Saskatchewan
Transfusion Resource Manual

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Transfusion Medicine Working Group

Prepared by:
Transfusion Resource Manual Sub-Committee

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Introduction

This manual was commissioned by the Transfusion Medicine Working Group (TMWG) as a template for Regional Health Authorities (RHA) to comply with anticipated Health Canada regulations pertaining to blood and plasma protein products based on the Canadian Standards Association (CSA) Z902 Blood and Blood Components.

The Saskatchewan Transfusion Resource Manual was developed by a multidisciplinary subcommittee made up of: medical laboratory technologists who are members of the TMWG; a registered nurse and a registered nurse (nurse practitioner) representing the Saskatchewan Registered Nurses' Association; and a licensed practical nurse representing the Saskatchewan Association of Licensed Practical Nurses.

The guidelines in this manual cover both minimum safety standards and best practices which will enhance the quality and safety of care for patients. Within the Scope and Related Policies section of each guideline are "Required" and "Best Practice" sections. The "Required" sections cover related minimum safety standards from the CSA Z902 whereas the "Best Practice" standards are found in the Canadian Society for Transfusion Medicine (CSTM) Standards. In Saskatchewan, the College of Physicians and Surgeons of Saskatchewan requires that laboratories meet the requirements of the CSTM standards.

The use of the term "shall" in this document implies that the statement is mandated in the CSA Z902. Failure to implement and comply with these guidelines means that the laboratory does not meet current acceptable expectations for the practice of transfusion medicine. The use of the term "should" implies that the guideline appears to be scientifically valid and useful and it is recommended that the laboratory implement this practice in conjunction with recommendations from the Transfusion Service Medical Director.

Within the text of the document there are text boxes to highlight areas of interpretation where other provincial legislation, regulations and/or bylaws may impact the delivery of transfusion services such as professional Scope of Practice. There are also areas where there is clinical discretion. In the latter, Senior Medical Officers from the regional health authorities have determined the practice is valid and should be treated as a provincial policy.

In order to ensure that this manual continues to evolve as a provincial resource, the TMWG has developed a Transfusion Guideline Change Request Form (See Appendix #1) to capture suggested revisions as health regions implement these guidelines. These revisions will be reviewed on an annual basis and incorporated into the guidelines as deemed appropriate.

Disclaimer

This transfusion resource manual has been prepared by the Transfusion Medicine Working Group – Transfusion Resource Manual Sub-committee for sole use by Saskatchewan Regional Health Authority employees and officials. The material contained in this document is intended for informational purposes only and is not intended to provide specific direction or legal advice for any situation and should not be relied upon in that regard. Nothing in this document is intended to take the place of a review of the relevant legislation and/or consultation with legal counsel. Although efforts have been made to ensure the accuracy of the information in this document, the members of the Transfusion Medicine Working Group disclaim any liability for any reliance upon or use of this material.

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Guideline SK 1

Informed Consent for the Administration of Blood Components and Plasma Protein Products

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1.0 Principle

1.1 To provide guidelines for informed consent for the administration of blood components and plasma protein products. (See Appendix #2 – Glossary of Terms)

2.0 Scope and Related Policies

2.1 *Required:*

2.1.1 All regional health authorities (RHAs) shall establish and maintain written policies and procedures for obtaining informed consent of the patient prior to the transfusion of blood components and plasma protein products. [CSA 4.1.1 4.1.2(h), 11.2.1]

SK Application – Duration of Consent: For the purposes of transfusion medicine in Saskatchewan, the duration of consent is for either one admission or, if a patient suffers from a chronic condition, for one course of treatment within 12 months, so long as the patient's condition or medical knowledge in general about the condition has not significantly changed. (Approved by the Senior Medical Officer Committee on May 11, 2011.)

2.1.2 In accordance with applicable provincial legislation, regulations and bylaws, practitioners authorized to obtain informed consent include physicians, and in some circumstances, a Registered Nurse (Nurse Practitioner), RN(NP). [Government of Saskatchewan, 9(1)b, 9(2)b; SRNA, 2010] (See text box below.)

SK Application - Registered Nurse (Nurse Practitioner): In accordance with applicable provincial legislation, regulations and/or bylaws, a Registered Nurse (Nurse Practitioner) may be authorized to obtain informed consent if this involves common medical disorders for which he/she is currently competent and this is within his/her chosen specialty area of practice. Common medical disorders shall be interpreted to mean health problems, conditions, diseases or disorders that the RN(NP) sees with regularity within the context of his/her practice. Informed consent is not within the scope of practice for Registered Nurses or Licensed Practical Nurses nor is it a medical function that is transferable to these health professionals. (See Appendix #3 - Nurse Practitioner Primer)

2.1.3 The information given to the patient shall include [CSA 11.2.1]:

- a description of the blood or plasma protein product to be transfused;

- the associated risks and benefits, including life-threatening risks; and
- alternative therapies, if clinically appropriate, including benefits and risks.

2.1.4 Each RHA shall have a process in place to provide each patient transfused with written notification of the transfusion. [CSA 11.2.2] It may be provided when the patient is discharged from the facility.

2.2 *Best Practice:*

2.2.1 The patient or substitute decision maker receives both verbal and written information from the physician/authorized RN(NP) to allow them to make an informed decision about their treatment. (See Saskatchewan application text box regarding authorized RN(NP)s.

2.2.2 If possible the discussion should take place well in advance of the intended surgical procedure or blood therapy. Refer to RHA policy and procedure.

2.2.3 Information is provided in a language the patient or substitute decision maker understands and in a manner that permits questions, repetition and sufficient time to assimilate the information.

2.2.4 After this discussion the patient is asked to provide consent, refusal or consent with restrictions such as use of certain products or autologous blood.

2.2.5 The discussion should be documented on the patient's health record.

2.2.6 Refusal of consent or limitation to receive blood components and plasma protein products should be documented in the patient's health record. Refer to RHA policy and procedures.

2.2.7 In the event of an emergent or life threatening circumstance informed consent may not be obtained, however, the physician/authorized RN(NP) should obtain consent once the emergent or life threatening circumstance has been resolved. Each RHA should have a policy and procedure to address emergency situation consent.

3.0 Materials

3.1 Refer to RHA policies and procedures.

3.2 Related materials may include:

- Informed Consent Form/Refusal to Consent Form for Blood Components and Plasma Protein Products
- Patient Information Handbook (See Appendix #4 for public version of blood transfusion patient handbook or download RHA template version at http://www.health.gov.sk.ca/transfusion-medicine)
- Patient Notification of Transfusion

4.0 Quality Management

4.1 An RHA-based quality improvement system or process should be in place to monitor compliance to the informed consent policy for blood components and plasma protein products. This could be done through random patient and health record audits and /or other quality improvement mechanisms.

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter.[CSA 4.3.3.1]

5.0 Procedure

5.1 The physician/authorized RN(NP) will obtain the consent, refusal or limited consent for the transfusion of blood components and/or plasma protein products.

5.2 The transfusionist will confirm that the consent has been obtained before any transfusion begins.

SK Application – Professional Designations for Transfusionist:

In accordance with applicable provincial legislation, regulations and/or bylaws, it is within the scope of practice for a physician, Registered Nurse, Nurse Practitioner (RN (NP)), Registered Nurse (RN), Registered Psychiatric Nurse (RPN) or Licensed Practical Nurse (LPN) who has completed the IV Therapy/Blood and Blood Products Completer Course to transfuse blood components and plasma protein products. Graduate RN and Graduate LPN must be supervised by a licensed professional.

5.3 In the event that there is no signed consent or relevant documentation and/or the patient disclaims knowledge or understanding of the intended transfusion, the transfusionist will notify the physician /authorized RN(NP) and will not initiate the transfusion until the situation has been resolved.

6.0 Documentation

6.1 The informed consent process should be documented in the patient's health record. The form(s) should include the signatures of the patient or substitute decision maker and the physician/authorized RN(NP).

6.2 The transfusionist should document any additional actions taken pertaining to informed consent on the patient health record.

6.3 The RHA shall provide written notification of transfusion and this should be documented on the patient health record.

7.0 References

7.1 Canadian Medical Protective Association. *eLearning. Informed consent: obtaining valid consent.* http://www.cmpa-acpm.ca/cmpapd04/docs/highlights-e.cfm. Accessed May 11, 2010.

7.2 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

7.3 College of Physicians and Surgeons of Saskatchewan. *Laboratory quality assurance policy manual.* 2010 edition.

7.4 Government of Saskatchewan. 2009. *The Attending Health Professionals Regulations*.

7.5 Manitoba Health. *Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing.* June 2007.

7.6 Saskatchewan Registered Nurses' Association. *Common medical disorders for primary care and neonatal RN(NP)s*. http://www.srna.org/nurse-practitioner/common-medical-disorders. Accessed May 10, 2010.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 2

Treatment Requests for Blood Components and Plasma Protein Products

1.0 Principle

1.1 A request from a physician or authorized Registered Nurse (Nurse Practitioner) (RN(NP)) is required for the pre-transfusion testing and administration of all blood components and plasma protein products.

SK Application - Registered Nurse (Nurse Practitioner): In accordance with applicable provincial legislation, regulations and/or bylaws, a Registered Nurse (Nurse Practitioner) may be authorized to obtain informed consent if this involves common medical disorders for which he/she is currently competent and is within his/her chosen specialty area of practice. Common medical disorders shall be interpreted to mean health problems, conditions, diseases or disorders that the RN(NP) sees with regularity within the context of his/her practice. Informed consent is not within the scope of practice for Registered Nurses or Licensed Practical Nurses nor is it a medical function that is transferable to these health professionals. (See Appendix #3 - Nurse Practitioner Primer)

2.0 Scope and Related Policies

2.1 *Required:*

2.1.1 The request shall specify:

- Patient's first and last name(s); CSA 10.2.1 (a)
- Saskatchewan Health Services number (HSN) or unique identifier; CSA 10.2.1 (b)
- Patient's location; CSA 10.2.1(c)
- Pre-transfusion testing of required blood component or plasma protein product; CSA 10.1 (b) (c)
- Volume and dosage of specific blood component or plasma protein product required; CSA 10.2.1 (d) (e)
- Date and time of request; CSTM 5.2.1.2 (e)
- Date and time of intended transfusion, if available; CSTM 5.2.1.2 (f)
- Special transfusion requirements CSTM 5.2.1.2(g) (e.g. Anti-CMV negative; modifications to the blood component such as irradiation, washing or splitting).
- Clinical indication CSTM 5.2.1.2(h)

2.2 *Best Practice:*

2.2.1 The request (or health record) will reflect the clinical indication for the transfusion. The decision to use blood components or plasma protein products should permit optimal patient care while fostering prudent clinical use of the blood supply.

2.2.2 Additional information that should be included with the treatment request to enhance the quality and safety includes:

- Sequence in which multiple products are to be transfused;
- Rate of transfusion or duration;
- The use of a blood warmer or rapid transfusion device, with the exception of clinical areas where there is an established regional health authority (RHA) policy and procedure;
- Pre and/or post transfusion medication requests related to the transfusion.

2.2.3 Refer to related RHA policies and procedures.

2.2.4 Refer to Guideline SK 1 – Informed Consent for the Administration of Blood Components and Plasma Protein Products.

3.0 Materials

3.1 Related materials may include:

- A request as established by the RHA's policies and procedures;
- Informed consent form(s) as per the RHA's policies and procedures;
- A completed requisition or electronic request form.

4.0 Quality Management

4.1 A RHA-based quality improvement system or process should be in place to monitor:

- Appropriate processing of the request prior to requesting the product from the transfusion service/laboratory;
- Checking of the request prior to the administration of the blood component or plasma protein product;
- Appropriate utilization of blood components and/or plasma protein products;
- Presence of informed consent or in cases of emergent or life threatening situations, documentation of use of product without consent; and
- Documentation of the clinical indication for transfusion.

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter.[CSA 4.3.3.1]

5.0 Procedure

5.1 Process treatment request as per established RHA policies and procedures.

6.0 Documentation

6.1 Ensure documentation is on the patient's health record.

7.0 References

7.1 Canadian Society of Transfusion Medicine. Standards for Hospital Transfusion Services. Version 3. May 2011.

7.2 Canadian Standards Association. Blood and Blood Components. CAN/CSA-Z902-10. February 2010.

7.3 Manitoba Health. Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing. June 2007.

7.4 Saskatchewan Registered Nurses' Association. Common medical disorders for primary care and neonatal RN(NP)s. http://www.srna.org/nurse-practitioner/common-medical-disorders. Accessed May 10, 2010.

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Facility effective date: _____
(Date of implementation)

Guideline SK 3

Request for Blood Components and Plasma Protein Products from the Transfusion Service/Laboratory

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1.0 Principle

1.1 Requests for blood components and plasma protein products shall be in writing and contain sufficient information to allow for unequivocal identification of the patient. CSA 10.2.1

2.0 Scope and Related Policies

2.1 *Required:*

2.1.1 The request shall be in writing and contain sufficient information to allow for unequivocal identification of the patient. The request shall contain at least the following information: CSA 10.2.1, 10.2.2, 10.2.3

- First and last names of the patient. If information is not available, refer to the regional health authority's (RHA's) policy for patient identification when patient identification is unknown;
- Patient's Saskatchewan Health Services number (HSN) or unique identifier;
- Patient's location;
- Blood component or plasma protein product requested; and
- Volume of product required.

2.1.2 If any of this information is incomplete, inaccurate, or illegible, the request shall not be accepted by the transfusion service/laboratory unless an alternative procedure is being used (e.g. unidentified patients).CSA 10.2.1-10.2.4 (See Appendix # 2 Glossary of terms for the definition of transfusion service.)

2.2 *Best Practice:*

2.2.1 Other information that should be included on the request that is considered to be best practice is:

- Patient's recent transfusion history and if applicable obstetrical history;
- Patient's diagnosis; CSTM 5.2.1.2(h)
- Date and time of intended transfusion, if available; CSTM 5.2.1.2(f)
- Special transfusion/infusion requirements of the blood component and/or plasma protein product (e.g. irradiation, washing, CMV negative products); CSTM 5.2.1.2(g)
- Sequence of product infusion in cases where multiple products are to be transfused; and
- Signature of the individual making the request.

3.0 Materials

3.1 A product and test request form as established by the RHA's policy and procedure.

4.0 Quality Management

4.1 A RHA-based quality improvement system or process should be in place to monitor:

- The accurate transfer of treatment request to the request form;
- Confirmation that the product received was the product requested; and
- Appropriate utilization and conservation of all blood components and plasma protein products transfused/ infused within the RHA.

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter.[CSA 4.3.3.1]

5.0 Procedure

5.1 Process the treatment request as per established RHA-based policies and procedures.

6.0 Documentation

6.1 Ensure documentation on the patient's health record.

7.0 References

7.1 Canadian Society of Transfusion Medicine. *Standards for hospital transfusion services.* Version 3. May 2011.

7.2 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

7.3 Manitoba Health. *Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing.* June 2007.

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Guideline SK 4

Patient Identification and Sample Collection Labelling

1.0 Principle

1.1 To positively identify a patient and accurately label blood samples that will be used for pre-transfusion testing.

2.0 Scope and Related Policies

2.1 *Required:*

2.1.1 Policies and procedures for the preparation of a request form/requisition, identification of a patient, and the collection and labelling of a blood sample must be established by each regional health authority (RHA). CSA 10.1, 10.2, 10.3

2.1.2 The transfusion service/laboratory shall only accept samples with complete, accurate and legible labels. Most hemolytic transfusion reactions result from errors in patient sample identification. CSA 10.2.1

2.1.3 Request forms/requisitions shall identify the patient by last and first name(s) and by the patient's Saskatchewan Health Services number (HSN) or unique identifier. Request forms/requisitions without proper patient identification will not be accepted by the transfusion service/laboratory. The request form/requisition may be a requisition or an electronic request. Phone requests are acceptable providing there is a mechanism to unequivocally identify the intended patient, the patient location and requested product. Phone requests must be followed up in writing. CSA 10.2.1

2.1.4 Positive identification of the patient shall be made before drawing blood samples, including a check of the patient's identification band. If errors, discrepancies are found during the process of identification, blood samples must not be drawn until the problem has been satisfactorily resolved. In situations where patients do not have an identification band, a procedure to identify the patient shall be in place. CSA 10.2.2, 10.2.3, 10.2.4 (See Guideline SK 5 Determination of Sample Suitability.)

2.1.5 Blood samples shall be labelled at the "bedside" with the patient's last and first name(s), HSN or unique identifier and the date and time of collection. The completed label shall be attached to the sample tube before leaving the patient's bedside. CSA 10.3.2

2.1.6 The name, initials or computer identification code of the person drawing the sample shall be documented on the request form/requisition or electronic order, as well as the date and time of collection. CSA 10.3.1 (See Guideline SK 21 Record Retention Requirements)

2.2 *Best Practice:*

2.2.1 All patients being transfused must have an identification band that provides continuous positive identification of the patient from the time of sample collection to the completion of the transfusion episode.

3.0 Materials

3.1 Refer to RHA policies and procedures.

3.2 Supplies include:

- Request form/requisition or electronic request showing the patient's last and first name(s) and HSN or unique identifier.
- Labels, if applicable with the patient's last and first name(s) and HSN or unique identifier.
- Materials for venipuncture as per established RHA procedures.

4.0 Quality Management

4.1 All errors in patient identification and sample labelling must be documented in an incident or patient safety report according to the RHA established procedure. Corrective action must be taken and documented.

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter.[CSA 4.3.3.1]

5.0 Procedure

5.1 Identify the patient.

5.1.1 If samples are to be collected from more than 1 patient, keep request form/requisition and labels separate for each patient.

5.1.2 Ensure that the identification band is physically attached to the patient (i.e. not to the bed, wall or door).

5.1.2.1 If the patient is an outpatient and requires pre-transfusion testing, follow established RHA procedures for using appropriate patient identification. Verbal confirmation of the patient's identification must be obtained and recorded prior to blood being collected.

5.1.2.2 If the patient is an inpatient and is not wearing an identification band, ask a qualified person to identify and put an identification band on the patient before collecting the sample(s). If the sample collection is STAT and/or there is no qualified person available to place identification band on the patient, follow the RHA

procedures for emergency transfusions and for situations where the patient identity is unknown.

5.1.3 Compare the patient's name and unique identifier on the identification band with the corresponding information on the request form/requisition and/or computer label. The patient's name and HSN or unique identifier must be identical. If they are not the discrepancy must be corrected before the sample is collected.

5.1.4 If possible, ask the patient to spell or verbalize his or her name and date of birth. DO NOT say "are you….." If the patient can not communicate, ask a qualified person to identify the patient. This person may be required to sign the request form/requisition identifying the patient before collecting the samples.

If any of the information is incorrect, ask for a corrected identification band to be placed on the patient. If time does not permit and transfusion is required, follow the RHA's established policy and procedure for emergency transfusion or situations where the patient identity is unknown.

5.1.5 (Optional) Ask the patient if he/she was transfused in the last 3 months (and/or pregnant if applicable). Document this information on the request form/requisition or computer label.

