479.

RECORDS

The following routine records must be retained and available as required by applicable federal and local law; but, in no instance for fewer than 5 years after the records for processing have been completed, or 6 months after the latest expiration date for an individual component (whichever is later), in accordance with 21 CFR 606.160(d) and 42CFR493.1202 through 493.1221.

****REVISED**** **09/27/2007**

TRM.32250 **Phase II** **N/A YES NO**

Are immunohematology records 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:

<i>TYPE OF RECORD</i>	<i>RETENTION PERIOD</i>
<i>Donor Records</i>	
Blood/component donor information, consent and collection Donor blood testing Donor notification of significant findings Component production Look back investigation/disease reporting Final unit disposition	<i>10 years</i>
Indefinitely and permanently deferred donors Donors placed under surveillance (for recipient protection)	<i>Indefinitely</i>
<i>Patient Records</i>	
Transfusion administration records (TRM.41450) Therapeutic phlebotomy/apheresis records Final unit disposition	<i>10 years</i>

Patient pre-transfusion testing results/interpretation Immediate evaluation/interpretation of transfusion reactions	5 years
Transfusion problems such as transfusion reactions, unexpected antibodies, and special transfusion requirements.	<i>Indefinitely</i>
Employee signatures, initials, and identification codes	10 years
<i>Quality Control Records</i>	
Quality management reviews Proficiency testing records Inspections of blood/critical materials Instrument/equipment quality control and maintenance Irradiation dose delivery Control systems for patient testing Retyping of donor units Annual procedure review/procedures discontinued	5 years
Control systems for donor testing	10 years
<i>Tissue Records (including bone marrow and/or progenitor cells)</i>	
Collection, transportation, processing, issuing, disposition	10 yrs beyond tissue's disposition or expiration, whichever is longer
Daily temperature monitoring	10 years

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

COMMENTARY:

N/A

****NEW****

09/27/2007

TRM.32275

Phase II

N/A YES NO

Do the records include documentation of each component from receipt/collection through processing, storage, and testing, to final disposition?

NOTE: The inspector should review the records of selected units (one or more component types) to document successful completion of all steps required by this checklist, from receipt of blood components, through storage and testing, to final disposition (including transfusion records).

COMMENTARY:

N/A

TRM.32300

Phase II

N/A YES NO

Do records include information about all blood received from outside sources?

COMMENTARY:

N/A

TRM.32350

Phase II

N/A YES NO

Is a process 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.

COMMENTARY:

N/A

TRM.32900

Phase II

N/A YES NO

Do records include information about bacteriologic studies (when indicated)?

COMMENTARY:

N/A

TRM.33200

Phase II

N/A YES NO

Can the laboratory 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 in that all relevant data are available. This would include not only results, but also 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.

COMMENTARY:

N/A

REFERENCE: Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.160].

TRM.33300

Phase II

N/A YES NO

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

COMMENTARY:

N/A

PROCEDURES AND TESTS

IMMUNOHEMATOLOGICAL PROCEDURES

TRM.40050 **Phase II** **N/A YES NO**

Are criteria for agglutination and/or hemolysis 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.)

COMMENTARY:

N/A

TRM.40100 **Phase II** **N/A YES NO**

Are observations of all test results recorded properly at the time done?

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

COMMENTARY:

N/A

TRM.40120 **Phase II** **N/A YES NO**

Are control specimens tested in the same manner and by the same personnel as patient samples?

NOTE: It is implicit in quality control (QC) that control specimens are tested in the same manner as patient/client specimens. Moreover, QC specimens must be analyzed by personnel who routinely perform patient/client 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/clients.

COMMENTARY:

N/A

REFERENCE: 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):7166 [42CFR493.1256(e)(1)].

TRM.40140

Phase II

N/A YES NO

Are the results of controls 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.

COMMENTARY:

N/A

REFERENCE: 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):7166 [42CFR493.1256(d)(8)].

TRM.40150

Phase II

N/A YES NO

Are appropriate control(s) used for anti-D testing?

NOTE: High protein anti-D reagents require concurrent testing of an inert preparation of the manufacturer's diluent. Monoclonal anti-D reagents do not ordinarily require a separate reagent control (see manufacturer instructions). Incorrect assignment of a D-positive phenotype can be ruled out by observing negative reactions in any tube containing red cells and patient serum, or, alternatively, patient cells suspended in 5% bovine albumin.

COMMENTARY:

N/A

TRM.40200 **Phase II** **N/A YES NO**

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

NOTE: IgG-coated red blood cells must be used to confirm all negative antiglobulin tests when the antiglobulin reagent used for testing has anti-IgG reactivity. Tests found negative by tube methodology must be checked with the addition of appropriate check cells. If a licensed system is used that does not require the use of IgG-coated cells, an appropriate quality control system must be followed, as recommended by the manufacturer.

COMMENTARY:

N/A

TRM.40210 **Phase I** **N/A YES NO**

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

NOTE: Complement-coated red blood cells should be used to confirm all negative antiglobulin tests when the antiglobulin reagent used for testing has anti-C3 reactivity. Tests found negative by tube methodology should be checked with the addition of appropriate check cells. If a licensed system is used that does not require the use of C3-coated cells, an appropriate quality control system must be followed, as recommended by the manufacturer. If polyspecific antiglobulin is used, refer to question TRM.40200.

COMMENTARY:

N/A

TRM.40220 **Phase II** **N/A YES NO**

Are critical results established for certain tests that are important for prompt patient management decisions?

NOTE: The laboratory must establish critical results for certain tests in immunohematology, in conjunction with the medical staff, to ensure immediate notification of a physician or other clinical personnel responsible for patient care. These critical results may be indicated in the procedure manual and/or in a separate manual or policy. The bench technologists must be familiar with critical results and the related procedures. For example, the finding of hemolysis and/or a positive direct antiglobulin test result in the investigation of an acute transfusion reaction might be defined by the laboratory as a critical result.

COMMENTARY:

N/A

REFERENCES: 1) Kost GJ. Critical limits for urgent clinician notification at US medical centers. *JAMA*. 1990;263:704-707; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):[42CFR493.11251(b)(13),CFR493.1291(g)]; 3) Steindel SJ, Heard NV. Critical values: data analysis and critique. Q-Probes 92-04. Northfield, IL: College of American Pathologists, 1992; 4) Kost GJ. Using critical limits to improve patient outcome. *Med Lab Observ*. 1993;25(3):22-27; 5) Tate KE, Gardner RM. Computers, quality, and the clinical laboratory: a look at critical values. *Proc Annu Symp Comput Appl Med Care*. 1993;193-197; 6) Kaufman HW, Collins C. Notifying clients of life-threatening results. *Med Lab Observ*. 1994;26(8):44-45; 7) Emancipator K. Critical values. ASCP practice parameter. *Am J Clin Pathol*. 1997;108:247-253; 8) Dalton-Beninato K. Critical value notifications are never welcome news. *Lab Med*. 2000;31:319-323; 9) Howanitz PJ, et al. Laboratory critical values policies and procedures. A College of American Pathologists Q-probes study in 623 institutions. *Arch Pathol Lab Med*. 2000;126:663-669.

COMPATIBILITY TESTING

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

TRM.40230

Phase II

N/A YES NO

Are all blood samples used for compatibility testing labeled at the time of specimen collection with the patient's first and last name, unique identification number, and the date of collection?

NOTE: Blood specimens taken for compatibility testing must be positively and completely identified before leaving the patient's side. Best practice is to use an electronic system to read the identifying information from the patient's wristband and generate a label at the bedside.

COMMENTARY:

N/A

REFERENCES: 1) Wenz B, et al. Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. *Am J Clin Pathol*. 1997;107(suppl 1):S12-S16; 2) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med*. 1997;28:203-207.

****NEW**** **09/27/2007**

TRM.40235 Phase II N/A YES NO

Is the patient asked to verbally verify his/her identity, whenever possible, at the time of specimen collection?

COMMENTARY:

N/A

TRM.40240 Phase II N/A YES NO

If the specimen label does not have the initials or other identifier of the phlebotomist, is there another system to identify which person collected each blood sample for compatibility testing?

NOTE: There must be a dependable method to identify the phlebotomist who collected the blood sample.

COMMENTARY:

N/A

TRM.40250 Phase II N/A YES NO

Does an appropriately trained member of the transfusion service confirm that all identifying data on the transfusion requisition is identical to the information on the specimen tube before immunohematology testing?

COMMENTARY:

N/A

TRM.40300 Phase II N/A YES NO

Are ABO, Rh, and antibody screen test results compared against the same tests performed 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.

COMMENTARY:

N/A

TRM.40350

Phase II

N/A YES NO

Are records available that document investigation and reconciliation of all cases in which 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.

COMMENTARY:

N/A

TRM.40450

Phase II

N/A YES NO

Are records available that document the confirmation of ABO/Rh type of all donor units as appropriate, using a sample 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 reconfirmation of the unit's ABO/Rh type if the transfusion service patient pre-transfusion and/or compatibility testing was performed at another CLIA-88-certified laboratory, with confirmation of the unit's ABO/Rh type.

COMMENTARY:

N/A

REFERENCE: 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 Phase II N/A YES NO

Is there 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 recently transfused, or pregnant within the past 3 months, or if relevant medical/transfusion history is unknown or uncertain.

COMMENTARY:

N/A

TRM.40550 Phase II N/A YES NO

Is there a test of each patient's blood sample with anti-A, anti-B, anti-D and A1 and B red cells?

NOTE: The ABO and the 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.

COMMENTARY:

N/A

****REVISED**** *10/31/2006*

TRM.40600 Phase II N/A YES NO

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

COMMENTARY:

N/A

****REVISED**** **10/31/2006**

TRM.40650 **Phase II** **N/A YES NO**

For allogeneic units, is a major serological crossmatch 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.

COMMENTARY:

N/A

****NEW**** **09/27/2007**

TRM.40651 **Phase I** **N/A YES NO**

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

COMMENTARY:

N/A

TRM.40652 **Phase II** **N/A YES NO**

For non-group O neonates receiving non-group O red blood cells, is there a process in place to screen the neonate's serum 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 B should include an anti-globulin phase.

COMMENTARY:

N/A

TRM.40655

Phase II

N/A YES NO

When a direct antiglobulin test is ordered by a patient's physician, does the test system allow detection of RBC-bound complement as well as IgG?

NOTE: This ensures detection of patients with paroxysmal cold hemoglobinuria, cold hemagglutinin disease (CHAD), warm autoimmune hemolytic anemia, and drug-induced hemolytic anemia. For the purpose of diagnosing hemolytic disease of the newborn, use of anti-C3 is not required.

Patients with cold hemagglutinin disease, anemia related to some immune complex-mediated hemolytic states (e.g., drug-induced immune complex hemolytic anemia), and up to 15% of patients with warm antibody autoimmune hemolytic anemia may have a positive direct antiglobulin test from complement coating of their red cells, without detectable IgG on the red cells.

COMMENTARY:

N/A

REFERENCES: 1) Sokol RJ, *et al.* Autoimmune haemolysis: an 18-year study of 865 cases referred to a regional transfusion centre. *Brit Med J.* 1981;282:2023-2027; 2) Packman CH, Leddy JP, Cryopathic hemolytic syndromes. In: Beutler E, *et al.*, eds. *William's Hematology*, 5th ed. New York: McGraw-Hill, 1995:685-691; 3) Vengelen-Tyler V, ed. *American Association of Blood Banks Technical Manual*, 13th ed. Bethesda, MD: AABB Press, 1999:259-262.

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Computer Crossmatches

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

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

TRM.40660

Phase II

N/A YES NO

Has the computer crossmatch system and protocol been validated on-site?

NOTE: The FDA recently modified the regulations on electronic crossmatching. The definition of "compatibility testing" in 21CFR606.15(c) had the reference to serological tests removed, making the definition more general to methods used to establish the matching of a donor's blood components with that of a potential recipient. This change permits current practices used in compatibility testing, such as electronic crossmatching and immediate spin crossmatch. Laboratories are no longer required to

request a variance from the FDA to allow for electronic crossmatching. However, the system must be validated in-house.

COMMENTARY:

N/A

REFERENCE: Food and Drug Administration. Revisions to the requirements applicable to blood, blood components, and source plasma. *Fed Register*. 1999(Aug 19):[42CFR606.15(c)].

TRM.40670 Phase II N/A YES NO

Has the recipient's ABO blood group 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.

COMMENTARY:

N/A

TRM.40680 Phase II N/A YES NO

Does the laboratory information system contain 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?

COMMENTARY:

N/A

TRM.40690 Phase II N/A YES NO

If a serologic crossmatch is not performed, is there a method to verify correct computer data entry before issuing blood or blood components, and does the computer alert 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

1992; 2) Guidelines for the use of platelet transfusions, *Br J Haematology* 122: 10, 2003 (<http://www.bcsghguidelines.com/pdf/platelettrans040703.pdf>); 3) Menitove, JE, Immunoprophylaxis for D- patients receiving platelet transfusions from D+ donors? *Transfusion* 42: 136, 2002; 4) Lichtiger B, Hester JP. Transfusion of Rh-incompatible blood components to cancer patients. *Haematologia*. 1986;19:81-88.

TRM.40720 **Phase II** **N/A YES NO**

In patients with immuno-hematologic conditions (clinically significant red cell antibodies, transplantation, etc.) requiring special blood components (red cell antigen-negative, irradiated, CMV-safe, hemoglobin S-negative, etc.), is there a procedure for providing appropriate components?

NOTE: A procedure must exist to provide blood components that are appropriately antigen-negative, crossmatch-compatible, irradiated, etc., based on a patient's individual needs. Exceptions may be made in certain clinical situations, but only with the approval of the physician responsible for the transfusion service, or designee.