5.2 Perform the venipuncture as per the established RHA-policy and procedure.

5.3 Label sample(s) immediately after the sample collection, before leaving the patient's bedside.

5.3.1 The samples must be labelled with a computer-generated or hand-written label and must contain the following information:

- Patient last and first name(s);
- Patient's HSN or unique identifier;
- Date and time of collection;
- Identification of the phlebotomist (name, initials or computer identification); and
- Patient date of birth (Optional).

5.3.2 Attach the labels to the sample tube(s) before leaving the patient's bedside. Note that the label must NOT obstruct any of the relevant patient information on the sample tube.

5.3.3 If a transfusion-specific identification band is used, perform the following steps:

5.3.3.1 Transcribe the patient's last name and first name(s) and the HSN or unique identifier from the request form/requisition onto the transfusion-specific identification band.

5.3.3.2 Attach the transfusion-specific identification labels to the sample tubes and the request form/requisition.

5.3.3.3 Attach the transfusion-specific band to the patient's wrist or ankle.

5.4 Sign and write the date and time of collection on the request form/requisition.

5.5 Perform a final check before leaving the bedside. Compare the patient names and HSN or unique identifier on:

- Sample tube label(s);
- Request form/requisition; and
- Identification band

6.0 Documentation

N/A

7.0 Procedural Notes

7.1 Each RHA shall have a policy and procedure for STAT collections on unidentified patients or for situations where the identity of the patient is unknown. [CSA 10.2.4]

8.0 References

8.1 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

8.2 Capital Health Hospital Transfusion Services, Alberta Health Services. Section 4 - specimens. *Clinical guide to blood transfusion.* January 2009.

8.3 Manitoba Health. *Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing.* June 2007.

8.4 Ontario Regional Blood Coordinating Network (ORBCON). Patient identification and specimen labelling, document #: PA.001*. Ontario regional blood coordinating network standard work instruction manual.* December 31, 2009.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

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(Senior Management) (Senior Management)

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(Date of implementation)

Guideline SK 5

Determination of Sample Suitability

1.0 Principle

To describe the criteria for accepting samples for compatibility testing. Strict enforcement of criteria for acceptable pre-transfusion samples will facilitate safe transfusion practice.

2.0 Scope and Related Policies

2.1 Any samples with missing and/or wrong name and/or identification number shall not be accepted for pre-transfusion testing. CSA 10.2.1(e), 11.3.1

2.2 For patients who have been transfused or pregnant within the last three months, or if history of transfusion or pregnancy is uncertain or unknown, samples for compatibility testing shall be no more than 96 hours old. CSA 10.4.2

2.3 For patients who have not been transfused or pregnant in the past three months, samples for compatibility testing may be stored and used for a time specified in the transfusion service/laboratory policy. CSTM 5.2.3.3

2.4 For repeat transfusions, the original blood sample may be used to crossmatch additional units within the 96 hour period following transfusion of the first unit of blood. CSA 10.4.3

2.5 The request form/requisition shall identify the patient by family and given names and by the patient's unique identifier. A request form/requisition without proper patient identification must not be accepted by the transfusion service/laboratory. CSA 10.2.1(a-e), 14.3. The request form may be a requisition or an electronic request.

2.6 The information on the blood sample and the request form/requisition shall be checked before testing begins. Any discrepancies or errors must be satisfactorily resolved or new samples collected. CSA 10.2.1(a-e), 10.3.3

2.6.1 The name and initials or the computer identification code of the person drawing the blood sample shall be documented. The date and time of collection must also be documented. This information shall be retained for one year in a place where it can be readily retrieved if needed (e.g., the patient's chart or the transfusion record). CSA 10.3.1, 14.3

2.7 The patient's blood sample shall be stored for at least seven days after transfusion. CSA 11.1.2.5

2.7.1 Samples must be stored between 1 – 6° C. Freezing plasma is not required. To reduce the risk of labeling/identification errors, separation of plasma should only be done in laboratory.

3.0 Materials

3.1 Samples collected for pre-transfusion testing

- EDTA anticoagulated whole blood

- Note: SST, PST and PLUS tubes must not be used for the collection of samples for transfusion service procedures.
- See Procedural Notes 7.1.

3.2 Request form/requisition or electronic request entry

4.0 Quality Management

4.1 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter.[CSA 4.3.3.1]

5.0 Procedure

5.1 Compare the sample(s) and corresponding request form/requisition (or electronic request entry) and ensure the following information is identical:

- Patient family and given names
- Patient's unique identifier and, if applicable, the identifier from an additional identification band (e.g., transfusion specific identification band)

Note: If any of the above is missing or incorrect, the sample(s) must not be used. A new sample must be collected. Complete an incident report according to RHA procedures and submit it to a supervisor.

5.2 Ensure the following information is present:

- Date and time of collection
- Identification of the phlebotomist (name, initials or computer identification)

5.3 Ensure that the following information is recorded on the request form/requisition (or electronic request entry):

- First and last names of the patient. If information is not available refer to the RHA's policy for patient identification when patient identification is unknown.
- Patient's Saskatchewan Health Services number or unique identifier
- Patient's location
- Blood component or plasma protein product requested
- Volume or amount of product required
- Clinical indication

Note: If the above information is missing, obtain this information from the ward or physician's office.

5.4 Verify the age of the sample

5.4.1 Review the patient's transfusion history and the date and time of sample collection to ensure the intended date of transfusion is within an

acceptable time period. See Scope and Related Policies 2.2 to 2.3 and Procedural Notes 7.2.

5.4.2 If the time period is unacceptable, arrange to have another sample collected.

5.5 Visually check samples for acceptability. See Procedural Notes 7.3.

5.5.1 If abnormal appearance present, record on the request form/requisition or in the computer.

5.5.2 Report findings of abnormal appearance to senior technologist or designate for discussion with Medical Director to determine if clinically significant.

5.5.3 Rejected samples must be documented and action taken according to RHA policy.

5.6 If the sample has been collected for tests other than pre-transfusion testing (e.g., DAT, cold agglutinin screen), the sample labelling criteria should conform to established laboratory practice.

6.0 Documentation

N/A

7.0 Procedural Notes

7.1 If an EDTA sample is not available and a clotted sample has been collected from a patient treated with heparin, it may not clot properly. Adding thrombin or protamine sulphate to the sample according to established procedures usually corrects the problem.

7.2 Calculating the age of a sample:

Day “0” is the day of collection. For example, a sample collected on April 10 may be used for pre-transfusion testing up to midnight on April 14.

7.3 Sample Appearance/Rejection Criteria.

7.3.1 Abnormal plasma colour such as red, brown or dark amber may indicate the presence of intravascular or delayed hemolysis.

7.3.2 Agglutination in the EDTA sample could be caused by the presence of a cold autoagglutinin. Warming the sample may be required.

7.3.3 Very low hematocrit may be due to contamination with intravenous (IV) fluid. If this is verified by the sample phlebotomist, obtain another sample.

Note: Samples collected from infusion lines are acceptable if collected correctly. The tubing should be flushed with normal saline and 5 mL or a volume of blood approximately twice the fluid volume in the line should be withdrawn and discarded before collecting the sample.

7.3.4 Rejection Criteria Summary:

Sample	Requisition	Collection
No requisition received with the sample	*Collector/identification signature missing	IV Fluid contamination
Unlabelled sample	*Same signature for collection and identification	Insufficient quantity for testing
Last and/or first name missing	Spelling error or incomplete name	Sample broke in transit
Spelling error or incomplete name	Name illegible	Marked hemolysis
Illegible name or unique identifier #	Full name missing	
Unique identifier missing	* Transfusion specific identification number missing	
*Transfusion specific identification number missing	Unique identifier missing	
* Transfusion specific identification number different than on the requisition	*2 different transfusion specific identification number's on requisition	
Date and time of collection missing	Date and time of collection missing	

*Rejection criteria only for pre-transfusion testing and blood product requests.

7.3.4.1 **Non-transfusion related testing requests**:

- Do not require a transfusion specific identification number.
- Laboratory collector's identification code is acceptable for "collected by" signature.

8.0 References

8.1 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

8.2 Capital Health Hospital Transfusion Services, Alberta Health Services. Section 4 - specimens. *Clinical guide to blood transfusion. January* 2009. http://www.capitalhealth.ca/NR/rdonlyres/ekd3amjapuygoufncc3u4c6n4e5ji23hyjpjihr576nk6cikvol2zyusthhkipzxih2c2vlg2uknxwsgmsaqgnzey6e/Section4.pdf. Accessed August 16, 2010.

8.3 Ontario Regional Blood Coordinating Network (ORBCON). Determining specimen suitability, document #: PA.002. *Ontario regional blood coordinating network standard work instruction manual.* December 31, 2009.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 6

Receipt of Blood Components and Plasma Protein Products into Inventory

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1.0 Principle

1.1 To receive blood components and plasma protein products into inventory from Canadian Blood Services (CBS), other facilities, or shipped with a patient.

1.2 To provide an accurate record of the receipt of blood components and plasma protein products.

2.0 Scope and Related Policies

2.1 *Required*

2.1.1 Blood components and plasma protein products shall be transported in a manner that prevents damage or deterioration. CSA 9,5.2.2

2.1.2 Transportation should not exceed 24 hours. Transportation times should be based on hospital or CBS container validation data. Discontinuation of agitation of platelets should not exceed 24 hours. CSA 9.5.2.2

2.1.3 A process shall be in place to ensure traceability of all blood components and plasma protein products received. CSA 9.1.2; 20.1.1

2.1.4 When a shipment is for blood inventory purposes, the receiving facility shall be responsible for final disposition documentation. CSA 9.5.2.7

2.1.5 When blood components are transported with a patient, the issuing facility shall be responsible to notify the receiving facility. The receiving facility shall be responsible for final disposition documentation. CSA 9.5.2.8

2.1.6 All blood components and plasma protein products must be shipped in a validated system to ensure that acceptable temperature ranges are maintained. CSA 9.5.2.1

2.1.7 A process shall be in place to ensure that segments from all transfused units are removed and stored at 1 to 6°C for at least 7 days after transfusion. CSA 11.1.2.5

2.1.8 All staff shall be trained in the proper handling of blood components and plasma protein products CSA 9.5.1

2.1.9 All deviations from the regional health authority's (RHA's) policies and procedures shall be documented, investigated and corrective action taken when required. CSA 4.6.2.1

2.2 *Best Practice*

2.2.1 All packing slips (issue vouchers) must be checked against the actual blood components and plasma protein products to ensure the accuracy of the information. CBS or the shipping facility must be notified of any discrepancies.

2.2.2 After verification, all shipping documents (e.g., packing slips, inter-hospital transfer forms) should be initialled and the date and time recorded by the person receiving the shipment. A copy of the plasma

protein product packing slip must be returned for plasma protein shipments received from CBS.

2.2.3 Blood components should be inspected for abnormal appearance upon receipt by the facility. If an obvious abnormality is detected the product must be quarantined until appropriate disposition is determined. The process must be documented and the shipper notified.

3.0 Materials

3.1 Equipment
- Blood Shipping Box
- Ice Packs
- Gel Packs

3.2 Supplies
- Packing Slip
- Issue /Transfusion Record (as RHA policy)
- Tamper Evident Seal

4.0 Quality Management

4.1 A RHA-based quality improvement system or process should be in place to monitor compliance with the policies and procedures for receiving blood components and plasma protein products.

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter.[CSA 4.3.3.1]

4.3 Optimal storage conditions for blood components are outlined in the *Canadian Blood Services Circular of Information.*

4.4 Specialized component requests are documented on the blood label and the packing slip. Examples of special component requests are: [CSA 8.6.5.2;8.6.5.3]

- Phenotyped units – all red cell units must be phenotyped on the current unit for transfusion to patients with atypical antibodies. Typing results are documented on the blood label with the antigen underlined or with a phenotype tag affixed to the unit.
- Anti-CMV Negative
- Irradiated.

5.0 Procedure

5.1 Receiving Blood Components

5.1.1 Ensure there is a tamper evident seal on the shipping box. If the seal is not present perform an investigation, contact the shipping facility and the transporter and:

5.1.1.1 If shipped by a public transport system such as bus, airline or taxi, discard the product immediately and notify the attending physician immediately if there is a delay in transfusion.

5.1.1.2 If shipped by a designated facility transport such as ambulance or facility/family member the Medical Director may authorize the release of the product. Document all decisions.

5.1.2 Determine the time from packing to unpacking of the shipment from the packing time found on the packing slip. Verify and document that the time from packing to unpacking is less than 24 hours (based on container validation).

5.1.3 Open the shipping containers one at a time and inspect the packing of the blood components inside.

5.1.4 Retrieve the packing slip and ensure that the paperwork is for the correct facility, initial and record the time and date of unpacking.

5.1.5 Inspect the contents of the plastic bag. If there is liquid in the bag, determine whether the blood components are damaged. If the blood component is damaged, notify the shipper immediately.

5.1.6 Remove the blood components from the plastic bag. Account for all units in the shipment and verify the information on the blood unit label or compatibility tag with the information on the packing slip.

5.1.7 If there are discrepancies, notify the shipper immediately.

5.1.8 Visually inspect each unit. Document the results of the visual inspection. Quarantine all products that do not pass visual inspection.

5.1.9 Confirm that request(s) for special blood components / testing were received from the CBS. Special blood components will have the attribute labelled on the blood label.

5.1.10 Store blood components in monitored and validated storage systems by expiration date to ensure that the oldest components will be selected first.

5.1.11 Document the receipt of all blood components in the Issue / Transfusion Log as per RHA procedure.

5.1.12 Remove and retain 2 segments from each of the red cell units upon receipt or prior to transfusion. Segments must be stored in a controlled refrigerator for 7 days post-transfusion or discard. CSA 11.1.2.5

5.1.13 Retain a copy of the packing slip indefinitely. CSA Table 4 Record Retention Guidelines

5.2 Receiving Plasma Protein Products

5.2.1 Refer to “Receiving Blood Components” above and complete all applicable steps with the addition of the following information:

5.2.1.1 Verify the lot number(s) and quantity (number of bottles/vials) received with the information on the packing slip.

5.2.1.2 Sign and date both copies of the packing slip in the appropriate area. Return one copy to CBS.

5.3 Receiving Autologous/Directed Blood Components

5.3.1 Refer to “Receiving Blood Components” above and complete all applicable steps with the addition of the following information:

5.3.1.1 Verify the unit number(s) with the packing slip and the autologous/directed form.

5.3.1.2 Verify the patient's first and last names, date of birth and Saskatchewan Health Services number on the autologous/directed tag attached to the unit(s) is identical to the information on the autologous/directed form and the packing slip.

5.3.1.3 Verify the patient's first and last names are printed on the blood unit label.

5.3.1.4 Ensure that the units are labelled "For Autologous Use Only". [CSA 12.3.2.1]

5.3.1.5 Store autologous/directed blood components in a designated area for autologous/directed donations. [CSA 12.1.5]

6.0 Documentation

6.1 For all discrepancies, notify the shipping facility and complete an occurrence report.

6.2 Document the receipt of blood components or plasma protein products in the applicable Issue/Transfusion log.

7.0 Procedural Notes

7.1 The attending physician must be notified immediately in the case of blood components or plasma protein products that are deemed unsuitable for transfusion if it will result in a delay in transfusion.

7.2 If units were transfused to a patient en route, the transfusion information should be recorded. If the units are sent but not received and the disposition was not recorded an investigation must be done to determine if the units were transfused.

8.0 References

8.1 British Columbia Technical Resource Manual for Hospital Transfusion Services Receiving Blood, Blood Components and Other Related Products (IM.002) January 1, 2005

8.2 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

8.3 Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing Receiving Blood, Blood Components and Derivatives Guideline MB12 Version 1 2007

8.4 Transfusion Ontario Ottawa – Standard Work Instruction Manual Receiving Blood, Blood Components and Fractionated Products (IM.002) April 5,2004

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 7

Transport of Blood Components and Plasma Protein Products Within a Facility

1.0 Principle

1.1 To provide guidelines for transport of blood components and plasma protein products from the transfusion service/laboratory to an authorized staff member at the patient's location, or to a controlled satellite transfusion service/laboratory refrigerator.

2.0 Scope and Related Policies

2.1 *Required*

2.1.1 Regional Health Authority (RHA) policies must be in place that clearly define individuals who may transport blood components or plasma protein products from transfusion service/laboratory and subsequently transport them to the patient's location. CSA 9.5.3(a)

2.1.2 Documentation of appropriate training for the handling and transportation of blood components or plasma protein products must be in place and maintained. CSA 9.5.1

2.1.3 For each blood product issued, a record system shall be in place which documents the identity of the person issuing the blood product and/or transporting the blood product to the patient's location.CSA 11.1.2.1

2.1.4 The blood components or plasma protein products must be transported to the patient's location immediately. CSA 9.5.3(b,c,d)

2.1.5 Blood component administration shall begin within 30 minutes from the time the product is released from temperature controlled storage and shall not exceed 4 hours from the time-of-issue from the temperature-controlled storage. CSA 11.4.6

2.1.6 Blood components and plasma protein products shall be returned to transfusion service/laboratory immediately if a decision is made not to transfuse.CSA 9.5.3(b,c,d), 17.5

2.1.6.1 Blood products that have been returned to the transfusion service/laboratory shall not be re-released unless: CSA 10.10.5; 11.4.7; 14.6.2

- There is at least one remaining sealed segment of integral donor tubing attached to the blood bag;
- A suitable monitoring system indicates that they have been maintained within acceptable temperatures since their release; or in the absence of a temperature monitoring system, the blood or blood component has not been outside the controlled environment for more than 30 minutes.

- There is documentation that confirms the blood product has been visually inspected before release; and
- The vial or container is undisturbed.

3.0 Materials

3.1 Issue/Transfusion Log (laboratory log or laboratory information system (LIS)).

3.2 Blood product portering competency training and assessment tools.

4.0 Quality Management

4.1 A RHA-based quality improvement system or process shall be in place to audit transportation time for blood components or plasma protein products to the patient's location, to audit returned blood components or plasma protein products, and to regularly audit rate of returned products.

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter.[CSA 4.3.3.1]

5.0 Procedure

Contact transporter personnel (facility-specific) either verbally or electronically. **Note:** In some facilities the issuer and the transporter may be the same individual and must adhere to the following guidelines:

- Guideline 10- Issue, Return, and Documentation of Final Disposition for Blood Components and Plasma Protein Products; and
- Guideline 7- Transport of Blood Components and Plasma Protein Products within a Facility.

5.1 **Manual Transport**

Manual transport of blood components or plasma protein products.

The transporter will:

5.1.1 Respond to the request on a priority basis as per established RHA policies and procedures and proceed to the transfusion service/laboratory.

5.1.2 Receive patient information and request for blood components or plasma protein products from the patient's location.

5.1.3 If the transporter is also the issuer then follow Guideline SK 10- Issue, Return and Documentation of Final Disposition of Blood Components and Plasma Protein Products.

5.1.4 Sign for the blood components or plasma protein products, in the appropriate column of the Issue/Transfusion Log (laboratory log) or provide information to the transfusion service/laboratory staff which identifies the transporter. [CSA 9.2.2]

5.1.5 Transport the blood components or plasma protein products and relevant documentation to the patient's location immediately.

- Protective covering for blood components or plasma protein products is recommended (e.g. plastic or ziplock bag). Ensure any patient information is adequately protected.