COMMENTARY:

N/A

TRM.40740 **Phase II** **N/A YES NO**

Is there a policy to prevent or limit the administration of ABO-incompatible donor plasma in platelets given to infants?

NOTE: For infant recipients, donor plasma in platelets must 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 saline or albumin solution.

COMMENTARY:

N/A

TRM.40760 **Phase II** **N/A YES NO**

Are the red cells in granulocytes and/or platelets crossmatch-compatible with the recipient's plasma, except when the method of procurement results in a component with less than 2 mL of donor red cells?

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

COMMENTARY:

N/A

TRM.40770

Phase II

N/A YES NO

Have adequate policies and procedures 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 of 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.

COMMENTARY:

N/A

REFERENCES: 1) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Laboratory controls. Compatibility testing. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.151]; 2) *ibid*. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.160].

PERINATAL TESTING

TRM.40780

Phase II

N/A YES NO

Is there 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-88-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.

COMMENTARY:

N/A

REFERENCE: NCCLS. *Fetal Red Cell Detection; Approved Guideline*. NCCLS document H52-A (ISBN 1-56238-452-X). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

TRM.40790

Phase II

N/A YES NO

Are identified Rh immune globulin candidates 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 reliable method should be used to determine the appropriate dosage of Rh immune globulin, based on the estimated quantity of fetal blood in the maternal circulation. Consideration should be given to use of a quantitative method, such as flow cytometry to detect fetal erythrocytes, instead of the manual microscopic Kleihauer-Braun-Betke method.

COMMENTARY:

N/A

REFERENCES: 1) Pollack W, *et al.* Studies of Rh prophylaxis: relationship between dose of anti-Rh globulin and size of antigen stimulus. *Transfusion*. 1971;11:333-339; 2) Thein SL, Reittie JE. F cells by immunofluorescent staining of erythrocyte smears. *Hemoglobin*. 1998;22:427-444; 3) Casey M, *et al.* Comparison of 2 methods of detecting fetomaternal hemorrhage in Rh-negative women. *Am J Clin Pathol*. 1999;112:556; 4) NCCLS. *Fetal Red Cell Detection; Approved Guideline*. NCCLS document H52-A (ISBN 1-56238-452-X). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001; 5) Sandrick K. Keep the classic or move to modern? Weighing whether flow cytometry can replace Kleihauer-Braun-Betke. *College of American Pathologists CAP Today*. 2000;14(4):76-82; 6) Pourbabak S, Crookston KP. Massive fetomaternal hemorrhage may occur without clinical suspicion. *Am J Clin Pathol*. 2000;114:313.

TRM.40800 Phase II N/A YES NO

Is there a mechanism to ensure that Rh immune globulin is administered to all identified candidates within 72 hours of an 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.

COMMENTARY:

N/A

TRM.40820 Phase II N/A YES NO

Is there 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.

COMMENTARY:

N/A

TRANSFUSION PROCEDURES

TRM.40850 Phase I N/A YES NO

Is there documentation that the transfusion service medical director actively participates in establishing criteria for transfusion, reviewing cases not meeting transfusion audit criteria, and monitoring transfusion practices?

NOTE: The transfusion service medical director should 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.

COMMENTARY:

N/A

REFERENCE: Toy P. Guiding the decision to transfuse. Interventions that do and do not work. *Arch Pathol Lab Med.* 1999;123:592-594.

TRM.40875

Phase I

N/A YES NO

Is there documentation that the transfusion service medical director participates in the development of policies, processes, and procedures regarding recipient consent for transfusion/transplantation?

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.

COMMENTARY:

N/A

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; 2) Sherman LA. Legal issues in blood banking. Elements of informed consent. *Clin Lab Med.* 1996 Dec;16(4):931-46.

****REVISED** 09/27/2007**

TRM.40900

Phase II

N/A YES NO

Does the procedure for signing blood/tissue out of the laboratory provide 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.

COMMENTARY:

N/A

TRM.40950

Phase II

N/A YES NO

Do 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?

COMMENTARY:

N/A

REFERENCE: Wenz B, *et al.* Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. *Am J Clin Pathol.* 1997;107(suppl 1):S12-S16.

TRM.41000

Phase II

N/A YES NO

Is there a procedure for blood administration, including positive identification of transfusion recipients and blood components, and observation of recipients, and is there evidence that all transfusing personnel have been trained and are competent in the procedure?

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

COMMENTARY:

N/A

REFERENCES: 1) Renner SW, *et al.* Wristband identification error reporting in 712 hospitals. A College of American Pathologists' Q-Probes study of quality issues in transfusion practice. *Arch Pathol Lab Med.* 1993;117:573-577; 2) Mancini ME. Performance improvement in transfusion medicine. What do nurses need and want? *Arch Pathol Lab Med.* 1999;123:496-502; 3) Shulman IA, *et al.* Assessing blood administering practices. *Arch Pathol Lab Med.* 1999;123:595-598.

TRM.41050 Phase II N/A YES NO

Are there 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.

COMMENTARY:

N/A

TRM.41150 Phase II N/A YES NO

Is there 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.

COMMENTARY:

N/A

The Inspector should observe a transfusion in progress, whenever possible, to answer the following three questions.

****REVISED** 09/27/2007**

TRM.41300 Phase II N/A YES NO

Is the recipient 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; and is this information matched to the unit of blood (or components) before transfusion?

COMMENTARY:

N/A

REFERENCES: 1) Mancini ME. Performance improvement in transfusion medicine. What do nurses need and want? *Arch Pathol Lab Med.* 1999;123:496-502; 2) Shulman IA, et al. Assessing blood

administering practices. *Arch Pathol Lab Med.* 1999;123:595-598; 3) Wenz B, et al. Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. *Am J Clin Pathol.* 1997;107(suppl 1):S12-S16; 4) Dale JC, Renner SW. Wristband errors in small hospitals. A College of American Pathologists' Q-Probes study of quality issues in patient identification. *Lab Med.* 1997;28:203-207.

TRM.41350 **Phase II** **N/A** **YES** **NO**

Is a compatibility label or tag securely attached to each unit before issuance, and does it remain 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, crossmatching testing results, and interpretations.

COMMENTARY:

N/A

REFERENCE: Wenz B, et al. Practical methods to improve transfusion safety by using novel blood unit and patient identification systems. *Am J Clin Pathol.* 1997;107(suppl 1):S12-S16.

TRM.41450 **Phase II** **N/A** **YES** **NO**

Is there 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?

NOTE: Inspectors should perform a random review of the transfusion records to verify compliance with the required documentation as well as the institution's transfusion administration policies, including the length of time for the transfusion and the monitoring of the patient before, during and after the transfusion.

COMMENTARY:

N/A

REFERENCE: Shulman IA, et al. Assessing blood administering practices. *Arch Pathol Lab Med.* 1999;123:595-598.

COMMENTARY:

N/A

REFERENCE: Yawn DH. Ensuring quality during intraoperative blood salvage. *Lab Med.* 1994;25:626-631.

TRM.41600**Phase I****N/A YES NO**

Is the transfusion service medical director involved in establishing policies and procedures related to intra- and peri-operative collection and reinfusion procedures?

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

COMMENTARY:

N/A

REFERENCE: Yawn DH. Ensuring quality during intraoperative blood salvage. *Lab Med.* 1994;25:626-631.

ADVERSE REACTION PROCEDURES

TRM.41650**Phase II****N/A YES NO**

Are criteria for the recognition of transfusion reactions documented, and is there documentation of periodic in-service education on the recognition of such reactions?

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

COMMENTARY:

N/A

REFERENCE: Sazama K, *et al.* Practice parameter for the recognition, management, and prevention of adverse consequences of blood transfusion. *Arch Pathol Lab Med.* 2000;124:61-70.

TRM.41700 **Phase II** **N/A YES NO**

Are there documented procedures describing actions to be taken in the event of a transfusion reaction?

COMMENTARY:

N/A

REFERENCES: 1) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Adverse reaction file. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.170(b)]; 2) Sazama K, *et al.* Practice parameter for the recognition, management, and prevention of adverse consequences of blood transfusion. *Arch Pathol Lab Med.* 2000;124:61-70.

TRM.41750 **Phase II** **N/A YES NO**

Do policies require that transfusion reactions or incidents be 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.

COMMENTARY:

N/A

TRM.41770 **Phase I** **N/A YES NO**

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

COMMENTARY:

N/A

REFERENCE: AuBuchon JP. The role of transfusion medicine physicians. A vanishing breed? *Arch Pathol Lab Med.* 1999;123:663-667.

TRM.42000 **Phase II** **N/A** **YES** **NO**

Has the transfusion service medical director established a documented protocol indicating under what circumstances additional testing will be done after a transfusion reaction, and the nature of that testing?

COMMENTARY:

N/A

REFERENCE: AuBuchon JP. The role of transfusion medicine physicians. A vanishing breed? *Arch Pathol Lab Med.* 1999;123:663-667.**TRM.42050** **Phase II** **N/A** **YES** **NO**

Are the findings of an adverse reaction investigation 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.

COMMENTARY:

N/A

REFERENCES: 1) AuBuchon JP. The role of transfusion medicine physicians. A vanishing breed? *Arch Pathol Lab Med.* 1999;123:663-667; 2) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Adverse reaction file. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.170(b)].**TRM.42100** **Phase II** **N/A** **YES** **NO**

Is there 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)?

COMMENTARY:

N/A

REFERENCES: 1) Sazama K. The changing relationships in transfusion medicine. *Arch Pathol Lab Med.* 1999;123:668-671; 2) Food and Drug Administration. Current good manufacturing practice for

blood and blood components. Records and reports. Adverse reaction file. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.170(b)].

****NEW****

09/27/2007

TRM.42110

Phase I

N/A YES NO

Is the laboratory developing a plan to reduce the risk of transfusion-related acute lung injury (TRALI)?

NOTE: The laboratory should track the frequency of TRALI.

COMMENTARY:

N/A

REFERENCES: 1) Kleinman S, Caulfield T, Chan P, *et al.* Toward an understanding of transfusion-related acute lung injury: Statement of a consensus panel. *Transfusion* 2004;44:1774-89; 2) Kopko PM, Marshall CS, MacKenzie MR, *et al.* Transfusion-related acute lung injury: Report of a clinical look-back investigation. *JAMA* 2002;287:1968-71; 3) Stainsby D, Cohen H, Jones H, *et al.* Serious Hazards of Transfusion (SHOT) Annual Report 2004. Manchester, UK: SHOT Office, 2005. [Available at <http://www.shot-uk.org>.]; 4) Insunza A, Romon I, Gonzlaes-Ponte ML, *et al.* Implementation of a strategy to prevent TRALI in a regional blood centre. *Transfus Med* 2004;14:157-64.

TRM.42120

Phase II

N/A YES NO

Is there 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.

COMMENTARY:

N/A

REFERENCES: 1) FDA. Enforcement policy. Recall communications. Washington DC: US Government Printing Office. 1999(Apr 1)21 CFR 7.41(d); 2) Food and Drug Administration. General biological products standards. Human immunodeficiency virus (HIV) requirements. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR610.45]; 3) Food and Drug Administration. General biological products standards. "Lookback" requirements. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR610.46 and 610.47].

- 4. Nature and volume of components removed and replaced
- 5. Patient data and criteria for measuring patient response, as available
- 6. Adverse reactions, with medications administered

COMMENTARY:

N/A

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 inspector should verify that procedures are in place to ensure that appropriate temperatures are maintained and documented for each storage area during the time blood and blood components are stored. Whenever practical, the inspector should visit one or more remote blood storage units to verify maintenance and documentation of proper storage temperatures for blood and blood components.

The following component definitions are offered as a convenience:

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

****REVISED**** **10/31/2006**

TRM.42350 **Phase II** **N/A YES NO**

Is the blood storage refrigerator 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.

COMMENTARY:

N/A

TRM.42400

Phase II

N/A YES NO

Does the storage system for blood components minimize 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.

COMMENTARY:

N/A

****REVISED**** **09/27/2007**

TRM.42450

Phase II

N/A YES NO

Are all blood/blood components and tissues inspected upon receipt from the supplier, immediately before use, and at defined intervals, and are records 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.

COMMENTARY:

N/A

REFERENCE: Kim DM, et al. Visual identification of bacterially contaminated red cells. *Transfusion*. 1992;32:221-225.

REFERENCE: Food and Drug Administration. General biological products standards. Dating periods for licensed biological products. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR610.53].

TRM.42500**Phase II****N/A YES NO**

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

COMMENTARY:

N/A

REFERENCES: 1) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Equipment. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.60]; 2) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Records. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.160(b)(3)(iii)].

TRM.42550**Phase II****N/A YES NO**

If the proper storage temperature range is not maintained (inspector will check 4 weeks of recordings), is there 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.

COMMENTARY:

N/A

TRM.42600**Phase II****N/A YES NO**

Is there 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.

COMMENTARY:

N/A

TRM.42650**Phase I****N/A YES NO**

Is the temperature of refrigerators 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.

COMMENTARY:

N/A

TRM.42700**Phase II****N/A YES NO**

Do the blood/blood components and tissue refrigerator(s) and freezer(s) have an emergency power supply?

COMMENTARY:

N/A

TRM.42750 Phase II N/A YES NO

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

COMMENTARY:

N/A

TRM.42800 Phase II N/A YES NO

Are alarm systems checked at specified periodic intervals (for both low and high settings) and results recorded?

COMMENTARY:

N/A

TRM.42850 Phase II N/A YES NO

Are alarms 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 minus 25°C may exhibit increased breakage rates upon handling.

COMMENTARY:

N/A

TRM.42900 Phase II N/A YES NO

Will the alarms continue to function if the power is interrupted?

TRM.43650

Phase II

N/A YES NO

For each component, are there defined procedures for maintaining sterility, including pooling and the use of sterile connecting devices, and is there 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.