5.1.6 Deliver the blood components or plasma protein products directly to an authorized staff member at the patient's location.

Note: Blood components or plasma protein products must not be left without the acknowledgement of the staff at the patient's location.

5.2 Pneumatic Tube Transport

Transport of blood components or plasma protein products using pneumatic tube system.

The transfusion service/laboratory staff will:

5.2.1 Receive patient information and request for blood components or plasma protein products from the patient's location.

5.2.2 Issue blood components and/or plasma protein products as described in Guideline SK 10 - Issue, Return, and Documentation of Final Disposition for Blood Components and Plasma Protein Products.

5.2.3 Pack blood components and/or plasma protein products in the pneumatic tube as per system specifications.

The receiving station will:

5.2.4 Unpack the blood components or plasma protein products and relevant documentation from the pneumatic tube.

5.2.5 Sign the relevant documentation and return to facility transfusion service/laboratory via the pneumatic tube.

5.2.6 Deliver the blood components or plasma protein products directly to an authorized staff member at the patient's location.

Note: Blood components or plasma protein products must not be left without the acknowledgement of the staff at the patient's location.

6.0 Documentation

6.1 Document on appropriate record as per established RHA policies and procedures, the following:

- Date and time of issue; and
- Identity of the transporter (as applicable)

7.0 Procedural Notes

7.1 Blood components or plasma protein products for transfusion/infusion must be:

- Initiated; or

- Stored in a controlled satellite transfusion service/laboratory refrigerator; or
- Returned to the transfusion service/laboratory within 30 minutes.

8.0 References

8.1 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

8.2 Manitoba Health. *Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing.* June 2007.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 8

Selection of Blood Products and Specialized Product Usage Criteria

1.0 Principle

1.1 This procedure provides guidelines on the selection of blood products and specialized products for certain patient populations.

2.0 Scope and Related Policies

2.1 *Required*

2.1.1 The transfusion service/laboratory shall have a written policy indicating which patients or categories of patients are to receive cellular blood components selected or processed to reduce the risk of Cytomegalo Virus (CMV) transmission. CSA 11.6

2.1.2 The transfusion service/laboratory shall have a written policy indicating which patients or categories of patients are to receive irradiated cellular blood components. CSA 11.7.1

2.1.3 The transfusion service/laboratory shall have a written policy indicating the use of CMV negative, irradiated blood components for neonatal patients. CSA 10.9.1.8; 10.9.1.10

2.1.4 In the case of massive transfusion in neonatal patients, including exchange transfusion, only red blood cells that have been screened and found negative for hemoglobin S should be transfused. CSA 10.9.1.9

2.1.5 Patients shall be transfused with ABO group-specific whole blood or ABO group-compatible red blood cells. CSA 10.7.1

2.1.6 Blood components and plasma protein products shall not be used after their expiration date unless such use has been approved in writing by a licensed physician. CSA 10.7.2

2.1.7 Rh-positive patients may receive red blood cells that are either Rh-positive or Rh-negative. Rh-negative patients should receive Rh-negative red blood cells. An Rh-negative individual may be transfused with Rh-Positive red blood cells when Rh-negative red cells are in short supply, provided that the decision or policy has been approved by the medical director. CSA 10.7.3

2.1.8 When clinically significant red cell antibodies are found or the patient's history contains a record of such antibodies, whole blood or red blood cells lacking the corresponding antigen should be selected for transfusion/ infusion and shall be demonstrated to be compatible by a crossmatch method designed to detect such antibodies, except when the clinical situation justifies an exception. Any exception shall be approved by the medical director or his or her designate. Whole blood and plasma-containing blood components that contain clinically significant red cell antibodies should be transfused only to patients known to be negative for the corresponding antigen, except when approved by the licensed physician responsible for the transfusion service. CSA 10.7.4

2.1.9 Plasma selected for transfusion/infusion shall be ABO compatible with the patient's red cells but does not require a crossmatch. CSA 10.7.5

2.1.10 Cryoprecipitated antihemophilic factor (AHF) and cryoprecipitate should be ABO compatible with the patient's red cells but crossmatching is not required. A policy shall be in place concerning group substitution when ABO compatible cryoprecipitate components are not available. CSA 10.7.6

2.1.11 The donor plasma in platelets should be ABO compatible with the patient's red cells. A policy shall be place concerning group substitution when compatible platelets are not available. CSA 10...7.7.

2.1.12 The transfusion service shall have a written policy indicating which patients or categories of patients are to receive irradiated cellular blood components. CSA 11.7.1

2.1.13 Cellular blood components should be irradiated in order to reduce the risk of graft-versus-host disease in patient categories that include, but are not limited to:

(a) intrauterine transfusions;

(b) Selected immunocompromised patients;

(c) Patients of cellular blood components known to be from a blood relative;

(d) Patients who have undergone hematopoietic progenitor cell (stem cell) transplantation; or

(e) Patients of human leukocyte antigen (HLA) -selected platelets or platelets known to be HLA homozygous.

2.1.14 Once it has been determined that a patient requires irradiated cellular blood components, there shall be a mechanism in place to ensure that all future cellular blood components for that patient are irradiated, as long as clinically indicated.

2.1.15 Irradiated blood components may be released for transfusion of patients for whom irradiated blood components are not required, provided that there is compliance with required storage conditions and

2.2 *Best Practice*

2.2.1 The transfusion service/laboratory should have guidelines indicating the use of washed blood components.

2.2.2 The transfusion service/laboratory should have guidelines indicating the use of HLA compatible platelets.

2.2.3 The transfusion service/laboratory should have guidelines to follow in selecting blood components for Sickle Cell Disease patients.

3.0 Quality Management

3.1 A Regional Health Authority (RHA) -based quality improvement system or process shall be in place to monitor compliance with the policies and procedures for selection of specialized blood components.

3.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion/infusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. [CSA 4.3.3.1]

4.0 Procedure

4.1 Select ABO group-compatible red blood cells and plasma products as per table below. Check RHA policy for product selection in emergency situations.

For the selection of red blood cells:

Patient's blood group	Alternate ABO
Group O	No alternate
Group A	Group O
Group B	Group O
Group AB	Group A(first), B(second), or O(third)

For the selection of plasma, platelets, and cryoprecipitate:

Patient's blood group	Alternate ABO
Group O	Group A(first), B(second), or AB(third)
Group A	Group AB
Group B	Group AB
Group AB	No alternate

4.2 Ensure that the product has not reached its expiration date.

4.3 Select Rh group-compatible red blood cells and platelet products as per table below. Check RHA policy for product selection in emergency situations.

Patient's blood group	Alternate ABO
Rh-positive	Either Rh-positive or Rh-negative
Rh-negative	Rh-negative *in emergency situations Rh-negative units must be given to women of child bearing age and children (See Guideline #11 Request for Uncrossmatched Blood)

4.4 Check the patient record for clinically significant antibodies and select red cells and ensure that red cells are negative for the corresponding antigen.

4.5 Check the patient record for special transfusion requirements such as CMV-negative, irradiated and washed red cells

4.6 Patients that should receive washed red cell components should include, but not be limited to:

- Neonatal exchange transfusion
- Patients with anti-IgA, or with an IgA deficiency and a history of severe allergic reactions

- Patients with a history of anaphylactic transfusion reactions of unknown etiology

4.7 Patients that have Sickle Cell Disease should receive red cell components that are <14 days old and phenotypically-matched.

4.8 Patients with thrombocytopenia due to bone marrow failure/suppression who demonstrate alloimmune refractoriness to platelet transfusion should receive HLA compatible platelets.

4.9 Neonatal Transfusion:

SK Application – Neonatal Transfusions: In Saskatchewan, neonatal transfusions should only be performed in hospitals with neonatal intensive care units (NICU). In exceptional circumstances, such transfusions may be authorized outside of the NICU environment at the direction of a neonatologist. (Approved by the Senior Medical Officer Committee on May 11, 2011.)

4.9.1 For infants under 4 months, a pre-transfusion sample shall be tested to determine the ABO and Rh groupings and to detect clinically significant red cell antibodies. Cord blood shall not be used for pre-transfusion testing (however, it may be used for ABO and Rh groupings for other purposes). CSA 10.9.1.1

4.9.2 Neonates must receive ABO compatible or plasma reduced platelets.

4.9.3 There shall be a written policy with the respect to the permitted storage periods for irradiated blood for use in intrauterine or neonatal recipients CSA10.9.1.10 Blood that has been irradiated should be used as soon as possible after irradiation as increased potassium levels have been associated with irradiation.

4.9.4 A policy shall be place for the use of CMV sero-negative blood products in neonatal transfusions. CSA 10.9.1.8; 10.9.1.10

4.9.5 Neonates that are receiving exchange transfusion or massive transfusion should only have red blood cells that have been tested negative for hemoglobin S. CSA 10.9.1.9

5.0 Reporting

5.1 Medical Director approval should be required for the use of alternate ABO compatible blood components as per RHA policy

6.0 Documentation

6.1 Once it has been determined that a patient requires a specialized blood component, there shall be a mechanism in place to ensure that all future blood components are selected appropriately.

7.0 References

7.1 BC Provincial Blood Coordinating Office Transfusion Medicine Medical Policy Manual 1st Edition 2007.

7.2 Callum, JL; Lin, Y; Pinkerton, PH; Karkouti, K; Pendergrast, JM; Robitaille, N.; Tinmouth, AT; and Webert, KE. (2011) *Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions (3rd edition)*. Toronto, ON: Ontario Regional Blood Coordinating Network.

7.3 Canadian Blood Services. *Clinical Guide to Transfusion* (July 2006)

7.4 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services Version 3*. May 2011.

7.5 Ontario Regional Blood Coordinating Network. (2009). *Standard Work Instruction Manual.*

7.6 Canadian Standards Association. (2010) *Standards for Blood and Blood Components CSA Z902-10.*

7.7 Manitoba Transfusion Quality Manual for Blood Banks. Version 2 June 2007

7.8 Regina Qu'Appelle Health Region. *Nursing Procedure Manual* (February 2010), Regina, Saskatchewan.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 9

Visual Inspection of Blood Components and Plasma Protein Products

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1.0 Principle

1.1 To ensure that all blood components and plasma protein products received, issued for transfusion, returned to inventory or shipped out of the facility are visually inspected for abnormalities.

2.0 Scope and Related Policies

2.1 *Required*

2.1.1 Facilities shall have operating procedures for inspection of blood components and plasma protein products for visual abnormalities. CSA 8.1.1

2.1.2 Blood components and plasma protein products shall be visually inspected for leakage or abnormalities immediately before being placed into inventory. The visual inspection shall ensure that each blood component and plasma protein product is properly labelled and that it shows no leakage, discoloration, or abnormalities such as clots or hemolysis. CSA 8.5

2.1.3 Blood products and plasma protein products that fail the visual inspection shall not be placed into inventory. CSA 8.5

2.1.4 Blood components and plasma protein products shall be inspected immediately before being released from inventory. Blood products and plasma protein products shall not be released from inventory if visual leakage or abnormalities are noted. CSA 10.10.2

2.1.5 Prior to being packaged for shipment, each blood bag containing blood components or plasma protein products shall be visually inspected and this inspection shall be documented. Containers with visual leakage or abnormalities, or that have past their expiration dates, shall not be shipped for transfusion. CSA 9.5.2.5

2.1.5.1 If an unusable product is being shipped for investigation or disposal, the outside package shall clearly indicate that it is not for transfusion. CSA 9.5.2.5

2.1.6 All inspections shall be documented. CSA 8.5; 10.10.2

2.1.7 Blood components and plasma protein products shall not be used after their expiration date unless such use has been approved in writing by a licensed physician. CSA 10.7.2

2.1.8 Blood components and plasma protein products that have been returned to the transfusion service/laboratory shall not be re-released unless: CSA 10.10.5

- There is at least one remaining sealed segment of integral donor tubing attached to the blood bag.

- There is documentation with the unit of blood component or plasma protein product to indicate that it is being re-released and confirmation that it has been visually inspected before release.
- A suitable temperature monitoring system indicates that the blood component or plasma protein product has not reached unacceptable temperature since being released or, in absence of a temperature-monitoring system that the blood component or plasma protein product has not been outside of a controlled environment for more than 30 minutes.
- The blood bag closure is undisturbed.

2.1.9 The operating procedures for storage shall include provisions for the quarantine of blood components and plasma protein products to ensure that they cannot be released for use until documentation approved by qualified personnel indicates that they have undergone mandatory testing with satisfactory results. Blood components and plasma protein products without this documentation shall be stored in an identified and secured quarantine location. The procedure shall also assign responsibility for the release from quarantine. CSA 9.4.7

2.1.10 Blood components and plasma protein products that do not meet the necessary criteria for release due to test results or other factors shall be kept in a segregated and secure area until final disposition. CSA 9.4.8

3.0 Materials

3.1 Blood components or plasma protein products

3.2 Canadian Blood Services (CBS) Customer Feedback Form (Appendix #5)

3.3 Appropriate Issue/Transfusion log (lab log)

4.0 Quality Management

4.1 A Regional Health Authority (RHA)-based quality improvement system or process shall be in place to monitor the documentation for performance of visual inspection CSA 8.5; 10.10.2

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and outlined intervals thereafter. CSA 4.3.3.1

5.0 Procedure

5.1 Inspect blood components and plasma protein products at the following times:

- Upon receipt from the blood supplier or another facility
- At time of crossmatch
- Before being issued for transfusion
- Before being shipped to another facility

- Upon return to usable inventory

5.2 Determine if the blood component and plasma protein product is indate.

5.3 Visually inspect the blood components and plasma protein products for abnormalities. Refer to the following tables for inspection criteria.

VISUAL INSPECTION CHECKLIST

The following checklist may be used as a guide when inspecting blood components and plasma protein products. Refer to Visual Assessment Guide from CBS for detailed information on appearance of product.

Table 1. All Blood Components and Plasma Protein Products

ITEM	VISUAL APPEARANCE	ACCEPTABILITY CRITERIA
Expiry Dates Stickers/Labels	• Present – ensure date has not expired. • Ensure time (when applicable) has not expired.	• Product within expiry date.
Segments	• Sufficient and present	Sufficient segments to complete testing and for sample retention.
Packing External Covering	• Intact and dry. • No breaks or leaks	• Breaks, leaks, tears are unacceptable for transfusion. • Contract Transfusion Service/Laboratory
Port Covers	• Intact ports. • Exception: If product has been modified, at least one port must be intact.	• Not intact, loose or missing. • Contact Transfusion Service/Laboratory
Autologous Blood Label	• Specific autologous blood label and patient information attached to unit.	• Autologous blood label and patient information missing. • Contact transfusion service/laboratory.

Table 2. Red Blood Cells

ITEM	VISUAL APPEARANCE	ACCEPTIBILITY CRITERIA
Hemolysis	• Loss of intact red cell results in bright cherry red color. • Free hemoglobin imparts light pink tinge to a dark red almost purple to supernatant. • Occurs as part of normal aging process	• Some degree of hemolysis expected. • Contact transfusion service/laboratory if hemolysis suspected.
Lipemia	• Lighter shade or red and increased opacity of unit similar to “strawberry	• Blood components with lipemia are acceptable for

ITEM	VISUAL APPEARANCE	ACCEPTIBILITY CRITERIA
	milk shake".	transfusion.
Icterus	N/A	• Blood components with icterus are acceptable for transfusion.
Bacterial Contamination	• Dark purple to black discoloration in red cells. • Excessive and unusual air bubbles. • Clots and fibrin strands. • Increased opacity. • When associated with hemolysis, a pink to red discoloration may be seen in supernatant.	• Bacterial contaminated blood is <u>not suitable</u> for transfusion. • Contact transfusion service/laboratory if bacterial contamination is suspected.
Particulate Matter	• Clots appear as small to large dark red or purple masses that do not dissipate with gentle manipulation. • Cellular aggregates – white and opaque masses that do not dissipate with gentle manipulation. • White particular matter from flattened specs to a greasy film and may dissipate with a change in temperature. • Cold agglutinins from large red cell masses that do not dissipate with gentle manipulation.	• Blood components with clots and fibrin strands, cellular aggregates, cold agglutinins are <u>not acceptable</u> for transfusion. • Contract transfusion service/laboratory if suspected. • Blood components with white particulate matter are acceptable for transfusion.
Discoloration	• See Hemolysis, Lipemia, Bacterial Contamination	
Donor Antibody Information	• Information about donor antibodies is located on the lower left hand side of the donor label.	• Ensure that donor units containing antibodies are not transfused to neonates or pediatric patients

Table 3. Plasma, Platelet and Cryoprecipitate Components

ITEM	VISUAL APPEARANCE	ACCEPTIBILITY CRITERIA
Hemolysis	• Red cells in plasma will hemolyze during freeze/thaw and will impart a pink to red tinge depending on number of red cells involved.	• Some degree of hemolysis is possible depending on number of red cells in plasma.
Red Cell Contamination	• Varies from light pink/salmon color tinge to marked red discoloration.	• Platelets – compatibility testing when apheresis platelet contains more than 2 mL of red cells. • Currently there are no standards of acceptability for red cell contamination of plasma units.

ITEM	VISUAL APPEARANCE	ACCEPTIBILITY CRITERIA
Lipemia	• Increased opacity. • "milky" white appearance.	• Blood components with lipemia are acceptable for transfusion.
Icterus	• Bright yellow to brown.	• Blood components with icterus are acceptable for transfusion.
Bacterial Contamination	• Excessive and unusual air bubbles. • Clots and fibrin strands. • Increased opacity. • Grey discoloration.	• Bacterial contaminated blood components are <u>not acceptable</u> for transfusion. Contact transfusion service/laboratory if suspected.
Particulate Matter	• Clots and fibrin strands may appear as white/opaque masses on whitish thread-like strands that do not dissipate with gentle manipulation. • Cellular aggregates may appear as white and opaque masses that do not dissipate with gentle manipulation. • Particulate matter may vary considerably in size.	• Blood components containing: clots, fibrin strands and cellular aggregates <u>should not</u> be transfused. • Contact transfusion service/laboratory if suspected. • White particulate matter seen in thawed plasma that has been stored in fridge is acceptable for transfusion.
Discoloration	• Icterus – (Yellow) • Oral Contraceptives – (Green) • Vitamin A or large amount of carrots – (orange)	• Acceptable for transfusion.

Table 4. Plasma Protein Products

ITEM	VISUAL APPEARANCE	ACCEPTIBILITY CRITERIA
Lot Numbers	• Ensure lot numbers on box matches that of vial or bottle.	• If does not match, contact transfusion service/laboratory.
Products and cap(s)	• Ensure the product and cap(s) are intact.	• If is loose or not intact, contact transfusion service/laboratory.
Fractionation Products	• Refer to manufacturers instructions regarding product acceptability.	
Sign of breakage	• Check for cracks or leaking in vial or bottle	• If present contract transfusion service/laboratory.

NOTE: If blood component or plasma protein product fails the visual inspection – contact facility transfusion service/laboratory before initiating transfusion/infusion.

5.4 Quarantine all blood components and plasma protein products that fail the visual inspection to ensure that they are not inadvertently used.