COMMENTARY:

N/A

REFERENCE: 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

Phase II

N/A YES NO

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

COMMENTARY:

N/A

RED BLOOD CELLS

TRM.43750

Phase II

N/A YES NO

If the unit is entered for any reason without appropriate use of a sterile connection device, is a 24 hour expiration time assigned to refrigerated components?

NOTE: If a unit has to be entered to remove plasma, a 24 hours expiration date must be assigned, providing the unit is stored in a refrigerator. Closed systems retain the same expiration date as the original whole blood unit. Units that have been entered without use of a sterile connection device (open systems) must be used within 24 hours of entry.

COMMENTARY:

N/A

REFERENCE: 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/aprqrtr/pdf/21cfr610.53.pdf.

TRM.43800

Phase II

N/A YES NO

Does the method for preparing Red Blood Cells ensure 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.

COMMENTARY:

N/A

RED BLOOD CELLS WASHED

TRM.43850

Phase II

N/A YES NO

Are methods adequate to ensure removal of almost all of the plasma?

COMMENTARY:

N/A

RED BLOOD CELLS FROZEN

TRM.43900

Phase II

N/A YES NO

Are storage facilities 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.

COMMENTARY:

N/A

REFERENCE: *Technical Manual*, AABB, Methods 6.7 and 6.8, pg 741-745. [Meryman and Valeri high-glycerol methods.]

TRM.43950

Phase I

N/A YES NO

Are Red Blood Cells 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

COMMENTARY:

N/A

REFERENCES: 1) *Technical Manual*, AABB, Methods 6.7 and 6.8, pg 741-745. [Mearyman and Valeri high-glycerol methods]; 2) FDA Current Thinking on Irradiating and/or Freezing Blood Components Collected and Stored in Anticoagulant/Preservative Solutions Not Specifically Approved for Such Use. Information Sheet, FDA CBER, 3/5/2003:

<http://www.fda.gov/cber/infosheets/irradanti.htm>.

TRM.44000

Phase II

N/A YES NO

Are red blood cell samples from the unit available for pretransfusion testing?

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

COMMENTARY:

N/A

RED BLOOD CELLS DEGLYCEROLIZED

TRM.44100 Phase II N/A YES NO

Are reconstituted deglycerolized Red Blood Cells that have been prepared with an open system used within 24 hours or as approved by the FDA?

NOTE: Reconstituted deglycerolized Red Blood Cells that have been prepared with an open system must be used within 24 hours. The FDA also permits post-thaw storage for up to 14 days in a functionally closed, approved system.

COMMENTARY:

N/A

REFERENCE: 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.

TRM.44150 Phase II N/A YES NO

Does the method of deglycerolized Red Blood Cell preparation ensure 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.

COMMENTARY:

N/A

RED BLOOD CELLS LEUKOCYTE-REDUCED (LABORATORY-PREPARED)

TRM.44250 Phase II N/A YES NO

Do records indicate that leukocyte-reduced Red Blood Cells contain less than 5 X 10⁶ 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

N/A

TRM.44450 **Phase II** **N/A YES NO****Is Fresh Frozen Plasma thawed at 30-37°C with protection against water contamination of outlet ports?**

NOTE: If a microwave oven is used, it should 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 FFP is 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.

COMMENTARY:

N/A

****REVISED**** **10/31/2006****TRM.44525** **Phase II** **N/A YES NO****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, is it relabeled as "Thawed Plasma"?**

NOTE: Fresh Frozen Plasma that has been thawed at 30-37°C, and maintained at 1-6°C for 1 to 5 days, should be relabeled as "Thawed Plasma" and used for replacement therapy only in patients requiring stable clotting factors.

COMMENTARY:

N/A

****REVISED**** **10/31/2006****TRM.44537** **Phase I** **N/A YES NO****If cryoprecipitate-reduced plasma is thawed between 30-37°C and maintained at 1-6°C, is it used within 5 days?**

COMMENTARY:

N/A

TRM.44850 Phase II N/A YES NO

Are Platelets prepared within 8 hours of the collection of Whole Blood that has NOT been cooled below 20°C or, if prepared by apheresis methods, are they 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. Storage at lower temperatures may result in reduced platelet survival. Apheresis Platelets must be prepared according to the instructions of the manufacturer.

COMMENTARY:

N/A

REFERENCES: 1) Moroff G, Holme S. Concepts about current conditions for the preparation and storage of platelets. *Transf Med Rev.* 1991;5:48-59; 2) Food and Drug Administration. Additional standards for human blood and blood products. Platelets. Collection of source material. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR640.22(c)]; 3) *ibid.* Platelets. Processing. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR640.24]; 4) Silberman S. Platelets. Preparations, transfusion, modifications, and substitutes. *Arch Pathol Lab Med.* 1999;123:889-894.

TRM.44900 Phase II N/A YES NO

Do 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 5.5×10^{10} platelets/unit and Platelet Pheresis to have 3×10^{11} platelets/unit in at least 75% of units tested. Units with lower contents will provide a reduced clinical effect that may be confused with refractoriness or that may be inadequate to achieve hemostasis. Acidity must be controlled (to maintain pH of at least 6.2 in all units) to prevent irreversible loss of platelet viability and function. While reduced pH may be associated with high platelet or leukocyte contents, plastics currently approved and commonly used for Platelet unit storage permit adequate gas exchange to maintain pH of at least 6.2.

COMMENTARY:

N/A

REFERENCES: 1) Bordin JO, *et al.* Biologic effects of leukocytes presented in transfused cellular blood products. *Blood.* 1994;84:1703-1721; 2) Food and Drug Administration. Additional standards for human blood and blood products. Platelets. Washington, DC: US Government Printing Office,

1999(Apr 1):[21CFR640.22-640.25]; 3) Silberman S. Platelets. Preparations, transfusion, modifications, and substitutes. *Arch Pathol Lab Med.* 1999;123:889-894.

****NEW****

10/31/2006

TRM.44925

Phase I

N/A YES NO

Are platelet counts on platelet components determined, when required, using a method that has been calibrated 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/ μ L). 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 calibrated periodically using a preparation of known concentration (such as provided commercially or determined through a reference method).

COMMENTARY:

N/A

REFERENCES: 1) Dumont LJ, Moroff G. Platelet and residual leukocyte counting in platelet components. In, Seghatchian J, Snyder EL, Krailadsiri P, eds. Platelet therapy. Current status and future trends. New York: *Elsevier*, 2000:277-317; 2) Whitbread J, Moroff G, Coker SO, Finch S, Murphy S, Wenz B. Prospective comparisons of platelet counting in automated hematology analyzers. *Transfusion* 1998;38:86S; 3) Peoples BG, Moroff G, Friedman LI, Katz AJ. A multi-site study of variables affecting platelet counting for blood component quality control. *Transfusion* 1994;34:11S; 4) The influence of various hematology analyzers on component platelet counts. Moroff G, Sowemimo-Coker SO, Finch S, Murphy S, Brandwein H, Whitbread J, Wenz B for the BEST Collaborative. *Transf Med Rev* 2005;19:155-66; 5) International Council for Standardization in Hematology Expert Panel on Cytometry and International Society of Laboratory Hematology Task Force on Platelet Counting. Platelet counting by the RBC/platelet ratio method: a reference method. *Am J Clin Pathol* 2001;115:4604; 6) Harrison P, Horton A, Grant D, Briggs C, Machin S. Immunoplatelet counting: a proposed new reference procedure. *Br J Haematol* 2000;108:228-35.