- Affix a note onto the blood product clearly stating "Quarantined: DO NOT USE". Describe the reason for the quarantine. Date and initial the note.
- Place the blood components or plasma protein products in suitable storage that is clearly labeled and away from general inventory and assigned units.
- If product was received from CBS, complete CBS Customer Feedback Form. Fax form and supporting documents (packing slips, issuing forms, test results, etc) to CBS.
- If product is received from another facility notify the sending facility.
- Return unit to CBS or discard as appropriate.

5.5 Document the results of the visual inspection and the final disposition of the product in the appropriate Issue/Transfusion Log (lab log).

6.0 Documentation

6.1 Documentation of visual inspection of each blood product in appropriate Issue/Transfusion Log (lab log).

7.0 Procedural Notes

7.1 If there is information missing or the label is illegible on a blood component or plasma protein product, notify CBS and the Transfusion Service/Laboratory Medical Director. An incident report should be completed and submitted to a supervisor.

7.1.1 The Transfusion Service/Laboratory Medical Director or designate must authorize the release of the blood components or plasma protein product.

- This authorization must be documented.

7.2 Units that appear darker than normal or have murky plasma/supernatant may be bacterial contaminated and recommended follow-up is to culture and stain the contents of the unit.

7.3 Red cells units with a bright, red plasma color may indicate significant red cell hemolysis.

- If significant red cell hemolysis is noted, quarantine the unit. Notify CBS. Refer to Tables 2, and 3.

7.4 Plasma or platelet units with an intense, yellow color may indicate an abnormally high bilirubin level. Refer to Table 3

7.5 If other products such as plasma protein products appear cloudy, compare the product's contents with the contents of a similar product.

- If only the bottle or vial being inspected is cloudy, quarantine the product. Notify CBS. Refer to Table 4.

8.0 References

8.1 BC Provincial Blood Coordinating Office. Transfusion Medicine Policy Manual. 1st Edition, 2007

8.2 Canadian Blood Services, Visual Assessment Guide, January 2009.

8.3 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services. Version 3.* May 2011.

8.4 Canadian Standards Association. *Blood and Blood Components*. CAN/CSA-Z902-10. February 2010.

8.5 Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing. June 2007.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 10

Issue, Return and Documentation of Final Disposition for Blood Components and Plasma Protein Products

1.0 Principle

1.1 To issue blood components and plasma protein products for transfusion from the transfusion service / laboratory.

1.2 To return blood components and plasma protein products to the transfusion service / laboratory.

1.3 To document the release and final disposition of blood components and plasma protein products using the issue/transfusion log.

2.0 Scope and Related Policies

2.1 *Required*

2.1.1 A record keeping system shall be in place to maintain the chain of traceability so that it is possible to trace blood components and plasma protein products from their source (receipt from the manufacturer/supplier) to final disposition. CSA 9.1.2, 11.1.2.1

2.1.2 There shall be a system in place to unequivocally identify the patient of the blood components and plasma protein products to be issued. All discrepancies shall be resolved prior to issue. This shall include the:

2.1.2.1 First and last names of the patient or patient identification in an emergency situation;

2.1.2.2 Patient's Saskatchewan Health Services Number (HSN) or unique identifier;

2.1.2.3 Patient's location;

2.1.2.4 Blood component or plasma protein product requested; and

2.1.2.5 Required volume. CSA 10.2.1, 11.3.2

2.1.2.6 Clinical indications CSTM 5.2.1.2

2.1.3 Blood components and plasma protein products shall be visually inspected immediately prior to release from inventory. The results of this inspection shall be documented. Blood components and plasma protein products shall not be released from inventory if leakage or abnormalities are noted. CSA 10.10.2 (See Guideline SK9 - Visual Inspection of Blood Components and Plasma Protein Products)

2.1.4 When issued blood components and plasma protein products are transported out of the facility with a patient, the issuing facility shall be responsible to notify the receiving transfusion service. There shall be an agreement between the issuing and receiving facility that defines the roles in maintaining traceability to its final disposition. CSA 9.5.2.8

2.1.5 Blood components may be re-issued if the unit meets the criteria defined in the procedure. CSA 10.10.5

3.0 Materials

3.1 Supplies
Tagged blood component or plasma protein product
Issue /Transfusion log or laboratory information system, as per Regional Health Authority (RHA) policy
Ward request form

4.0 Quality Management

4.1 A RHA-based quality improvement system or process shall be in place to ensure that all staff issuing and transporting units are properly trained and have competency assessed on regular intervals. CSA 4.6.1.1, 4.3.1.1

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

4.3 Manipulation of components within the facility (i.e. divided or washed in lab) must be documented. CSA 8.6.3.2

4.4 Each of the original unit numbers of blood components contained in a pooled unit must be documented (pooled cryoprecipitate) CSA 10.8.4

5.0 Procedure

5.1 Issuing Procedure

5.1.1 The following information must be brought to the laboratory for all blood components and plasma protein products. The request shall include the patient's last name, first name, HSN or unique identifier, patient location, type of blood component or plasma protein product required and number of units or dose. CSA 10.2.1, 11.3.1

5.1.2 Prior to retrieving red cells, ensure the crossmatch is "in date".

5.1.3 Retrieve the correct amount and type of blood component or plasma protein product from the appropriate storage area.

5.1.4 Verify the applicable information on the request form, transfusion issue/transfusion log, or the laboratory information system (LIS) with the tag and blood component or plasma protein product:

- Patient last and first name
- Patient HSN or unique identifier
- Patient ABO and Rh
- Blood component unit or pool number or plasma protein lot number
- Blood component ABO/Rh
- Compatibility status for red cells from the transfusion tag

- Verification of special transfusion product requirement
- Barcode scanning of blood components is encouraged for facilities with electronic systems

5.1.5 Ensure that all discrepancies detected in 5.1.4 are resolved by the transfusion service/laboratory prior to issue.

5.1.6 Perform a visual inspection of each product. Do not issue any product that does not pass visual inspection. Document the visual inspection. CSA10.10.2

5.1.7 Verify the information in 5.1.4 with the transporter. If all information matches, document either by having the transporter sign and date in the transfusion log book, or document in the LIS. A process must be in place for facilities with electronic systems to document transporter identification. As some laboratories do not have 24/7 coverage there shall be a process in place for trained personnel to transport blood products.

5.1.8 File the appropriate forms.

5.2 Return of Blood Components and Plasma Protein Products

5.2.1 Document the date and time of return in the issue/transfusion log or LIS.

5.2.2 Visually inspect the product to ensure that the following criteria are met prior to returning the blood component or plasma protein product to inventory:

- There shall be at least one remaining sealed segment of integral donor tubing attached to the blood bag.
- A suitable temperature monitoring system indicates that the blood component or plasma protein product has not reached an unacceptable temperature since being released or, in absence of a temperature-monitoring system the blood component or plasma protein product has not been outside of a controlled environment for more than 30 minutes (measured per occurrence, not cumulatively). Check the applicable package insert for plasma protein products.
- The bag closure is undisturbed. CSA 10.10.5

5.2.3 Discard the blood component or plasma protein products if the above conditions are not met.

5.2.4 Return the blood component or plasma protein products to appropriate controlled storage if it has met the above conditions.

6.0 Documentation

6.1 All blood components and plasma protein products shall have the final disposition documented in the transfusion log or LIS. CSA 11.1.2.1

6.2 Discarded blood components and plasma protein products must have the reason for discard specified (e.g. expired, broken).

7.0 Procedural Notes

7.1 Blood components and plasma protein products can only be issued immediately prior to the patient being transfused to ensure proper storage.

7.2 Autologous and directed units shall be issued prior to allogenic units. CSA 12.4.2

7.3 Initials of individuals who issue and transport blood components and plasma protein products may only be used if an initial log of all employees is maintained and updated regularly. CSA 20.6.4.2

8.0 References

8.1 British Columbia Technical Resource Manual for Hospital Transfusion Services Receiving Blood, Blood Components and Other Related Products (IM.002) January 1, 2005

8.2 Canadian Standards Association, *Blood and Blood Components.* CAN/CSAZ902-10. February 2010.

8.3 Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing Receiving Blood, Blood Components and Derivatives Guideline MB12 Version 1 2007

8.4 Transfusion Ontario Ottawa – Standard Work Instruction Manual Receiving Blood, Blood Components and Fractionated Products (IM.002) April 5,2004

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 11

Request for Uncrossmatched Blood

1.0 Principle

1.1 In emergencies, when blood is urgently required for transfusion, it may be necessary to issue blood before pre-transfusion testing can be completed if the patient's physician considers the risk of delaying blood transfusion is greater than the benefit of completing pre-transfusion testing.

2.0 Scope and Related Policies

2.1 *Required:*

2.1.1 Transfusion records must include a signed declaration by the requesting physician confirming that the clinical situation was sufficiently urgent to justify releasing the blood component(s) before completion of pre-transfusion testing. CSA 10.9.3.5

2.1.2 Whenever clinically possible, patient consent should be obtained. CSA 10.9.3.5

2.1.3 In situations where delaying a transfusion may be deleterious to the patient's condition, red blood cells may be released without pre-transfusion testing. Red blood cells should be Rh-negative for CSA 10.9.3.1:

- children; and
- women of child-bearing age

SK Application – Children and Women of Child Bearing Age: for the purposes of transfusion medicine in Saskatchewan, a child is defined as less than 18 years of age and a woman of child bearing age is defined as less than 50 years of age. (Approved by the Senior Medical Officer Committee on May 11, 2011.)

2.1.4 Patients with an undetermined ABO group shall receive group O red blood cells. CSA10.9.3.2

2.1.5 Group specific red cell units are **never** released based on the blood group on the patient historic record. ABO group-specific or ABO group-compatible red blood cells may be transfused prior to completion of other tests for compatibility if the recipient's ABO group has been determined using a valid current blood sample without reliance on previous records. CSA 10.9.3.3

2.1.6 If pre-transfusion testing has not been completed, units must have a conspicuous label which clearly indicates that pre-transfusion testing has **not** been completed at the time of release. CSA 10.9.3.4; 9.3.2

2.1.7 Compatibility tests should be completed promptly and any incompatibility shall be immediately reported according to Regional Health Authority (RHA) written policies and procedures. CSA 10, 9.3.6

2.1.8 The transfusion service/laboratory shall confirm the ABO type of red cells collected and prepared by Canadian Blood Services (CBS) if a serologic crossmatch will not be performed prior to transfusion of the red cells. The confirmation test will be performed on a segment from the blood component. CSA 10.5.1

2.1.9 Operating procedures shall be in place that clearly define individuals who may sign out blood components from the transfusion service/laboratory and transport them to the patient's location CSA 9.5.3

2.2 *Best Practice:*

2.2.1 Whenever possible a pre-transfusion blood sample should be drawn from the patient prior to the transfusion of unmatched Group O red cells.

2.2.2 Notify the attending physician if patient has clinically significant antibody based on historical records.

2.2.3 The Rh(D) group of the blood component should be confirmed prior to release of uncrossmatched blood components.

2.2.4 Facilities that do not have the ability to perform the unit confirmation test should request "Group Confirmed" blood components for emergency stock from CBS. The units will be labelled as group confirmed when received.

3.0 Materials

3.1 Red blood cell units

3.2 Request for Uncrossmatched Blood

3.3 Request for Crossmatch

3.4 Patient sample

3.5 Unit tags

3.6 Signed requisition from requesting physician

4.0 Quality Management

4.1 A RHA-based quality improvement system or process shall be in place to monitor and audit requests for emergency uncrossmatched blood and appropriate utilization of Group O Rh negative blood.CSA 4.6.1.1

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA4.6.1.1

5.0 Procedure

5.1 For information on the procedure to request uncrossmatched blood, refer to Guideline SK 3 -Request for Blood Components and Plasma Protein Products from the Transfusion Service/Laboratory.

5.2 Confirm the physician request for emergency release of red cells. Confirm the requesting physician has signed the request requisition.

5.3 The request should indicate the urgency of the request. The urgency of the request will dictate whether the transfusion service/laboratory will issue O Rh Negative uncrossmatched red cells or group-specific uncrossmatched red cells.

5.4 Collect a sample for crossmatch from the patient.

5.4.1 It is preferable to collect the sample prior to transfusion of uncrossmatched blood. This is to ensure that the patient can receive their own ABO & Rh blood type, as soon as possible. As there is very little plasma in the red cell units, it is acceptable to move the patient to group-specific red cell units prior to 10 units of Group O red cells having been transfused.

5.5 If the patient identity is known, perform a patient history check:

- Clinically significant antibodies
- Transfusion requirements and
- Special instructions

Contact attending physician immediately if clinically significant antibodies have been reported.

ALERT: <u>Do not</u> use ABO/D historical records to select appropriate red cells to issue.

5.6 Confirm that ABO/D confirmation had been done on donor units. Facilities that do not have the ability to test the unit confirmation may request "Group Confirmed" blood for emergency stock from CBS.

5.7 If patients ABO blood group is undetermined, select appropriate uncrossmatched red cell units using either the RHA Massive Transfusion Protocol or below with the approval of the Transfusion Service/Laboratory Medical Director:

5.7.1 When supply of Group O Rh <u>negative red cells is adequate</u> then release Group O Rh negative red cells.

5.7.2 When supply of Group O Rh <u>negative red cells is low</u> :

- If patient is female **less than** 50 years of age or male **less than** 18 years of age then release Group O Rh negative red cells.
- If patient is female **greater than** 50 years of age or male **greater than** 18 years of age then release Group O Rh positive red cells.

5.7.3 When only Group O Rh <u>positive units are available:</u>

- Notify Transfusion Service/Laboratory Medical Director or designate within 24 hours if the patient is determined to be Rh negative and is a female less than 50 years of age or a male less than 18 years of age.
- Administration of Rh immune globulin will be determined by the Transfusion Service/Laboratory Medical Director after consultation with the attending physician. This consultation shall be documented by the Transfusion Service/Laboratory Medical Director.

5.8 If patient group and type have been verified with a current pre-transfusion sample, select appropriate ABO and Rh red blood cells.

5.9 Label the “Uncrossmatched tag” with the donor unit number and a conspicuous label which clearly indicates that pre-transfusion testing has **not** been completed at the time of release, i.e. “Unmatched Blood – Physician accepts responsibility for administration”. If the patient’s identify is known include the patient’s first and last name(s) and Saskatchewan Health Services Number (HSN) or unique identifier.

5.10 Remove a least 2 segments from the unit(s) prior to issue, so compatibility testing can be completed if an electronic crossmatch is not performed.

5.10.1 Affix bar code label from the red cell unit to the segments.

5.10.2 Bag and store segments for compatibility testing.

5.11 Issue the red cell units following RHA established protocol.

5.12 Complete the Issue/Transfusion log (lab log) with as much information as is available or becomes known.

5.13 RHA’s without 24 hour coverage must have an established protocol in place for emergency signout of Group O Rh negative red cell units by clinical personnel. The procedure to include:

5.13.1 Only trained and competent clinical personnel are approved to sign-out Group O Rh negative red cell units from the transfusion service/laboratory, or from specific locations where Group O Rh negative red cell units are stored within the facility.

5.13.2 Clinical personnel who perform this task should have their competence assessed at regular, defined intervals.

5.13.3 Results of competence assessment should be recorded as part of the employee record.

5.13.4 Names and signatures of such clinical staff should be on record in transfusion service/ laboratory.

5.14 Compatibility tests should be completed promptly and any incompatibility should be immediately reported to the attending physician to minimize and manage any adverse reaction.

5.15 Group O red cells will be transfused until the patient’s ABO/D can be determined on a current acceptable sample.

5.16 In cases when large volumes of red cells are transfused, passively acquired ABO antibodies may be detected in the patient’s plasma.

- If that should occur, transfusion with red cells that lack the corresponding ABO antigen should be continued.
- If there is any question about the patient’s true Rh type, follow the administration guidelines in 5.7.

6.0 Documentation

6.1 A signed declaration by the requesting physician requesting uncrossmatched blood.

7.0 References

7.1 AABB Technical Manual. Roback, John D.; Combs, Martha R.; Grossman, Brenda J.; Hillyer, Christopher D; 16th Edition. 2008.

7.2 BC Provincial Blood Coordinating Office. Transfusion Medicine Policy Manual. 1st Edition, 2007

7.3 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services. Version 3.* May 2011.

7.4 Canadian Standards Association. *Blood and Blood Components*. CAN/CSA-Z902-10. February 2010.

7.5 London Laboratory Service Group, Blood Transfusion Resource Manual. July 2009.

7.6 Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing. June 2007.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 12

Identification and Verification of Patient Prior to the Administration of Blood Components and Plasma Protein Products

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1.0 Principle

1.1 To provide instruction on whom is a qualified transfusionist.

1.2 To properly identify and verify a patient prior to the administration of blood components and plasma protein product.

SK Application – Professional Designations for Transfusionist: In accordance with applicable provincial legislation, regulations and/or bylaws, it is within the scope of practice for a physician, Registered Nurse, Nurse Practitioner (RN (NP)), Registered Nurse (RN), Registered Psychiatric Nurse (RPN) or Licensed Practical Nurse (LPN), who has completed the IV Therapy/Blood and Blood Products Completer Course, to transfuse blood components and plasma protein products. Graduate RN, RPN and LPN must be supervised by a licensed professional.

2.0 Scope and Related Policies

2.1 *Required:*

2.1.1 Regional Health Authority (RHA) policies, processes, and procedures shall be established to ensure continuous and unequivocal identification of the patient from the sample collection through to transfusion. CSA 11.3.1

2.1.2 There shall be unequivocal identification of the patient against the information in the written request for blood components and plasma protein products. CSA 10.2.1; 11.3.1

2.1.3 There shall be unequivocal identification of the blood component and plasma protein product. CSA 11.3.2

2.1.4 Immediately before transfusion/infusion and in the presence of the patient, the transfusionist shall confirm and document that all identifying information linking the patient and the blood component or plasma protein product matches. CSA 11.3.3 This includes:

- Patient's identification band
- Patient health record
- Compatibility label/tag

2.1.5 Transfusion shall not be initiated if any discrepancy is found in the identifying information until the discrepancy is resolved. CSA 11.3.5

2.1.6 The compatibility label/tag shall remain attached to the blood component or plasma protein product at least until completion of the transfusion/infusion. CSA 11.3.4

2.2 *Best practice:*

Blood Components	Plasma Protein Products
• red blood cells • plasma • platelets • cryoprecipitate	• albumin • Intravenous Immune Globulin (IVIG) • Coagulation Factors (i.e. factor VIII) • Rh immune globulin (RhIG) • Hepatitis B Immune Globulin (HBIG) • Varicella Zoster Immune Globulin (VZIG)

2.2.1 Verification for administration of blood components:

2.2.1.1 Upon receipt of the blood component and before the component can be administered, a **two-person verification** must be completed. This verification must compare the patient's first and last names, Saskatchewan Health Services number (HSN) or unique identifier, and blood component identification for consistency.

2.2.1.2 The first verifier must be the transfusionist who administers the blood component.

2.2.1.3 The second verifier must be a qualified transfusionist.

2.2.2 Verification for administration of plasma protein products:

2.2.2.1 Upon receipt of the plasma protein product and before the plasma protein product can be administered, a **one-person verification** must be completed. This verification must compare the patient's first and last names, HSN or unique identifier and product identifiers.

2.2.2.2 The one person verifier must be the transfusionist who administers the plasma protein product.

2.2.2.3 Plasma protein products are issued for individual patients and cannot be administered to anyone else. Unused doses must be returned to the transfusion service/laboratory immediately.

2.2.3 The verification and documentation process includes:

- verifying the order for transfusion therapy (treatment order);
- verifying that informed consent has been obtained and documented in the patient's health record;
- verifying the prescribed blood component and blood component compatibility if applicable;
- verifying appropriate clinical indication for the transfusion;

- verifying patient identification;
- the date and time of transfusion/infusion, type of blood component administered, in addition to the volume, infusion rate, and time of initiation and completion of transfusion;
- any medication administered, including premedication (if I.V. drugs are required during transfusion, another I.V. site is required);
- the use of special equipment, such as a blood warmer or specialized blood filters;
- the patient's clinical status throughout the transfusion therapy, including patient assessment data such as vital signs and lung sounds;
- the patient's response to therapy including any complications or adverse reactions, treatment required, and response to that treatment; the amount of blood transfused and the return of the unused portion to the transfusion service laboratory; and
- patient education provided, as well as the patient's understanding of information provided.

2.2.4 All information must be verified as correct throughout the identification process before transfusion/infusion can be initiated.

2.2.5 If there is any type of discrepancy, the transfusion service/laboratory must be immediately notified for resolution and direction before proceeding with administration.

2.2.6 Consider implementing a written checklist to guide staff responsible for the verification process.

3.0 Materials

3.1 Related materials include:

- Patient health record with the physician/authorized Registered Nurse (Nurse Practitioner) (RN(NP) order
- Transfusion Record
- Regional Blood Transfusion Service Requisition
- Patient identification band or equivalent identification process according to regional policies and procedures
- Product compatibility label/tag

4.0 Quality Management

4.1 An RHA-based quality improvement system or process should be in place to monitor compliance to the identification and verification process prior to

transfusion/infusion of blood components and plasma protein products. CSA 4.6.1.1

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

5.0 Procedure

5.1 Check the patient health record for:

- Physician/authorized RN(NP) request for blood components and plasma protein products
- Patient consent
- Patient education
- Completed blood group and antibody screen for blood components (if applicable)

5.2 Initial Verification

5.2.1 Perform a one or two-person check as per 2.2.1.1 and 2.2.2.1 to verify the consistency of the patient identification, and the blood component or plasma protein product identification.

5.2.2 Compare the information on the relevant documentation from the transfusion service/laboratory with the patient health record, blood product identification label, attached blood product compatibility tag and transfusion record.

Verify:

- Patient's first and last name(s)
- Patient's HSN or unique identifier
- Physician/ authorized RN(NP)'s order
- Ordered blood component
- Any special transfusion requirements
- Blood component unit number(s) or plasma protein product lot number(s)
- Blood component ABO and/or Rh type
- Expiry date
- Compatibility status - compatible/incompatible/least incompatible

5.3 Final Verification

5.3.1 Immediately prior to administration, using a one or two-person check as per 2.2.1.1 and 2.2.2.1 and in the presence of the patient, compare the patient's first and last name(s) and HSN or unique identifier using all of the following:

- Appropriate patient identification according to RHA polices and procedures.
- If no positive patient identification - NO BLOOD
- Attached blood component compatibility tag and blood component label
- Any other relevant laboratory documentation
- If possible, ask the patient to spell or verbalize his or her name and birth date

5.4 Document bedside verification process.

5.5 In the event there is any discrepancy and/or inaccuracy in any of the information, do not proceed, contact the transfusion service/laboratory immediately for resolution and direction.

5.6 Only after final verification and when all information is accurate, initiate transfusion/infusion.

IDENTIFIERS Verification must confirm consistency of patient and blood component or plasma protein product identifiers in the physical presence of the patient	
A. PATIENT IDENTIFIERS	
What	**Where to check for consistency of identifying data**
Mandatory unique identifiers: 1. Patient's first and last name 2. HSN or unique identifier 3. Patient date of birth (optional)	• Physician/authorized RN(NP) order • transfusion service/laboratory requisition • patient's verbal response as able **(this must be checked at the beside)** • patient identification band • blood component compatibility tag
B. PRODUCT IDENTIFIERS	
What	**Where to check for consistency of identifying data**
Blood Component: • Blood component name • Special product preparation (where applicable)	• Physician/authorized RN(NP) order • transfusion service/laboratory requisition • blood component compatibility tag • blood component label • patient's health record
• Patient's and/or donor blood group (ABO & Rh) – when applicable • Plasma protein product lot number and/or blood component unit number	• transfusion service/laboratory requisition/record • blood component compatibility tag • blood component label • patient's health record

C. TRANSFUSION SERVICE IDENTIFIERS	
What	**Where to check for consistency of identifying data**
• Transfusion Specific Identification Number (TSIN) where applicable	• blood component compatibility tag • transfusion service/laboratory requisition • TSIN/laboratory band **(this must be checked at the beside)**

6.0 Documentation

6.1 Transfusionists must sign and date on the appropriate permanent record as per RHA policies and procedures.

7.0 References

7.1 Canadian Society for Transfusion Medicine. *Standards for Hospital Transfusion Services Version 3.* May 2011*.* Ottawa, ON: Canadian Society for Transfusion Medicine.

7.2 Canadian Standards Association. 2010. *CSA Z902-10 Blood and Blood Components*. Mississauga, ON: Canadian Standards Association.

7.3 Capital Health. 2007. *Clinical Guide to Blood Transfusion.* Section 5.3.3, pages 39, 40, Patient Identification for Administration of Blood Products; January 2009. Edmonton, AB: Capital Region Health Authority.

7.4 Provincial Blood Programs Coordinating Office. 2007. *Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing, June 2007, Guideline MB 7: Patient Identification Prior to Initiation of Transfusion/Infusion of Blood, Blood Components and Derivatives.* Winnipeg, MB: Manitoba Health.

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Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 13

Administration of Blood Components and Plasma Protein Products

1.0 Principle

1.1 To provide guidelines for the preparation, initiation, administration and termination of transfusion/ infusion of blood components and plasma protein products.

2.0 Scope and Related Policies

2.1 *Required*

2.1.1 The Regional Health Authority (RHA) shall have operating procedures for the transfusion of blood components. CSA 11.1.1

2.1.2 Operating procedures shall be in place for the administration of blood components and plasma protein products and for the operation of infusion devices and associated equipment. CSA 11.4.1

2.1.3 All transfusion/infusion devices and ancillary equipment for transfusion of blood components and plasma protein products shall be approved by the RHA. CSA 11.4.2

2.1.4 Transfusions shall be prescribed by a physician/authorized Registered Nurse, Nurse Practitioner (RN(NP)) and administered according to operating procedures. CSA 11.4.3

2.1.5 The rate of transfusion/infusion should be specified either by a physician/authorized RN(NP) or in the standard operating procedures for transfusion. CSA 11.4.4

2.1.6 Blood components shall be maintained in a controlled environment at optimal temperature until released for transfusion. CSA 11.4.5

2.1.7 The transfusion of blood components shall be completed within 4 hours of removing the unit from its controlled-temperature location. CSA 11.4.6

2.1.8 Blood components and plasma protein products shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the patient. CSA 11.4.8

2.1.9 Before the transfusion/infusion of blood components or plasma protein products, the administration line and filter shall be primed with the blood component or a compatible solution. A sterile 0.9% sodium chloride (NaCl) solution is recommended. CSA 11.4.9

2.1.10 Air shall not be introduced into the blood bag nor into the administration set. CSA 11.4.10

2.1.11 Drugs or medications, including those intended for intravenous use, shall not be added to blood components. A sterile 0.9% sodium chloride solution may be added to blood components on the order of a physician/authorized RN(NP). Other solutions intended for intravenous

use may be used in an administration set, or added to blood components, under either of the following conditions:

- they have been approved for this use by the RHA having jurisdiction; or,
- there is documentation available to show that addition of the solution to the blood component involved is safe. CSA 11.4.11

2.1.12 Administration sets shall be changed at least once every 24 hours or as recommended by the manufacturer of the set or the filter component of the set. The set shall be changed after a maximum of four units of red blood cells have been transfused/infused through it or if the set becomes occluded. CSA 11.4.12

2.1.13 Patient vital signs shall be recorded before, during, and after transfusion/infusion. CSA 11.4.13

2.1.14 The patient shall be observed during the transfusion/infusion and for an appropriate time thereafter for suspected adverse events. Instructions concerning possible adverse events shall be provided to the patient or to a responsible caregiver, when direct medical observation or monitoring of the patient will not be available after transfusion/infusion. CSA 11.4.14

2.1.15 Following the transfusion/infusion, the blood transfusion record (or a copy) shall be added to the patient's health record. CSA 11.4.15

2.2 *Best Practice*

2.2.1 In non-urgent/non-bleeding/in-patient settings, blood components should be transfused during daytime hours (for patient safety) and transfused one unit at a time.

2.2.2 Transfusion/infusion of blood components and plasma protein products shall be prescribed by a physician/authorized RN(NP). The order shall specify: CSA 10.2.1(a-e)

- Patient's first and last name(s) and Saskatchewan Health Number (HSN) or unique identifier
- The number or dosage and specific blood component or plasma protein product required
- The date and time of the transfusion/infusion
- The rate of transfusion/infusion or duration
- The sequence in which multiple products are to be transfused
- Any modification to the blood component (ie: irradiation, washing, warming)
- Special transfusion requirements (ie: Anti-Cytomegalo virus (CMV) negative)
- Clinical indication for transfusion CSTM 5.2.1.2(h)

- The use of a blood warmer or rapid infusion device, with the exception of clinical areas where there is an established RHA policy and procedure
- Pre/post transfusion medication orders related to the transfusion

2.2.3 Blood components and plasma protein products must be requested from the transfusion service/laboratory immediately prior to initiation of the transfusion/infusion.

2.2.4 The blood component or plasma protein product should be returned immediately to the transfusion service/laboratory if the decision is made not to transfuse.

2.2.5 Venous access must be established as RHA policies and procedures.

- Establish and/or assess patency of direct venous access for administration of blood components or plasma protein products.
- Unless otherwise stated in the order or RHA policy, blood components must be transfused through a standard sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the patient (i.e. adults: 170 – 260 microns, pediatrics: refer to established facility policies and procedures). For plasma protein products, refer to product monograph for filter size, where applicable.

2.2.6 Administration set used for the administration of blood shall be changed after:

- A maximum of four (4) hours, or
- Four (4) consecutive units of red blood cells have been infused through it, or
- If the set becomes occluded.

Note: It is recommended that administration sets be changed between the administration of different blood components or plasma protein products.

2.2.7 Medication shall not be added directly to the blood component or plasma protein product and nor to the administration set containing the blood components or plasma protein products.

2.2.8 The use of a blood warmer or rapid infusion device requires a treatment order except in clinical areas where there are established RHA policies and procedures.

2.2.9 All connections are to be secured and directly locked to the insertion site or add-on extension tubing. Extension tubing volume is not to exceed 2.0 mL total volume.

2.2.10 Consider a slower rate for patients at risk of circulatory overload.

2.2.11 In the event that a transfusion reaction occurs or is suspected, do not discard the blood product container and administration set. It may have to be returned to the transfusion service/laboratory.

2.2.12 Disposal of all blood components and plasma protein product containers and administration sets must meet routine practice standards according to RHA policies and procedures .

2.2.13 Assess the patient prior to ordering another unit.

3.0 Materials

3.1 Materials required include:

- Blood components or plasma protein products
- Appropriate administration set specific to blood component or plasma protein product
- 0.9% saline (D5W for IVIG)
- Gloves
- Extension tubing, if required
- Blood warmer/rapid infusion device, as applicable
- Patient health care record/outpatient form
- Appropriate disposal container, as per RHA policy
- Transfusion Reaction Investigation Form, as applicable

4.0 Quality Management

4.1 A RHA-based quality improvement system or process shall be in place to monitor compliance with the policies and procedures for the administration of blood components and plasma protein products. (CSA 4.6.1.1)

4.2 A RHA-based quality improvement system or process should be in place to monitor:

- The wastage rates for unused blood components and/or plasma protein products that could not be re-entered into the usable blood inventory system.
- The use of random audits to identify compliance to transfusion policies.
- The quality control process for infusion/blood warmer devices.
- The disposal of biohazardous materials.

4.3 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. (CSA 4.3.3.1)

5.0 Procedure

5.1 Pre-Transfusion:

5.1.1 Confirm the order for date, type of blood component or plasma protein product to be transfused/infused and any special transfusion/infusion requirements.

5.1.2 Confirm patient is aware of transfusion therapy and informed consent has been obtained by the physician/authorized RN(NP).

5.1.3 Confirm blood product availability with the transfusion service/laboratory.

5.1.4 Obtain baseline vital signs pre transfusion/infusion.

5.1.5 Establish IV access or confirm patency with 0.9% saline (or in the case of IVIG, D5W as outlined in product monograph).

5.1.6 Assemble equipment (e.g. blood warmer, rapid infusion device, etc.).

5.1.7 Administer pre-medication if required and flush access line.

- Medication shall not be added directly to the blood component or plasma protein product and nor to the administration set containing the blood component or plasma protein product.

5.1.8 Obtain blood component(s) or plasma protein product(s) from the transfusion service/laboratory.

Note: Blood component(s) and/or plasma protein product(s) must not be out of a controlled transfusion service/laboratory refrigerator for longer than 30 minutes before initiating the transfusion/infusion. For plasma protein products refer to RHA policies and procedures.

5.1.9 It is essential to read the product monograph before administering plasma protein products.

5.1.10 The blood component or plasma protein product tag will be verbally checked and documented by two transfusionists with:

a) The patient's chart

- physician/authorized RN(NP)'s order
- patient's full name and correct spelling
- personal HSN or unique identifier
- patient ABO and Rh group if required

b) The blood component or plasma protein product

- donor ABO group, if applicable
- donor Rh group, if applicable
- unit number(s)

Attach the chart record to the transfusion record sheet and both parties sign where indicated.

SK Application – Professional Designations for Transfusionist: In accordance with applicable provincial legislation, regulations and/or bylaws, it is within the scope of practice for a physician, Registered Nurse, Nurse Practitioner (RN (NP)), Registered Nurse (RN), Registered Psychiatric Nurse (RPN) or Licensed Practical Nurse (LPN) who has completed the IV Therapy/Blood and Blood Products Completer Course to transfuse blood components and plasma protein products. Graduate RN, RPN and LPN must be supervised by a licensed professional.

5.1.11 Prime administration set with 0.9% saline (in the case of IVIG, D5W as outlined in product monograph).

5.1.12 Refer to Guideline SK 12 - Identification and Verification of Patient Prior to Administration of Blood Components and Plasma Protein Products.

5.1.13 Only after patient identification and visual inspection of blood component(s) or plasma protein product(s) check is confirmed, insert spike of administration set with clamp closed into the opening of designated blood container (refer to Guideline SK 9- Visual Inspection of Blood Components and Plasma Protein Products).

5.2 Intra Transfusion/Infusion:

Note: For pediatric patients, refer to RHA policies and procedures.

5.2.1 Open clamp, begin transfusion/infusion slowly for adults at 50 mL/hr during the first 15 minutes, where appropriate.

5.2.2 Transfusion/infusion shall be complete within 4 hours of issue from transfusion service/laboratory or removal from an approved blood satellite fridge.

5.2.3 Refer to Guideline SK 14 - Patient Monitoring During the Transfusion/Infusion Procedure.

5.2.4 In the event of an immediate or suspected transfusion reaction, refer to Guideline SK 16 - Identification and Management of a Transfusion Reaction.

5.2.5 Upon completion of the transfusion/infusion, the administration set may be flushed with 0.9% saline (in the case of IVIG, use D5W). For plasma protein products, refer to product monograph.

5.3 Post Transfusion:

5.3.1 Dispose of blood components or plasma protein product containers and administration sets following routine practice standards according to RHA policies and procedures.

5.3.2 Continue to assess the patient up to 1 hour or as clinically indicated.

- In out-patient areas, the patient should be encouraged to remain in the area for up to 1 hour after completion of transfusion/infusion for observation.

6.0 Reporting

6.1 Report any suspected transfusion reactions to the requesting physician/authorized RN(NP) and the transfusion service/laboratory.

7.0 Documentation

7.1 Document on the patient's health care record:

- Patient education
- Vital signs
- Blood component unit number(s) or plasma protein product lot number(s)
- Date and time transfusion/infusion initiated and completed
- Date and time if transfusion/infusion interrupted and reinitiated
- Transfusion rate and volume transfused
- Name of transfusionists starting and checking blood component or plasma protein product
- Patient's response to transfusion/infusion (e.g. did a transfusion reaction occur?)
- If required any follow-up testing done:
    - CBC after blood components
    - INR, PT/PTT after plasma
    - Fibrinogen level after cryoprecipitate

7.2 Complete required information on the RHA product tag attached to the unit/vial.

- Place health care record copy in patient's health care record.
- Return RHA copy to transfusion service/laboratory, as per RHA policy.

8.0 References

8.1 Callum, JL; Lin, Y; Pinkerton, PH; Karkouti, K; Pendergrast, JM; Robitaille, N.; Tinmouth, AT; and Webert, KE. (2011) *Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions, A Guide to Transfusion Medicine (3rd edition)*. Toronto, ON: Ontario Regional Blood Coordinating Network.

8.2 Canadian Blood Services Clinical Guide to Transfusion (July 2006)

8.3 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services Version 3*. May 2011.

8.4 Canadian Standards Association. (2010). *Standards for Blood and Blood Components CSA Z902-10.*

8.5 Manitoba Transfusion Quality Manual for Blood Banks. Version 2 June 2007

8.6 Ontario Regional Blood Coordinating Network. (2009). Standard Work Instruction Manual.

8.7 Regina Qu'Appelle Health Region Nursing Procedure Manual (February 2010). Regina, Saskatchewan.

8.8 Saskatoon Health Region Nursing Blood Administration Policy (June 2009). Saskatoon, Saskatchewan.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 14

Patient Monitoring during the Transfusion/Infusion Procedure

1.0 Principle

1.1 To provide guidelines for patient monitoring pre-, intra- and post-administration of all blood components and plasma protein products.

2.0 Scope and Related Policies

2.1 Required

2.1.1 Operating procedures shall be in place for the administration of blood components and for the operation of infusion devices and associated equipment.[CSA 11.4.1]

2.1.2 Patient vital signs shall be recorded before, during, and after transfusion.[CSA 11.4.13]

2.1.3 The patient shall be observed during the transfusion and for an appropriate time thereafter for suspected adverse events. Instructions concerning possible adverse events shall be provided to the patient or to a responsible caregiver, when direct medical observation or monitoring of the patient will not be available after transfusion.[CSA 11.4.14]

2.2 Best Practice

2.2.1 When transfusing/infusing blood components and/or plasma protein products, the transfusionist is responsible for performing a baseline assessment including vital signs.