TRM.44950

Phase II

N/A YES NO

Are Platelet components 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. Specific protocols to permit 7-day storage using bacterial detection systems have been approved by the FDA. Agitation during storage is necessary to ensure optimal gas exchange and maintenance of pH.

Data in the literature suggests that platelets may be stored up to 24 hours without agitation. However, platelet bag manufacturer instructions must be followed if more stringent.

COMMENTARY:

N/A

REFERENCES: 1) Shelton JB, *et al.* The effects of early agitation on the viability of stored platelets. *Am J Clin Pathol.* 1997;108:352-353; 2) Silberman S. Platelets. Preparations, transfusion, modifications, and substitutes. *Arch Pathol Lab Med.* 1999;123:889-894; 3) Moroff G, George VM. The maintenance of platelet properties upon limited discontinuation of agitation during storage. *Transfusion.* 1990;30:427-430.

TRM.44955

Phase II

N/A YES NO

Does the laboratory have a validated system to detect the presence of bacteria in platelet components?

NOTE: For random donor platelets, any of the following testing methods satisfy this checklist question: detection of decreased pH or glucose by analytic instrument or dipstick; gram stain; acridine orange stain. Though of low sensitivity, these methods may detect units that are heavily contaminated by bacteria. Culture or FDA-approved commercial detection systems have greater sensitivity. The swirling technique is not recommended because of its very low sensitivity.

Two commercial systems have been cleared by the FDA for in-process quality control culturing of platelet units; one detects the growth of bacteria by their generation of CO₂, and the other detects growth by their consumption of O₂. Another system has been cleared for bacterial detection by fluorescent staining. If this testing is performed by the supplier of platelet components, the transfusion service can satisfy this checklist requirement by having an agreement with the supplier to notify the transfusion service if any units suspected of containing bacteria have been transferred to the transfusion service.

COMMENTARY:

N/A

REFERENCES: 1) Wagner SJ, *et al.* Evaluation of swirling, pH, and glucose tests for the detection of bacterial contamination in platelet concentrates. *Transfusion.* 1996;36:989-993; 2) Ness PM, *et al.* Single donor platelets reduce the risk of septic transfusion reactions. *Transfusion.* 2001;41:857-861; 3) AuBuchon JP, *et al.* Experience with universal bacterial culturing to detect contamination of apheresis platelet units in a hospital transfusion service. *Transfusion.* 2002;42:855-881; 4) Blajchman MA,

Goldman M, Baeza F. Improving the Bacteriological Safety of Platelet Transfusions. *Trans Med Reviews* 2004;18(1):11-24; 5) Shulman IA. College of American Pathologists Laboratory Accreditation Checklist Item TRM.44955. *Arch Pathol Lab Med.* 2004;128:958-63.

PLATELETS LEUKOCYTE-REDUCED

TRM.44960

Phase II

N/A YES NO

Does the method of preparation ensure 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 8.3×10^5 WBCs, and for plateletpheresis units, less than 5×10^6 WBCs. After filtration, platelet recovery must be at least 85% of the original content.

COMMENTARY:

N/A

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; 2) Narvios AB, et al. Assessing the efficiency of leukoreduction of cellular blood components. Use of a simplified formalin-fixation and batch-counting method. *Am J Clin Pathol.* 1997;107:111-113; 3) Leparc GF. Leukocyte reduction in cellular blood components. *Lab Med.* 1997;28:328-331; 4) Silberman S. Platelets. Preparations, transfusion, modifications, and substitutes. *Arch Pathol Lab Med.* 1999;123:889-894; 5) Recommendations and licensure requirements for leukocyte-reduced Blood Products. Memorandum, FDA CBER, 5/29/1996. <http://www.fda.gov/cber/bldmem/mem52996.pdf>.

IRRADIATED CELLULAR COMPONENTS

****REVISED**** 10/31/2006

TRM.44970

Phase II

N/A YES NO

If the facility irradiates blood and components, is there 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.

COMMENTARY:

N/A

REFERENCES: 1) Przepiorka D, *et al.* Use of irradiated blood components. Practice parameter. *Am J Clin Pathol.* 1996; 106:6-11; 2) Moroff G, Leitman SF, Luban N. Principles of blood irradiation, dose validation, and quality control. *Transfusion.* 1997;37:1084-92; 3) Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products. Memorandum, FDA CBER, 7/22/1993. <http://www.fda.gov/cber/blmem/072293.pdf>.

TRM.44977

Phase I

N/A YES NO

Are irradiated blood and blood components permanently labeled as irradiated and are expiration dates for irradiated Red Blood Cell products modified not to exceed 28 days from the date of irradiation?

COMMENTARY:

N/A

TRM.44984

Phase II

N/A YES NO

Is there a maintenance schedule for all blood irradiation equipment including timer checks, back-up timer checks, turntable inspection, and radiation leakage testing and does documentation show that the maintenance is performed?

COMMENTARY:

N/A

N/A

TRM.45002 Phase II

N/A YES NO

Do 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.

COMMENTARY:

N/A

REFERENCE: Circular of Information for the Use of Cellular Therapy Products. Bethesda, MD: American Association of Blood Banks. 2003. Available at: http://www.aabb.org/All_About_Blood/COI/aabb_coi.htm.

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Collection

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TRM.45003 Phase II

N/A YES NO

Are procedures 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 of 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-88 certified laboratory and that compatibility is acceptable.

COMMENTARY:

N/A

TRM.45004 Phase II

N/A YES NO

Is appropriate consent obtained?

COMMENTARY:

N/A

TRM.45005 Phase II

N/A YES NO

Are autologous and allogeneic donors evaluated by a qualified individual prior to each apheresis procedure, as specified by the medical director?

COMMENTARY:

N/A

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Reagents, Supplies, and Equipment

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TRM.45006 Phase II

N/A YES NO

Are records of all critical reagents, supplies, and equipment used in collection and processing, including lot numbers and expiration dates, 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.

COMMENTARY:

N/A

TRM.45007 Phase II

N/A YES NO

Are reagents and supplies used in the collection, processing, cryopreservation, and administration of cellular therapy products 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.

COMMENTARY:

N/A

TRM.45008 Phase II N/A YES NO

Does the laboratory have a method to monitor and maintain adequate liquid nitrogen levels in frozen storage units?

COMMENTARY:

N/A

TRM.45009 Phase II N/A YES NO

Are all storage units monitored 24 hours/day and equipped with an alarm (either remote or in the laboratory) that is tested periodically for its ability to alert responsible staff at all times?

COMMENTARY:

N/A

TRM.45010 Phase II N/A YES NO

Does the laboratory have backup capability for all critical instrumentation and storage devices?

COMMENTARY:

N/A

TRM.45011 Phase II N/A YES NO

Is there documentation that the laminar flow hood is regularly cleaned, decontaminated and certified as appropriate?

COMMENTARY:

N/A

N/A

TRM.45022 Phase II

N/A YES NO

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

COMMENTARY:

N/A

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Reinfusion/Administration

.....

TRM.45023 Phase II

N/A YES NO

Are adverse reactions unique to administration/reinfusion of cellular therapy products 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 questions on Blood Component Administration and Adverse Reaction Procedures apply.

COMMENTARY:

N/A

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.

****REVISED**** **10/31/2006**

TRM.45050 **Phase II** **N/A YES NO**

Is the authority, responsibility and accountability of the tissue-handling program 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.

COMMENTARY:

N/A

REFERENCES: 1) Linden JV, Favreau TJ. Professional standards in cell and tissue processing. *Cell Transplant*. 1995;4:441-446; 2) Haimowitz MD. Practical issues in tissue banking. *Am J Clin Pathol*. 1997;107(suppl 1):S75-S81.

****NEW**** **10/31/2006**

TRM.45075 **Phase I** **N/A YES NO**

Are all source facilities registered or licensed as required by state and federal regulations?

COMMENTARY:

N/A

TRM.45100 **Phase II** **N/A YES NO**

Is there documentation available for each tissue stored of the infectious disease testing and type of processing performed?

COMMENTARY:

N/A

REFERENCES: 1) Newman-Gage H. Application of quality assurance practices in processing cells and tissues for transplantation. *Cell Transplant*. 1995;4:447-454; 2) Haimowitz MD. Practical issues in tissue banking. *Am J Clin Pathol*. 1997;107(suppl 1):S75-S81; 3) Food and Drug Administration. Current good manufacturing practice for finished pharmaceuticals. Production and process controls. Written procedures; deviations. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR211.100]; 4) *ibid*. Records and reports. Production record review. Washington, DC: US

COMMENTARY:

N/A

****NEW**** 10/31/2006**TRM.45170** Phase I N/A YES NO**Are there 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.*

COMMENTARY:

N/A

****NEW**** 10/31/2006**TRM.45180** Phase I N/A YES NO**Is there a system for completing and returning issue usage cards to the source facility?**

COMMENTARY:

N/A

****NEW**** 10/31/2006**TRM.45190** Phase I N/A YES NO**Are procedures and records retained for at least 10 years, or longer if required by state or federal regulations?***NOTE: JCAHO 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.*

COMMENTARY:

N/A

TRM.45200 Phase II

N/A YES NO

Do 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.

COMMENTARY:

N/A

REFERENCES: 1) Linden JV, Favreau TJ. Professional standards in cell and tissue processing. *Cell Transplant.* 1995;4:441-446; 2) Haimowitz MD. Practical issues in tissue banking. *Am J Clin Pathol.* 1997;107(suppl 1):S75-S81.

TRM.45250 Phase II

N/A YES NO

Do 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.

COMMENTARY:

N/A

REFERENCES: 1) Linden JV, Favreau TJ. Professional standards in cell and tissue processing. *Cell Transplant.* 1995;4:441-446; 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)

N/A

TRM.45253 Phase II**N/A YES NO**

Are there 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.

COMMENTARY:

N/A

TRM.45254 Phase II**N/A YES NO**

Are persons responsible for the donor selection process, predonation examination, and phlebotomy qualified, trained and competent for these tasks?

COMMENTARY:

N/A

TRM.45255 Phase II**N/A YES NO**

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

COMMENTARY:

N/A

TRM.45256 Phase II**N/A YES NO**

Do donor demographics include date of birth and address?

NOTE: All donor demographics must include birthdate. In the U.S., 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.

COMMENTARY:

N/A

REFERENCES: 1) Sherman LA. Legal issues in blood banking. Elements of informed consent. *Clin Lab Med.* 1996;16:931-946; 2) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2006(Jan 1):57 [21CFR606.160(b)(1)(x)].

TRM.45257**Phase II****N/A YES NO**

Do 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.

COMMENTARY:

N/A

TRM.45258**Phase II****N/A YES NO**

Is the donor weight recorded, and does it 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.

COMMENTARY:

N/A

REFERENCE: FDA algorithm for double RBCs: [Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods - Technical Correction February 2001 - 2/13/2001](http://www.fda.gov/cber/gdlns/rbcautoph2.htm) <http://www.fda.gov/cber/gdlns/rbcautoph2.htm>.

TRM.45263 **Phase II** **N/A YES NO**

Is an informed consent form signed by the donor?

COMMENTARY:

N/A

REFERENCE: Sherman LA. Legal issues in blood banking. Elements of informed consent. *Clin Lab Med.* 1996;16:931-946.

TRM.45264 **Phase II** **N/A YES NO**

Are the donor history, physical examination, and screening test results recorded (paper or electronic)?

NOTE: The Inspector must examine several donor records for compliance as to complete records for all phases of donor collection. Any discrepancies must be described in part B of the Inspectors Summation Report.

COMMENTARY:

N/A

TRM.45265 **Phase II** **N/A YES NO**

Is there evidence of follow up for significant findings in donor history, physical examination, and screening test results?

COMMENTARY:

N/A

TRM.45266 **Phase II** **N/A YES NO**

Is there a system in place to ensure that the numeric identification on pilot tubes, bags, and related donor records are in agreement?

COMMENTARY:

N/A

TRM.45267**Phase II****N/A YES NO****Is a documented procedure using sterile, prepackaged materials 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.

The Inspector should observe donor arm preparation, if possible.

COMMENTARY:

N/A

REFERENCES: 1) Strand CL, *et al.* Effect of iodophor vs iodine tincture skin preparation on blood culture contamination rate. *JAMA*. 1993;269:1004-1006; 2) Goldman M, *et al.* Evaluation of donor skin disinfection methods. *Transfusion*. 1997;37:309-312; 3) Options for arm preparation. Information sheet. FDA CBER, Jan 29, 2004 <http://www.fda.gov/cber/blood/armpreprev.htm>
McDonald CP *et al.* Evaluation of donor arm disinfection techniques. *Vox Sang* 2001; 80:135-41.

****NEW******09/27/2007****TRM.45268****Phase I****N/A YES NO****Is the first volume of the phlebotomy diverted from the whole blood or component collection?**

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

COMMENTARY:

N/A

REFERENCE: Yomtovian R. Practical aspects of preoperative autologous transfusion. *Arch Pathol Lab Med*. 1997;107(Suppl 1):S28-S35.

 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 questions in the previous "All Donors (Allogeneic and Autologous)" section. The presence of certain items does not imply that the donor must be rejected because of a positive response, but rather that the information is recorded and that an evaluation of that specific problem ensues. If blood is not collected from allogeneic donors, omit this section.