SK Application – Professional Designations for Transfusionist: In accordance with applicable provincial legislation, regulations and/or bylaws, it is within the scope of practice for a physician, Registered Nurse, Nurse Practitioner (RN (NP)), Registered Nurse (RN), Registered Psychiatric Nurse (RPN) or Licensed Practical Nurse (LPN) who has completed the IV Therapy/Blood and Blood Products Completer Course to transfuse blood components and plasma protein products. Graduate RN and Graduate LPN must be supervised by a licensed professional.

2.2.2 In the event the patient exhibits signs of an adverse event of transfusion/infusion reaction, refer to Guideline SK16 - Identification and Management of a Transfusion Reaction.

3.0 Materials

N/A

4.0 Quality Management

4.1 A Regional Health Authority (RHA)-based quality improvement system or process shall be in place to monitor compliance with the policies and procedures for patient assessment and monitoring related to transfusion/infusion of blood components and plasma protein products. CSA 4.6.1.1

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion/infusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

5.0 Procedure

Blood Components

5.1 Pre-Transfusion/Infusion:

5.1.1 Explain administration procedure to patient when possible.

- Advise the patient to report if experiencing any side effects such as shortness of breath, rash, urticaria, hemoglobinuria, pain (chest or lower back), fever or chills. (Refer to Guideline SK 16 - Identification and Management of a Transfusion Reaction).

5.1.2 Obtain patient baseline vital signs including blood pressure, temperature, pulse and respiration (BP/TPR) prior to administration, within the previous 30 minutes.

- Pulse oximetry to be included if clinically indicated.

5.1.3 Assess patient for existing clinical manifestations that may be confused with a transfusion/infusion reaction (i.e. shortness of breath, fever, itching, pain or chills) and document findings on patient health record.

5.1.4 Conduct cardiovascular/respiratory assessment on patients identified at risk for circulatory overload (i.e. pediatric, geriatric, patients with pre-existing cardiovascular/respiratory disease).

5.2 Intra-Transfusion/Infusion:

Note: Most reactions occur within 1 to 30 minutes of administration.

5.2.1 Closely monitor the patient for the first 15 minutes

5.2.2 Repeat and document vital signs including blood pressure, temperature, pulse and respiration (BP/TPR):
- 15 minutes after commencing
- q1h until infusion complete and
- following completion of the transfusion

5.3 Post-Transfusion/Infusion:

5.3.1 Continue to assess patient for up to 4 hour or as clinically indicated, or as per RHA policy.
- In outpatient areas the patient should be encouraged to remain in the area for observation for up to 1 hour after completion of transfusion/infusion dependant on the blood/blood component transfused and the RHA policy.

5.3.2 Outpatients must be educated with regards to possible post-transfusion reaction signs and symptoms and appropriate action (e.g. when and whom to report to).

Repeat steps 5.1 through 5.3 for each and every blood component transfused.

Plasma Protein products

5.4 Pre-Transfusion/Infusion

5.4.1 Obtain patient baseline vital signs including blood pressure, temperature, pulse and respiration (BP/TPR) prior to administration, within the previous 30 minutes.
- Pulse oximetry to be included if clinically indicated.

5.4.2 Document date and time plasma protein product commenced, lot number and product concentration.

5.4.3 Repeat and document vital signs including blood pressure, temperature, pulse and respiration (BP/TPR):
- 15 minutes after commencing
- q1h until infusion complete and
- following completion of the transfusion

5.4.4 When administering IVIg products, it is recommended that vital signs be monitored when increasing infusion rates and if lot number changes with product infused. It is not necessary to slow down the infusion rate when changing lot numbers. Refer to manufacturer's instructions.

5.5 Intra-Transfusion/Infusion:

Note: Most reactions occur within 1 to 30 minutes of administration.

5.5.1 Closely monitor the patient for the first 15 minutes

5.5.2 Repeat and document vital signs including blood pressure, temperature, pulse and respiration (BP/TPR):
- 15 minutes after commencing
- q1h until infusion complete and
- following completion of the transfusion

5.6 Post-Transfusion/Infusion:

5.6.1 Continue to assess patient for up to 4 hour or as clinically indicated, or as per RHA policy.
- In outpatient areas the patient should be encouraged to remain in the area for observation for up to 1 hour after completion of transfusion/infusion dependant on the blood/blood component transfused and the RHA policy.

5.6.2 Outpatients must be educated with regards to possible post-transfusion reaction signs and symptoms and appropriate action (e.g. when and whom to report to).

Repeat steps 5.4 through 5.6 for each and every plasma protein product transfused.

6.0 Documentation

6.1 Document on health record throughout the transfusion/infusion process:
- Patient education
- Pre-transfusion/infusion clinical assessment including any medication related to transfusion/infusion preparation, e.g. diuretics, antihistamines
- Vital signs
- Type of blood component or plasma protein product transfused/infused
- Blood component unit number or plasma protein product lot number(s)
- Date and time transfusion/infusion initiated and completed
- Date and time if transfusion/infusion interrupted and reinitiated
- Chart patient's response to transfusion/infusion in patient's health record as per RHA procedure.
- All orders or interventions related to the transfusion/infusion procedure or reaction.
- All signs and symptoms related to transfusion/infusion reaction. Refer to established RHA policy for reporting transfusion/infusion reaction

7.0 References

7.1 Callum, JL; Lin, Y; Pinkerton, PH; Karkouti, K; Pendergrast, JM; Robitaille, N.; Tinmouth, AT; and Webert, KE. (2011) *Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions (3rd edition)*. Toronto, ON: Ontario Regional Blood Coordinating Network.

7.2 *Canadian Society of Transfusion Medicine Standards for Hospital Transfusion Services Version 3*. May 2011.

7.3 Canadian Standards Association. (2010). *Standards for Blood and Blood Components CSA Z902-10.*

7.4 Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing (Version 1- June 2007)

7.5 Ontario Regional Blood Coordinating Network. (2009). *Standard Work Instruction Manual.*

7.6 Regina Qu'Appelle Health Region Nursing Procedure Manual (February 2010).

7.7 Saskatoon Health Region Policies and procedures (November 2008).

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation

Guideline SK 15

Use of Autologous and Directed Blood Components

1.0 Principle

1.1 Patients undergoing elective surgery should be informed of alternatives to allogeneic blood transfusion. Preoperative autologous (or one's own blood) blood donation is one alternative. Canadian Blood Services (CBS) offers this service as well as a directed donation program for parent or legal guardian to child under the age of 17.

2.0 Scope and Related Policies

2.1 Required

2.1.2 Autologous blood collections shall take place only on the order of the donor-patient's physician/authorized Registered Nurse, Nurse Practitioner RN(NP) and shall require written approval from the physician responsible for the autologous program or his or her delegate. Informed consent shall be obtained. CSA 12.1.3; CSA11.2.1

2.1.3 Blood components collected for autologous transfusion/infusion shall be clearly labeled and segregated from the allogeneic blood supply. Autologous blood components collected for transfusion shall be used for that purpose. Unused units shall be destroyed. CSA 12.1.5

2.1.4 Autologous collections shall be transported, and stored in accordance with SK Guideline 7 – Transport of Blood Components and Plasma Protein Products within a Facility and SK Guideline 18 – Temperature Storage Guidelines for Blood Components and Plasma Protein Products. CSA 12.1.6

2.1.5 Tests for the following diseases shall be performed on the first unit collected from an autologous donor within each 42-day period:

a) HIV 1 and 2;
b) HCV;
c) HBV; and
d) HTLV I/II

Only test kits licensed under the Medical Devices Regulations and intended for donor screening shall be used. Nucleic acid testing and syphilis testing are not required for autologous collections. CSA 12.3.1.2

2.1.6 If an autologous donation that is repeat reactive for any required transfusion-transmitted disease agent testing must to be shipped to another facility, the shipping facility shall advise the receiving facility's transfusion service/laboratory of the reactive tests. This shall be done regardless of the results of confirmatory testing. CSA 12.3.1.4

2.1.7 Further to the usual labeling requirements at the time of collection or processing and before release, a green label or tag shall be affixed to the blood bag with the following information:
   a) the statement “For Autologous Use Only”;
   b) the donor-patient’s name;
   c) the identity of the intended transfusing facility, if known;
   d) the patient’s Saskatchewan Health Services Number (HSN) or unique identification number (or, if this is not available, the patient’s birth date or comparable identifying information); and
   e) a biohazard label on every blood component bag from a donor
      (i) repeatedly reactive or positive for a disease agent identified in 2.1.5 or
      (ii) repeatedly reactive or positive results for any other transfusion-transmissible disease tests performed in addition to those listed in 2.1.5 CSA12.3.2.1

2.1.8 Blood components that have not undergone the tests specified in 2.1.5 shall be labeled as “untested for transmissible diseases”. CSA12.3.2.2

2.1.9 Pre-transfusion testing shall conform to the requirements for sample collection and identification and for ABO and Rh grouping of donor blood and patient. CSA12.4.1

2.1.10 An operating procedure shall be in place to ensure that autologous blood components are used prior to the transfusion of allogeneic blood. CSA12.4.2

2.1.11 An operating procedure shall be in place to ensure the accurate identity of the transfusion patient. CSA12.4.3

2.1.12 Directed donors shall meet all the criteria for allogeneic blood donors; however, donors who do not meet the criteria for the frequency of donation, hemoglobin level, or recent delivery may be allowed to donate with the approval of the medical director. CSA15.1.3

2.1.13 Donor/patient compatibility shall be determined prior to collection of a directed donation. CSA15.1.4

2.1.14 The particular risks associated with directed donations shall be disclosed to the donor and to the patient (or the patient’s guardian or legal representative) when obtaining informed consent for transfusion. CSA15.1.5

2.1.15 Donations shall be labeled as “Directed Use Only” and the label shall provide unequivocal identification of the intended patient. The label may also contain the name of the donor. CSA15.1.6

2.1.16 Blood components from directed donations shall not be crossed over to the regular allogeneic blood supply. CSA15.1.7

2.1.17 Donations from blood relatives shall be irradiated. CSA 15.1.8

3.0 Materials

3.1 CBS F020079- Autologous Utilization Report

3.2 CBS COL035 – Directed Utilization Report

3.3 CBS form F020721- Physician's request for consideration for autologous transfusion (copy sent from CBS)

3.4 Facility log book or Lab Information System

4.0 Quality Management

4.1 A Regional Health Authority (RHA) -based quality improvement system or process shall be in place to monitor compliance with the policies and procedures for storage and issue of autologous and directed blood products. CSA 4.6.1.1

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

5.0 Procedure

5.1 Autologous Donation

5.1.1 CBS offers a program whereby patients about to undergo elective surgery may, at the request of their physician, pre-deposit their own blood for use during the surgery. CSA 12.1.3

5.1.2 All the autologous blood donations will be fully tested by the routine CBS procedures for hepatitis B and C, HIV, HTLV, syphilis and West Nile virus. CSA 12.3.1.2

5.1.3 The donation will be processed into red cells and frozen plasma (FP) and will be labeled with the usual CBS donor unit number. All plasma will be discarded unless specifically requested in advance of collection.

5.1.4 A green autologous tag will be attached to the blood unit. This green tag will contain the patient/donor name, birth date, name of surgeon, hospital, date of surgery and number of units collected. As well, each tag will bear the CBS donor unit number, a patient identifying number (HSN) and the patient's signature. The unit is to be used by that patient/donor only. CSA 12.1.5; CSA 12.3.2.1

5.1.5 The autologous donor red cell unit will be stored at 1 – 6° C. The units will be sent to the hospital for storage as soon as they are tested. The section

of the request form bearing all the patient information will accompany the first unit (form F020721-physician's request for consideration for autologous transfusion and F020079-autologous utilization report). These forms will be stored in a separate area to be completed upon transfusion of the blood unit or expiration of the blood unit. CSA 12.1.6

5.1.6 The hospital should store the autologous units distinctly separate from their standard inventory. CSA 12.1.5

5.1.7 When a patient is admitted, they will bring 1 section from each of the autologous blood tags (1 for each unit donated) and give them to the RN, which can be matched up with those in the transfusion service/laboratory refrigerator.

5.1.8 A blood sample from the patient and a segment from the autologous units should be tested for blood group and Rh type. Although it is not a requirement for the units to be crossmatched, a crossmatch may be performed. CSA 12.4.1

5.1.9 All available autologous units will be issued to the patient first. Unless the patient has stated otherwise on their Hospital Consent Form any additional blood requirements, for that patient, should be met with allogeneic units from the routine blood inventory.

5.1.10 Keep autologous units not used during surgery. Do not return them to the CBS Centre. When outdated, the autologous units will be disposed of by the hospital and CBS form F020079- Autologous Utilization Report will be completed and sent to the CBS centre.

5.1.11 Once patient sample is received in the transfusion service/laboratory, perform a routine ABO group, Rh and antibody screen.

5.1.12 Perform an Immediate Spin or serological crossmatch on each autologous unit.(optional)

5.1.13 Record all donor unit numbers on the patient's transfusion record and identify them as autologous red cells, and/or enter them into the computer or manual transfusion log.

5.1.14 Record donor numbers on the transfusion service/laboratory requisition/record indicating that units are autologous.

5.1.15 If non-autologous units of blood have also been requested, they are crossmatched following crossmatch guidelines.

5.1.16 The patient's green cards must be sent to the transfusion service/laboratory, prior to the issue of autologous units, for comparison with the signature on the green tags to confirm patient/donor identity. If the green cards are not available a copy of the patient's signature on the hospital consent form may be used.

5.1.17 The Autologous Utilization Report (F020079) form is placed with the patient's record, which is then stored in the appropriate place as defined by the transfusion service/laboratory.

5.1.18 Once testing has been performed, the patient's blood is stored in the transfusion service/laboratory refrigerator separated from the allogeneic inventory.

5.1.19 Autologous units are issued by the standard process.

5.2 Directed Donation

5.2.1 The request for a directed donation must be received from the attending physician/authorized RN(NPs). If a parent or another individual makes inquiries, they should be referred to the patient's attending physician.

5.2.2 Each potential donor will be tested for Blood Group and antibody screen, and Cytomegalo Virus (CMV) testing.

5.2.3 Acceptable Blood Groups:
The ideal directed donor is ABO identical and Rh compatible. However, a blood group compatible but not identical is acceptable for red cell transfusions ONLY.
i.e. - Group O donor cells to non group O recipients
- Group A donor cells to group AB recipients
There will be no donor directed FP or platelets issued if the donors' plasma is incompatible with the recipient. Incompatible directed donor plasma is discarded. All plasma will be discarded unless specifically requested in advance of collection.

5.2.4 All units shall be irradiated. [CSA 15.1.8]

5.2.5 A pink Directed Donor tag will be attached to the blood unit. This pink tag states for "Directed use only". It will contain unequivocal identification of the intended patient. The label may also contain the name of the donor. As well, each tag will bear the CBS donor unit number, a patient identifying number (HSN). The unit is to be used by the intended patient only. [CSA 12.1.5; CSA 12.3.2.1]

5.2.6 Unused directed donation units are kept until the end of their shelf life and discarded. They must not be given to another patient or returned to the blood supplier. [CSA 15.1.7]

6.0 Reporting

6.1 Following the surgery, CBS requires that the Autologous Utilization Report be completed and sent to the Centre. The number and type of autologous units received the number and type of autologous units transfused, any additional homologous blood products used, and number of units not used by the patient must be entered on this form.

7.0 Documentation

7.1 CBS form F020079- Autologous Utilization Report must be completed and returned to CBS.

7.2 CBS form COL035- Directed Donation Utilization Report must be completed and returned to CBS

8.0 References

8.1 *Canadian Society of Transfusion Medicine Standards for Hospital Transfusion Services Version 3*. May 2011.

8.2 Canadian Standards Association. (2010). *Standards for Blood and Blood Components CSA Z902-10.*

8.3 Ontario Regional Blood Coordinating Network. (2009). *Standard Work Instruction Manual.*

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 16

Identification and Management of a Transfusion Reaction

1.0 Principle

1.1 To provide guidelines for identifying and managing minor or serious adverse reactions to the transfusion/infusion of blood components or plasma protein products.

1.2 A transfusion/infusion reaction is characterized by, but not limited to, one or any combination of the following symptoms: (Transfusion Transmitted Injury Surveillance System (TTISS) User Manual Version 3.0)

Reaction Type	Symptoms
Minor Allergic	• Transient urticaria or other skin rash associated with pruritus associated with transfusion. • Localized angioedema without respiratory distress
Minor Febrile	• Febrile (≥38°C or a change of ≥1°C with no other apparent reason) • Chills/rigors • Sensation of cold
Serious Signs and Symptoms	• Severe hypotension/shock • Airway compromise • Laryngeal or pulmonary distress • Loss of consciousness • Circulatory collapse • Anxiety • Back/chest pain • Dyspnea/SOB • Orthopnea or cyanosis • Congestive heart failure • Bleeding/heat/pain at IV site • Nausea and vomiting • Hemoglobinuria or oliguria • Febrile and 1°C rise over baseline • Tachycardia/arrhythmias • Generalized flushing • Hives/ rash covering greater than 25% of body • Bilateral Pulmonary Edema/ wheezing • Facial/ tongue swelling • Headache • Jaundice • Drop in hemoglobin or platelet count • Death

2.0 Scope and Related Policies

2.1 Required

2.1.1 A transfusion service/laboratory shall have operating procedures for documenting, reporting, evaluating, and following-up on all adverse events. CSA 18.1.1

2.1.2 All significant errors and accidents shall be evaluated and appropriate corrective measures shall be documented. CSA 18.1.2)

2.1.3 All Regional Health Authority's (RHA) shall have operating procedures in place for reporting serious adverse events (critical incidents) to RHA Risk Management for reporting to Saskatchewan Health.

2.1.4 Health care personnel shall promptly report all serious adverse events to the transfusion service/laboratory. Serious adverse events include, but are not limited to CSA 18.2.5 shall apply:
(a) immediate hemolytic reactions;
(b) delayed hemolysis;
(c) transfusion-related acute lung injury (TRALI);
(d) systemic allergic reactions, including anaphylactic shock;
(e) bacterial sepsis;
(f) other transfusion-transmissible infections;
(g) Transfusion Associated Graft vs. Host Disease (TA-GVHD);
(h) post-transfusion purpura;
(i) other serious reactions; and
(j) death

A list of common signs and symptoms of serious adverse transfusion events shall be included in the nursing and transfusion service/laboratory manuals. CSA 18.2.1

2.2 Best Practice

2.2.1 All transfusion/infusion reaction investigations should be initiated immediately upon recognition of potential signs or symptoms.

2.2.2 In the event the patient exhibits signs of transfusion/infusion reaction the transfusionist must follow established RHA policies and procedures for management of transfusion/infusion reaction.

2.2.3 The transfusionist is responsible for immediately reporting transfusion/infusion reactions to the physician/authorized Registered Nurse(Nurse Practitioner) RN(NP).

- The physician/authorized RN(NP) is responsible for ordering a transfusion/infusion reaction investigation.

SK Application – Professional Designations for Transfusionist: In accordance with applicable provincial legislation, regulations and/or bylaws, it is within the scope of practice for a physician, Registered Nurse, Nurse Practitioner (RN (NP)), Registered Nurse (RN), Registered Psychiatric Nurse (RPN) or Licensed Practical Nurse (LPN) who has completed the IV Therapy/Blood and Blood Products Completer Course to transfuse blood components and plasma protein products. Graduate RN, RPN and LPN must be supervised by a licensed professional.