TRM.45273	Phase II	N/A	YES	NO
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Are potential allogeneic donors 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.

COMMENTARY:

N/A

REFERENCES: 1) Food and Drug Administration. Memorandum for HIV risk screening, 4/23/1992; 2) Food and Drug Administration. Guidelines regarding exclusion of donors with a history of CJD or incarceration, 1995 (Jun); 3) Food and Drug Administration. General biological products standards. History of hepatitis B surface antigen. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR610.41]; 4) Food and Drug Administration. Guidance for industry. Revised preventive measures to reduce possible risk of transmission of Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products. January 2002.

TRM.45275	Phase II	N/A	YES	NO
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Is there 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.

COMMENTARY:

N/A

TRM.45276

Phase II

N/A YES NO

For allogeneic whole blood donations, does the time interval between donations meet 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.

COMMENTARY:

N/A

****NEW****

10/31/2006

TRM.46138

Phase II

N/A YES NO

Is there documentation that allogeneic donors are evaluated in a manner consistent with the uniform Donor History Questionnaire?

NOTE: If the laboratory develops its own donor history questionnaire, it must have documentation showing that it is equivalent (e.g., by a crosswalk) to the most recent Uniform Donor History Questionnaire accepted by the FDA.

COMMENTARY:

N/A

REFERENCE: Draft Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components <http://www.fda.gov/cber/gdlns/donorhistques.htm> - 4/23/2004.

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., hepatitis, 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.

****REVISED**** **10/31/2006**

TRM.47000 **Phase II** **N/A YES NO**

Does the routine procedure include 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.

COMMENTARY:

N/A

REFERENCE: 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 **Phase II** **N/A YES NO**

Does testing include a screen for unexpected antibodies on all donors with history of prior transfusions or pregnancy?

COMMENTARY:

N/A

TRM.47100 **Phase II** **N/A YES NO**

Are all FDA-required or recommended infectious disease tests 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.

COMMENTARY:

N/A

TRM.47320**Phase II****N/A YES NO**

Is there a procedure for identifying previous donations from persons who now test reactive for viral marker screening tests, and is there a defined mechanism for notifying consignees of components from those units, when applicable?

NOTE: In the U.S., 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.

COMMENTARY:

N/A

REFERENCES: 1) Food and Drug Administration. General biological products standards. History of hepatitis B surface antigen. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR610.41]; 2) Food and Drug Administration. General biological products standards. Human immunodeficiency virus (HIV) requirements. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR610.45]; 3) Food and Drug Administration. General biological products standards. "Lookback" requirements. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR610.46]; 4) Food and Drug Administration. Additional standards for human blood and blood products. Platelets. Collection of source material. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR640.22(c)]; 5) Proposed rule for HCV 1.0, *Fed Register*. 2000(Nov 16):65:69377; 6) Draft guidance, HCV: [Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: \(1\) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus \(HCV\); \(2\) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV \(Anti-HCV\) - 6/17/1999](http://www.fda.gov/cber/gdlns/hcvlkbk.htm) <http://www.fda.gov/cber/gdlns/hcvlkbk.htm>; 7) Draft guidance, HIV and HCV NAT and lookback: [Draft Guidance for Industry: Nucleic Acid Testing \(NAT\) for Human Immunodeficiency Virus Type 1 \(HIV-1\) and Hepatitis C Virus \(HCV\): Testing, Product Disposition, and Donor Deferral and Reentry - 7/19/2005](http://www.fda.gov/cber/gdlns/nathivhcv.htm) <http://www.fda.gov/cber/gdlns/nathivhcv.htm>.

TRM.47350**Phase I****N/A YES NO**

Is there evidence that standard operating procedures provide for appropriate quarantine and unit disposal steps, and are these procedures followed?

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.

COMMENTARY:

N/A

TRM.47650 Phase II N/A YES NO

Is a qualified physician 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 must have the opportunity to ask questions, and should be encouraged to sign a document indicating agreement.

COMMENTARY:

N/A

REFERENCES: 1) Food and Drug Administration. Additional standards for human blood and blood products. Source plasma. Informed consent. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR640.61]; 2) Sazama K. Practical issues in informed consent for transfusion. *Am J Clin Pathol.* 1997;107(suppl 1):S72-S74; 3) Sherman LA. Legal issues in blood banking. Elements of informed consent. *Clin Lab Med.* 1996;16:931-946.

TRM.47700 Phase II N/A YES NO

Is a physician experienced in donor apheresis available for prompt consultation when apheresis is performed?

COMMENTARY:

N/A

REFERENCE: Food and Drug Administration. Current good manufacturing practice for blood and blood components. Production and process control. Plateletpheresis, leukapheresis, and plasmapheresis. Washington, DC: US Government Printing Office, 1999(Apr 1):[21CFR606.110].

TRM.47860**Phase II****N/A YES NO****Are complete records kept of each apheresis procedure?**

NOTE: The record of each apheresis procedure must include donor identity, results of all laboratory tests, anticoagulants used, volume of component(s), drugs used, lot numbers of disposables and replacement fluids used, and reactions, if any, and treatment for reaction.

COMMENTARY:

N/A

TRM.47870**Phase II****N/A YES NO****For apheresis donations, does the time interval since prior donations meet 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 200mL, but less than 300mL, the donor must be deferred for 8 weeks. If the loss is equal to or greater than 300mL, the donor must be deferred for 16 weeks (112 days).*
- 4. The interval between platelet apheresis 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 8 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/ μ L 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.*

COMMENTARY:

N/A

TRM.50100 Phase II N/A YES NO

Is the medical director of the transfusion service involved in development of all policies and procedures related to transfusion?

COMMENTARY:

N/A

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

TRM.60000 Phase I N/A YES NO

Is there 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.

COMMENTARY:

N/A

TRM.60100 Phase I N/A YES NO

Is there adequate space for administrative and clerical functions?

COMMENTARY:

N/A

TRM.60200 Phase I N/A YES NO

Is there adequate space for technical work (bench space), instruments and equipment?

COMMENTARY:

N/A

TRM.60400 Phase I

N/A YES NO

Is there adequate space for blood storage refrigerators and freezers, reagent refrigerators, and platelet rotators?

COMMENTARY:

N/A

TRM.60600 Phase I

N/A YES NO

Is there 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.

COMMENTARY:

N/A

TRM.60700 Phase I

N/A YES NO

Is there adequate space for therapeutic apheresis?

COMMENTARY:

N/A

TRM.60800 Phase II

N/A YES NO

Is sufficient space available so that there is no compromise of the quality of work, (including quality control activities) or safety of personnel?

COMMENTARY:

N/A

TRM.61300 Phase I

N/A YES NO

Are ventilation and temperature control adequate?

COMMENTARY:

N/A

TRM.61400 Phase I

N/A YES NO

Are telephones conveniently located, and are calls easily transferred?

COMMENTARY:

N/A