2.2.4 The transfusionist is responsible for reporting transfusion/infusion reactions to the transfusion service/laboratory.

Note: Any fatal or serious adverse reactions shall be reported to the attending physician/authorized RN(NP) immediately. The attending physician/authorized RN(NP) shall immediately report fatalities, TRALI, anaphylactic or hemolytic reactions to the Transfusion Service/Laboratory Medical Director.

2.2.5 Following the transfusion reaction investigation, the ordering physician/authorized RN(NP) will determine if any special instructions will be required prior to further blood components being transfused.

2.2.6 All transfusion/infusion reactions are reported to the Transfusion Transmitted Injuries Surveillance System (TTISS). (See Appendix # 6 – Transfusion Transmitted Injuries Surveillance System.)

2.2.7 Refer to guidelines:

- Guideline SK 1 - Informed Consent for the Administration of Blood Components and Plasma Protein Products
- Guideline SK 12 - Identification and Verification of Patient Prior to Administration of Blood Components and Plasma Protein Products
- Guideline SK 14 - Patient Monitoring during the Transfusion/Infusion Procedure
- Guideline SK 17 - Adverse Event Reporting

3.0 Materials

3.1 Post-Transfusion Sample: (as required in RHA procedure)

- Transfusion Reaction Investigation Form
- Correctly identified and labeled tubes. Refer to Guideline SK 4 - Patient Identification and Sample Collection Labeling (where applicable)
- Adults: 10-12 mL in EDTA (lavender) tubes
- Pediatrics: 3 mL in EDTA (lavender) tube
- Urine – post-transfusion reaction (where applicable)
- Blood cultures where applicable
- Urinalysis requisition (where applicable)
- Blood culture requisition
- 0.9% saline and IV infusion set

- Implicated blood component(s) or plasma protein product and administration set

4.0 Quality Management

4.1 A RHA-based quality improvement system or process shall be in place to monitor compliance with the policies and procedures for identification and management of a transfusion reaction. [CSA 4.6.1.1]

4.2 There should also be a system or process in place to review all confirmed reactions and outcome reports.

4.3 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. [CSA 4.3.3.1]

5.0 Procedure

5.1 Assess and report observations that may assist in determining type of reactions. Refer to Appendix # 7- Transfusion Reaction Algorithm.

5.2 For all cases of suspected transfusion/infusion reaction:

5.2.1 Stop transfusion/infusion immediately
- DO NOT DISCARD component and blood infusion set or IV set in the case of plasma protein products.

5.2.2 Infuse 0.9% saline in a separate IV set to maintain patency as per RHA policy.

5.2.3 Obtain vital signs and document. Assess patient vital signs and monitor as indicated.

5.2.4 Notify physician/authorized RN(NP) immediately. The physician/RN(NP) is responsible for ordering a transfusion/infusion reaction investigation.

5.2.5 Perform transfusionist clerical check by re-checking patient and product information on the discontinued blood component bag or plasma protein product vial, product compatibility tag, patient chart report, patient's identification band and units already infused (if available).

5.2.6 Implement therapeutic interventions as per physician/authorized RN (NP) order.
- The blood components or plasma protein products may be restarted following physician/RN(NP) assessment / treatment.

5.2.7 Immediately notify the transfusion service/laboratory and complete appropriate RHA Laboratory Transfusion Reaction Form.

5.2.8 Collect blood sample if ordered.

- In the event of a minor allergic reaction (hives/itching) or minor febrile reaction, the physician/ authorized RN(NP) will determine if an investigation will be commenced.
- Obtain the first voided urine sample if the patient exhibits hemoglobinuria. Refer for testing if requested. Mark urinalysis requisition "Post-Transfusion Reaction."

5.2.9 Collect samples/obtain diagnostics as per treatment order

- Collect patient and blood component blood culture when the temperature rise is ≥1°C from pre-transfusion value and T≥38°C PLUS any one of rigors, hypotension, shock, tachycardia (rise > 40 beats from pre-transfusion value), dyspnea or nausea and vomiting.
- Obtain chest X-ray (if TRALI or TACO is suspected)

5.3 Send to the transfusion service/laboratory:

- Completed Transfusion Reaction Investigation
- Sealed blood components and all related tubing including previously completed units, if available
- Required blood/urine samples

6.0 Reporting

6.1 All suspected transfusion reactions will be reported to the ordering physician/RN(NP).

6.2 All suspected transfusion reactions will be reported to the transfusion service/laboratory.

6.3 Any adverse reactions that can be attributed to the quality of the blood or blood products shall be reported to the blood supplier or to the blood product manufacturer. CSTM 7.2.2.5

6.4 The report of an adverse reaction investigation, including recommendations for management of future transfusion, should be placed in the patient's permanent health record. The transfusion service/laboratory shall retain a copy, and the information should be assessed if the patient requires future transfusion. CSTM 7.2.2.6

6.5 The transfusion service/laboratory shall submit reports to authorities as required by national and provincial territorial regulations. CSTM 7.2.2.4 (See Guideline SK 17 - Adverse Event Reporting.)

6.6 Adverse events should be reported to the provincial Transfusion Safety officer for documentation in the TTISS.

6.7 All serious adverse reactions including fatalities related to blood transfusion shall be reported to Canadian Blood Services (CBS). CSTM 7.2.2.5

6.8 Notify CBS immediately if blood cultures are positive on a donor unit.

7.0 Documentation

7.1 Document reaction on:

- Permanent record in patient's health record
- Transfusion Reaction Investigation Form
- Product compatibility tag,
- Patient's health record
- RHA Laboratory Transfusion Reaction Form
- Transfusion Reaction Algorithm (Appendix #7)

8.0 References

8.1 Callum, JL; Lin, Y; Pinkerton, PH; Karkouti, K; Pendergrast, JM; Robitaille, N.; Tinmouth, AT; and Webert, KE. (2011) *Bloody Easy 3: Blood Transfusions, Blood Alternatives and Transfusion Reactions (3rd edition)*. Toronto, ON: Ontario Regional Blood Coordinating Network.

8.2 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services Version 3.* May 2011.

8.3 Canadian Standards Association. (2010). *Standards for Blood and Blood Components CSA Z902-10.*

8.4 Government of Saskatchewan. (2004). *The critical incident regulations.* Regina, SK: Queen's Printer.

8.5 Government of Saskatchewan. (2010). The Regional Health Services Act. Regina, SK: Queen's Printer

8.6 Guideline for the Investigation of Suspected Transfusion Transmitted Bacterial Contamination, Canadian Communicable Disease Report Supplement January 2008

8.7 Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing (version 1- June 2007)

8.8 Newfoundland Policy for Blood Component and Blood Product Administration Version 2, Oct 2008)

8.9 Ontario Regional Blood Coordinating Network. (2009). *Standard Work Instruction Manual.*

8.10 Regina Qu'Appelle Health Region Nursing Procedures Manual (February 2010)

8.11 Saskatchewan Ministry of Health (2004). S*askatchewan critical incident reporting guidelines.* Regina, SK

8.12 Saskatoon Health Region Policies and procedures (June 2009)

8.13 Transfusion Transmitted Injuries Surveillance System (TTISS) User's Manual Version 3.0, Public Health Agency of Canada.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

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(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

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Guideline SK 17

Adverse Event Reporting

1.0 Principle

1.1 To provide guidelines for reporting adverse events.

2.0 Scope and Related Policies

2.1 Required

2.1.1 A transfusion service/laboratory shall have operating procedures for documenting, reporting, evaluating, and following-up on all adverse events. CSA 18.1.1

2.1.2 Health care personnel shall promptly report all serious adverse events to the transfusion service/laboratory. Serious adverse events include, but are not limited to:

a) Immediate hemolytic reactions;
b) Delayed hemolysis;
c) Transfusion-related acute lung injury (TRALI);
d) Systemic allergic reactions, including anaphylactic shock;
e) Bacterial sepsis;
f) Other transfusion-transmissible infections;
g) Transfusion Associated Graft vs. Host Disease (TA-GVHD);
h) Post-transfusion purpura;
i) Other serious reactions; and
j) Death CSA 18.2.5 shall apply.

A list of common signs and symptoms of serious adverse transfusion events shall be included in the nursing and transfusion service/laboratory manuals.

2.1.3 Following notification of a serious adverse event, the transfusion service/laboratory shall conduct investigations, including laboratory tests, to determine the probable cause. Reports shall be submitted to the appropriate authorities in accordance with applicable requirements. CSA 18.2.2

2.1.4 The transfusion service/laboratory shall immediately report to Canadian Blood Services (CBS) any serious adverse event that appears to be caused by an attribute of the blood components. CSA 18.2.3

2.1.5 If CBS deems the serious adverse event to be attributable to the transfused blood component, CBS shall report the serious adverse event to Health Canada within 15 days of receiving the initial report from the transfusion service/laboratory. CSA 18.2.4

2.1.6 If a fatality occurs and an initial investigation by the transfusion service/laboratory indicates the fatality is attributable to the blood transfusion, the transfusion service/laboratory shall report the fatality to CBS within 24 hrs. CSA 18.2.5

2.1.7 If the investigation of a fatality by a transfusion service/laboratory or CBS indicates that the fatality is attributable to transfusion, CBS shall report the fatality to Health Canada without undue delay, with a written report within 7 days. CSA 18.2.

2.1.8 The original investigation report (including recommendations for future transfusions) shall become part of the patient's health record. A copy of the investigator's report on the serious adverse event shall be kept on file by the transfusion service/laboratory. A system shall be in place for checking this information if the patient requires subsequent transfusion. CSA 18.2.7

2.1.9 All serious adverse events shall be reported to Regional Health Authority (RHA) Risk Management for reporting to Saskatchewan Health as per *The Regional Health Services Act; The Critical Incident Regulations* and *Saskatchewan Critical Incident Reporting Guidelines, 2004*. (See 6.2.1)

2.2 *Best Practice*

2.2.1 The transfusion service/laboratory should report any serious adverse event that appears to be caused by an attribute of the blood components or plasma protein products to Transfusion Transmitted Injuries Surveillance System (TTISS) through the provincial reporting program. (See Appendix #6.)

3.0 Materials

3.1 Public Health Agency of Canada Transfusion Transmitted Injuries Surveillance System (TTISS) User's Manual Version 3.0
3.2 Saskatchewan Hospitals Adverse Event Reporting Form – November 06
3.3 Canadian Transfusion Adverse Event Reporting Form (F100_V3.OE (November 2007))

4.0 Quality Management

4.1 A RHA-based quality improvement system or process shall be in place to monitor compliance with the policies and procedures for adverse event reporting. CSA 4.6.1.1

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

5.0 Procedure

5.1 Notify the laboratory/transfusion service and the physician/authorized RN(NP) immediately for all suspected transfusion reactions. All facilities must detect, manage, investigate and report all transfusion reactions.

5.2 If it appears that the adverse event may have been caused by an attribute in the blood component such as bacterial contamination, notify CBS immediately so that companion products can be removed prior to transfusion. (i.e. a large increase in temperature without an underlying cause can be indicative of bacterially contaminated units).

5.3 If the adverse event resulted in a fatality notify the manufacturer (either CBS or the plasma protein manufacturer) immediately.

5.4 Adverse events to plasma protein product must be reported to the product manufacturer. Complete the Canadian Adverse Event Reporting form and forward.

5.5 Complete the Saskatchewan Hospital Adverse Events Reporting form following the Saskatchewan Instructions in the TTISS User's Manual with the following information:

- Patient first and last name;
- Patient date of birth;
- Saskatchewan Health Services number (HSN) or unique identification number;
- Sex;
- Facility Information – hospital name and phone number;
- Facility ward/service;
- Patient diagnosis;
- Patient transfusion and pregnancy history;
- Patient vital signs;
- Measures taken;
- Suspected Products;
- Results of check; and
- Name of the reporter

5.6 Fax the completed Adverse Event Reporting form as per the instructions in the TTISS User's Manual, Saskatchewan Instructions.

5.7 Complete the Canadian Adverse Event Reporting Form for more complicated adverse events as requested.

6.0 Reporting

6.1 Place a copy of the completed investigation and recommendations for future transfusions on the patient's health records chart.

6.2 Report all serious adverse events to RHA Risk Management for reporting to Saskatchewan Health Critical Incident.

6.2.1 In Saskatchewan, all RHA's are required by law to notify the Ministry of Health within three business days of first becoming aware of a critical incident. Following this initial notification, the region/agency is required to investigate the incident and provide a written report to the Ministry of Health within 60 days. When necessary, organizations can request an additional 120 days to complete and submit their written report to the Ministry.

A "critical incident" is defined as "a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a regional health authority or health care organization." In addition to this definition of critical incident, a number of specific events must be reported to the Ministry, including patient death or serious disability associated with:

- a hemolytic reaction due to the administration of ABO-incompatible blood or blood products; and
- a medication or fluid error including, but not limited to, errors involving the wrong blood or blood component, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration (excluding reasonable differences in clinical judgement on selection and dose); and
- the use of contaminated blood, blood components or devices (including generally detectable contaminants such as infectious matter or foreign substances in blood, blood components or devices regardless of the source of contamination and/or product).

7.0 Documentation

7.1 A system must be in place within the transfusion service/laboratory to check adverse event information and recommendations for future transfusions for subsequent transfusions.

8.0 References

8.1 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services Version 3.* May 2011.

8.2 Canadian Standards Association. (2010). *Standards for Blood and Blood Components CSA Z902-10.*

8.3 Government of Saskatchewan. (2010). *The regional health services act.* Regina, SK: Queen's Printer.

8.4 Government of Saskatchewan. (2004). *The critical incident regulations.* Regina, SK: Queen's Printer

8.5 Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing (version 1- June 2007)

8.6 Newfoundland Policy for Blood Component and Blood Product Administration (Version 2, Oct 2008)

8.7 Ontario Regional Blood Coordinating Network. 2009). Standard Work Instruction Manual.

8.8 Public Health Agency of Canada Transfusion Transmitted Injuries Surveillance System User's Manual, Version 3.0

8.9 Regina Qu'Appelle Health Region Nursing Procedures Manual (February 2010)

8.10 Saskatchewan Ministry of Health (2004). S*askatchewan critical incident reporting guidelines.* Regina, SK.

8.11 Saskatoon Health Region Policies and procedures (June 2009)

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Guideline SK 18

Temperature Storage Guidelines for Blood Components and Plasma Protein Products

1.0 Principle

1.1 To provide guidelines for the proper storage of blood components and plasma protein products at temperatures demonstrated to be optimal for their function and safety.

1.2 Proper storage is critical to safe transfusion because blood, as a biological product, carries a risk of bacterial contamination if stored improperly. Improper storage may also affect the efficacy of blood components and plasma protein products.

2.0 Scope and Related Policies

2.1 Required:

2.1.1 Blood components and plasma protein products shall be stored under optimal temperature conditions as recommended by Canadian Blood Services (CBS) and/or the manufacturer. CSA 9.1.1/9.4.1/11.4.5/14.1.2

2.1.2 Blood components and plasma protein products shall be stored separately from all other substances, including blood samples, tissues for transplantation, and reagents. This may involve the use of clearly identified segregated areas within the same storage equipment. CSA 9.4.2

2.1.3 Red cells shall be stored at 1–6°C. Red cell expiry dates shall be assigned by the blood supplier. CSA 7.5.1.4/7.5.1.5

2.1.4 Modified red cells prepared in an open system shall be stored at 1–6°C and shall have an expiry of 24 hours after preparation. CSA 7.2.1

2.1.5 Red cells-washed shall be stored at 1–6°C and shall have an expiry of 24 hours after preparation. CSA 7.5.3.4

2.1.6 Red cells-frozen, after thawing shall be stored at 1–6°C. If prepared in an open system, shall have an expiry of 24 hours after thawing. CSA 7.5.2.9

2.1.7 Thawed plasma shall be stored at 1-6°C and shall have an expiry of 5 days after thawing. CSA 7.6.2.3

2.1.8 Cryoprecipitate shall be stored at ≤ -18°C until date of expiry. CSA 7.6.3.1

2.1.9 Thawed cryoprecipitate shall be stored at 20–24°C and shall have an expiry of 4 hours after thawing. CSA 7.6.3.4

2.1.10 Platelet components shall be stored at 20–24°C with gentle agitation until date of expiry. CSA 7.7.5

2.1.11 Pooled or mixed platelet components or cryoprecipitate prepared using an open system shall be stored at 20–24°C and shall have an expiry of 4 hours after preparation. CSA 7.2.1/7.11.3

2.1.12 The transfusion/infusion of blood components shall be completed within 4 hours of removing the unit from its controlled temperature location. CSA 11.4.6

2.1.13 Red blood cells should not be returned to usable inventory unless:

- A suitable monitoring system indicates that they have been maintained within acceptable temperatures since their release CSA 11.4.7;or
- They have been outside of a controlled environment for less than 30 minutes CSA 11.4.7
- Refer to Guideline SK 10- Issue, Return and Documentation of Final Disposition of Blood Components and Plasma Protein Products, section 5.2 for further information

3.0 Materials

3.1 Equipment:

- Blood component and plasma protein product storage equipment
- Manufacturer's internal calibrated thermal probe for each piece of equipment used for blood product storage
- Independent certified calibrated thermometers
- Continuous temperature recording chart

3.2 Supplies:

- Daily temperature record for refrigerators, freezers and platelet incubators
- Equipment malfunction and corrective action record forms

4.0 Quality Management

4.1 A Regional Health Authority (RHA)-based quality system shall be in place for the temperature storage guidelines for blood components and plasma protein products. CSA 4.6.1

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

5.0 Procedure

5.1 General Storage

5.1.1 Blood components and plasma protein products shall be stored in a separate area from donor and patient specimens as well as reagents.

5.1.2 A secure area, segregated from available inventory, is required for autologous, donor-directed and other quarantined units.

5.2 RBC Component Storage

5.2.1 All blood components must be stored at 1- 6°C. Shelf life depends upon the anticoagulant/additive used.

5.2.2 In an open system (uncontrolled environment), components stored at 1 - 6°C must be used within 24 hours.

5.2.3 RBC units must not be out of the controlled environment of the blood storage refrigerator for longer than 30 minutes to be eligible to be placed back into inventory.

- This should be followed by transfusion services/laboratory and closely monitored by all personnel who handle or transport blood components.

5.2.4 The transfusion/infusion should be completed within four hours of the time the component is removed from the controlled refrigerator.

5.3 Platelet Component Storage

5.3.1 Platelet components must be stored at 20-24°C under continuous agitation. Their shelf-life is five days from the date of collection.

5.3.2 Platelet products, as a biological and with room temperature storage conditions, carry an increased risk of bacterial contamination because of their storage at room temperature.

5.3.3 **When there is no Platelet Component Storage Agitator/Incubator in the Hospital Transfusion Service:**

5.3.3.1 Small laboratories may not have a platelet agitator and/or incubator but occasionally must order platelets for transfusion. In these cases, RHA policies and procedures that address this type of situation should be written. In the policy and procedures, the following items should be included:

5.3.3.1.1 Platelets are not stored on site but, when needed for transfusion purposes, are issued immediately upon receipt from CBS.

5.3.3.1.2 Communication mechanism with nursing to ensure that the component is used as soon as possible after receipt.

5.3.3.1.3 Steps taken when the platelets have been in transit for more than 24 hours. If more than 24 hours have passed, the platelets should not be used for transfusion (or the Medical Director responsible for the transfusion service must authorize the issue of such platelets after determining the clinical need with the patient's physician).

5.3.3.1.4 Visual inspection criteria for platelet components.

5.4 Frozen Plasma and Cryoprecipitated Antihemophilic Factor (AHF) Component Storage

5.4.1 All frozen components must be stored in a controlled, monitored freezer at -18°C or colder until expiry date.

5.4.2 In an open system (uncontrolled environment), components stored at 1-6°C must be used within 24 hours.

5.5 Plasma Protein Products

5.5.1 Plasma protein products shall be stored and reconstituted according to the manufacturer's instructions. Shelf life is determined by the manufacturer.

5.5.2 Storage temperatures are usually not greater than 25-30°C.

5.5.3 Refer to applicable plasma protein product package insert for individual storage requirements.

5.6 Reagent and Specimen Storage

5.6.1 The refrigerator temperature for reagent and specimen storage must be within 1-8°C.

Blood Component Storage, Transportation and Expiration Table:

Component	Storage Temperature Range (non-manufacturer)	Transport	Storage Time from the Date of Donation / Expiration
Red cells (except as below)	1-6°C	1-10°C	SAGM - 42 days
Red cells – washed	1-6°C	1-10°C	24 hours expiration
Red cells - frozen	Temperature dependent on cryoprotectant	Keep frozen	10 years expiration
Red cells – frozen (thawed)	1-6°C	1-10°C	24 hours expiration
Platelet / CPD Platelets, Pooled, LR	20-24°C	20-24°C	5 days, if continually agitated
Pooled Platelets (Open system)	20-24°C	20-24°C	5 days, if continually agitated
Granulocytes	20-24°C	20-24°C	24 hours without agitation
Frozen Plasma / Fresh Frozen Plasma	-18°C or colder	Keep frozen	12 months
Cryosupernatant Plasma	-18°C or colder	Keep frozen	12 months unless a lower temperature and longer expiration are recommended by manufacturer
Frozen Plasma - thawed	1-6°C	1-10°C	5 days Thaw at 30-37°C or use an approved microwave
Cryoprecipitate - frozen	-18°C or colder	Keep frozen	12 months
Cryoprecipitate - thawed	20-24°C	20-24°C	4 hours Thaw at 30-37°C or use an approved microwave
Cryoprecipitate – as a source of fibrinogen	20-24°C	20-24°C	24 hours Closed system
Open system components at 20-24°C	20-24°C	20-24°C	4 hours

Note: Blood supplier's recommendations for storage shall take precedence over this table.

6.0 Documentation

6.1 The transfusion service shall keep current and accurate records for scheduled monitoring of storage temperatures for blood components and plasma protein products to ensure conformance to all relevant standards. CSA 23.3.1/23.4.2

7.0 References

7.1 Canadian Blood Services, Transfusion Medicine, Storage of Blood Components. http://www.transfusionmedicine.ca.

7.2 Canadian Society of Transfusion Medicine. Standards for Hospital Transfusion Services. Version 3. May 2011.

7.3 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010

7.4 College of Physicians and Surgeons of Saskatchewan. Laboratory Accreditation Checklist for Transfusion Medicine, 2007.

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Guideline SK 19

Temperature Documentation of Blood Product Storage Equipment

1.0 Principle

1.1 To read and document the temperature of blood product storage equipment used in the transfusion services/laboratory.

2.0 Scope and Related Policies

2.1 Required:

2.1.1 Refrigerators, freezers, room temperature storage areas and platelet incubators with continuous temperature monitoring devices using an automated system shall be visually checked and recorded daily to ensure that they are operating properly. CSA 9.4.4

2.1.1.1 The temperature of the storage area without an automated continuous monitoring system shall be taken and documented every four hours. CSA 9.4.4(b)

2.1.1.2 Blood storage equipment located outside of the transfusion service/laboratory must meet the same blood monitoring standards. CSA 14.6.1

2.1.2 Refrigerators, freezers and platelet incubators used for blood component storage must be able to maintain a temperature throughout the cabinets within the range recommended by the supplier of the blood component. CSA 9.4.3

2.1.3 All calibrating devices shall be verified by a reference standard on a defined schedule and documented. CSA 23.3.3

2.1.4 The transfusion service/laboratory shall have a written procedure outlining actions to be taken when the temperature of a refrigerator, freezer or

incubator for platelet storage exceeds or falls below the allowable temperature range including evaluation of the potential effects on the quality of products and documentation of any actions taken. CSA 9.4.1

2.1.5 Alarm activation points should be set to provide sufficient time to relocate products prior to minimum or maximum temperature being exceeded. CSA 9.4.5

2.1.6 All temperature records shall be kept for a minimum of five years. CSA 20.6.4.3

2.2 Best Practice:

2.2.1 A supervisor must review, and sign temperature records on a monthly basis, or sooner if needed.

2.2.2 The independent certified calibrated thermometer should be immersed in a fluid similar to blood (e.g., 10% glycerol).

2.2.3 The independent certified calibrated thermometer should be readable to 0.1°C

2.2.4 When a daily visual temperature check is not possible (i.e. for labs that are not staffed 7 days a week) the laboratory should implement a process to ensure that the storage device has maintained an appropriate temperature between visual checks. This process should be documented prior to use of the blood components or plasma protein products. CSTM 3.2.1.6

2.2.5 All thermometers used in refrigerators and freezers that store blood components and plasma protein products shall be checked against a certified calibrated thermometer at least annually, and the check shall be documented. Appropriate corrective action shall be taken if required. CSTM 3.2.2.4

3.0 Materials

3.1 Equipment:

- Manufacturer's internal calibrated thermal probe for each piece of equipment used for blood product storage
- Independent certified calibrated thermometers
- Continuous temperature recording chart

3.2 Supplies:

- Daily temperature record for refrigerators, freezers, platelet incubators, and room temperature storage areas
- Equipment malfunction and corrective action record forms

4.0 Quality Management

4.1 A Regional Health Authority (RHA)- based quality system shall be in place for temperature documentation of blood component storage equipment. [CSA 4.6.1]

4.2 Temperature of equipment for blood component storage must be within the following range:

4.2.1 Refrigerators for blood component storage: 1 – 6° C
4.2.2 Freezers for frozen plasma components: -18° C or colder
4.2.3 Platelet incubators: 20 – 24° C
4.2.4 Refrigerators for reagent and specimen storage: 1 – 8° C
4.2.5 For room temperature products: as indicated by the product manufacturer, usually not greater than 25 – 30° C.

4.3 An independent certified calibrated thermometer should be placed inside each piece of equipment and be rotated through a different shelf daily. It is recommended that the location of the independent thermometer be alternated between the front and back of the shelf.

4.4 Shelves of temperature controlled storage equipment should be labelled to aid in the description of the independent certified calibrated thermometer location inside the blood storage.

4.5 Temperature monitoring records for blood components and plasma protein products must be kept for 5 years from the date of product use or expiry, whichever comes first.

4.6 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

5.0 Procedure

5.1 Daily: Temperature Monitoring

5.1.1 On equipment with continuous temperature recording devices, perform the following steps daily.

For those sites that do not have 7 day/week coverage a process must be in place whereby the temperature of storage equipment with continuous monitoring devices is taken manually and recorded once a day. CSA 9.4.4

5.1.1.1 Read the chart on the continuous recording device and ensure that the temperature has remained within acceptable range since the last documented record of temperature.

5.1.1.2 If the temperature is outside the acceptable range, see Procedural Notes. Document any actions taken. Proceed to step 5.4.

5.1.1.3 Read and record the temperature of the manufacturer's internal calibrated thermal probe.

5.1.1.4 Find the location of the independent certified calibrated thermometer. Read and record this temperature.

5.1.1.5 Compare the temperature of the manufacturer's internal calibrated thermal probe to the continuous recording device and the independent thermometer. If the temperature readings are not within 2° C, see step 5.5.

5.1.1.6 Move the independent certified calibrated thermometer to a different shelf and document location on appropriate form. See Procedural Notes 7.4.

5.1.1.7 A medical laboratory technologist or supervisor must review the documented temperatures monthly and document review on relevant form.

5.2 Weekly: Temperature Monitoring

5.2.1 Weekly, change the temperature chart on the continuous temperature recording device if the recorder has a weekly chart.

5.2.2 Select the correct type and size of chart for the equipment. Charts usually have a stock number that corresponds to the temperature range of the chart.

5.2.3 Remove the completed temperature recording chart from the equipment. Label the chart with the equipment identifier if multiple pieces of equipment are in use.

5.2.3.1 Review the chart to ensure that the temperatures recorded have remained within acceptable range for the blood products stored and initial chart to document review.

5.2.3.2 File the completed chart for 5 years from the date of product use or expiry, whichever comes first.

5.2.3 Record the date near the centre of the new temperature recording chart. Label the chart with an equipment identifier if multiple pieces of equipment are in use.

5.2.4 At this point, some recording devices may need winding. Remove “key” and wind temperature recording device, if applicable.

5.2.5 Place the new temperature recording chart on the device.

- Move the chart so that the recording pen is set to the correct day and time (e.g., Monday at 10:00 am)
- Check to see that the temperature recorded by the pen on the device corresponds closely to the internal temperature (± 2° C)

5.3 For blood storage equipment and / or areas without temperature recording device perform the following:

5.3.1 Read and record the manufacturer's internal calibrated thermal probe every 4 hours.

5.3.2 Move the independent certified calibrated thermometer to the next appropriate shelf once daily and document location on appropriate form.

5.3.3 A medical laboratory technologist or supervisor must review the documented temperatures monthly and document review on relevant form.

5.4 When the refrigerator temperature is found to be outside the acceptable storage range of 1 - 6° C; the following steps should be taken:

5.4.1 Follow directions on "Equipment Malfunction" in operating manual.

5.4.2 Report incident to a supervisor or laboratory manager according to RHA policy.

5.4.3 The investigation of the incident should include determination of the following information:

- The length of time the blood components have been outside the acceptable temperature
- Whether the blood components should be discarded or should remain in inventory. See Procedural Notes 7.1
- The cause of the unacceptable temperature

5.4.4 If storage temperature falls outside the recommended temperature range for any blood component storage equipment, components shall be moved to an alternate storage area of appropriate temperature. This move must be documented.

5.5 If the temperature of the manufacturer's internal calibrated thermal probe, the continuous recording device and/or the independent thermometer do not agree within 2° C, the following steps may be required.

5.5.1 Calibrate the manufacturer's internal calibrated thermal probe. In the interim, replace the manufacturer's thermometer with an independent certified calibrated thermometer, allow the thermometer to equilibrate for 1 hour and re-read and record the temperature.

5.5.2 Determine whether the chart is recording correctly. If it is suspected that there is a malfunction with the chart recorder report incident to a supervisor or laboratory manager.

5.5.3 Determine whether the manufacturer's internal calibrated thermal probe is functioning correctly.

6.0 Documentation

6.1 The transfusion service/laboratory shall keep current and accurate records for scheduled monitoring of storage temperatures for blood components and plasma protein products to ensure conformance to all relevant standards. CSA 23.3.1/23.4.2

6.2 A blood bank/medical laboratory technologist shall review the temperature records daily.

6.3 A supervisor must review, and sign temperature records on a monthly basis, or sooner if needed.

6.4 The visual checking of continuous recording device rolls/graphs must be recorded daily.

6.5 Keep temperature records for 5 years from the date of product use or expiry, whichever comes first.

7.0 Procedural Notes

7.1 The independent certified calibrated thermometer is moved to verify that the temperature throughout the storage equipment is within the acceptable range. It is recommended that the location of the independent thermometer be alternated between the front and back, and upper and lower shelves

8.0 References

8.1 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services. Version 3.* May 2011.

8.2 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

8.3 College of Physicians and Surgeons of Saskatchewan. Laboratory Accreditation Checklist for Transfusion Medicine, 2007

8.4 Ontario Regional Blood Coordinating Network (ORBCON). Document No: QCA.002. Ontario Regional Blood Coordinating Network Standard Work Instruction Manual. December 31, 2009.

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 20

Maintenance of Blood Component Storage Refrigerators, Freezers and Platelet Incubators

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1.0 Principle

1.1 To check the alarm system of blood component storage refrigerators, freezers and platelet incubators and to maintain storage equipment in good working condition.

2.0 Scope and Related Policies

2.1 Required:

2.1.1 Equipment used in the collection, processing, serological testing, storage and distribution of blood components shall be maintained in a clean and orderly manner and shall have regular documented calibration and preventative maintenance. Records of maintenance, validation, calibration, malfunction and repair must be kept during the working lifetime of the equipment plus five years. Records must also document the disposal of equipment. CSA 23.4.1

2.1.2 Storage equipment for blood components and plasma protein products shall be able to maintain a temperature throughout the cabinets within the range recommended by the supplier. CSA 9.4.3

2.1.3 The temperature of refrigerators for blood component storage shall have a temperature range between 1 – 6° C. CSA 7.5.1.4

2.1.4 The temperature of freezers for plasma storage shall have a temperature range of -18° C or colder. CSA 7.6.2

2.1.5 The temperature of incubators for platelet storage shall have a temperature range between 20 – 24° C. CSA 7.7.5

2.1.6 Storage equipment shall be validated to maintain a temperature throughout the storage area. CSA 23.1.3(d)

2.1.7 Equipment used for blood component storage situated in areas other than the transfusion service/laboratory shall conform to relevant standards. CSA 14.6.1

2.1.8 Equipment for blood components and plasma protein products storage shall monitor and record the temperature continuously. If an automated system is not available, the temperature shall be manually checked and recorded every 4 hours. The system shall be visually checked and documented every day to ensure that it is operating. CSA 9.4.4

2.1.9 Freezers and refrigerators for storage of blood components and plasma protein products shall be equipped with an audible alarm which will be activated when the temperature reaches the upper or lower limit of the temperature range. CSA 9.4.5

2.1.9.1 There shall be a procedure for testing the alarm probes for upper and lower limits at least once every six months and documented. CSA 23.1

2.1.10 The alarm shall be set to activate at a temperature that will allow proper action to be taken before the blood components or plasma protein products reach undesirable temperature. CSA 9.4.5

2.1.11 Audible alarms on temperature monitored equipment shall be located in an area that is continually monitored or staffed at all times so corrective action can be taken immediately. CSA 9.4.5

2.1.12 The transfusion service/laboratory shall have a written procedure outlining actions to be taken when the temperature of storage equipment falls outside the allowable temperature range. Corrective actions must be documented. CSA 9.4.1, 20.7.2

2.1.13 Records of maintenance malfunction and repair must be kept during the working lifetime of the storage equipment. CSA 23.4.2

2.1.14 All blood component storage equipment needs to be validated prior to being placed into service (on receipt or following repair) to ensure it is functioning as intended. CSA 23.2.1

2.2 Best Practice

2.2.1 Each piece of equipment must be labelled with a unique identifier. CSTM 3.1.4

2.2.2 If platelets are not stored in a controlled environment, the ambient temperature in the area where the platelets are stored shall be checked and documented at least every four hours. The temperature must be within the range specified by the supplier or appropriate corrective action must be taken. The temperature range of the area should range between 20 – 24° C. CSTM 3.2.3.2

2.2.3 All manufacturers' internal-calibrated thermometers used in refrigerators and freezers that store blood components and plasma protein products shall be checked against an independent-certified calibrated thermometer at least annually, and the check shall be documented. Appropriate corrective action shall be taken if required. CSTM 3.2.2.4

2.2.4 Equipment used for blood component storage shall be connected to an emergency power supply. The system should be checked monthly to ensure an immediate switch to emergency power supply in the event of a power failure. This check must be documented. CSTM 3.2.2.2

2.2.5 The audible alarm must have a back-up power supply. The alarm and back-up power supply must be checked monthly. This check must be documented. [CSTM 3.2.2.2]

2.2.6 Other semi-annual procedures shall include checking air circulation, door seals, cleaning inside, cleaning dust from compressors, and testing the alarm probes for upper and lower limits.

3.0 Materials

3.1 Equipment:

- Manufacturer's internal-calibrated thermal probe for each piece of equipment used for blood component storage
- Independent-certified calibrated thermometers
- Continuous temperature recording chart

3.2 Supplies:

- Monthly and biannual maintenance record forms
- Repair records for each piece of equipment
- Equipment malfunction and corrective action record forms

For Alarm Probe Testing:

Refrigerators	Freezers	Platelet Incubators
• Solution of ice slush and water (salt water) in a container	• Cold water in a container	• Warm water
• 10% glycerol in a container		• Freezer packs
• Warm water (12 – 15° C) in a container		

** Follow Manufacturers directions where applicable

4.0 Quality Management

4.1 A Regional Health Authority (RHA) –based quality system or process shall be in place for the maintenance of blood component storage refrigerators, freezers and platelet incubators. [CSA 23.1.1]

4.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. [CSA 4.3.3.1]

5.0 Procedure

Maintenance shall be done following the manufacturer's instructions. [CSA 23.1.2] It should include the following:

5.1 Monthly Maintenance

5.1.1 Check the alarm for sound. Follow the manufacturer's directions. If these are unavailable or do not describe how to test the alarm, perform the following steps.

5.1.1.1 Press the "alarm test" button.

- Some models have an indicator light as well as an alarm.
- For platelet incubators, pull the plug if there is no special test button.

5.1.1.2 If the alarm rings (and light flashes, if applicable), document response.

5.1.1.3 If the alarm is malfunctioning, document response. Notify supervisor and check and record the temperature of the storage equipment manually every 4 hours until the alarm is repaired.

5.1.2 Check the back-up power supply according to the manufacturer's instructions. If these are unavailable, or if testing is done as a part of the back-up power supply of the hospital (if the electrical outlet is connected to an emergency power supply), proceed to step 5.2.1.

5.1.2.1 Disconnect the storage equipment from the power supply and then remove the back-up power supply (if there is a separate one) to the audible alarm.

5.1.2.2 When the back-up power supply is disconnected, there should be a visible or audible signal. Document response.

5.1.2.3 If the back-up power supply is not functional, document the response. Notify supervisor and record the temperature of the storage equipment every 4 hours until the back-up power is restored.

5.2 Semi Annual Maintenance

5.2.1 Testing the alarm probes for upper and lower limits.
Every 6 months, check the temperature sensors for low and high temperatures according to the manufacturer's instructions. If these are not available or not described, the following procedure should be done:

5.2.1.1 Blood Component Storage Refrigerators:

5.2.1.1.1 Place a calibrated thermometer into the container that the temperature sensor is stored in.

5.2.1.1.2 Place the container with the thermometer and temperature sensor into a container of ice slush and water. Close the refrigerator door.

5.2.1.1.3 When the alarm sounds, read the temperature indicated on the digital and/or continuous temperature recorder and on the thermometer in the sensor container.

5.2.1.1.4 Record the low-activation temperature.

5.2.1.1.5 The alarm should sound when the temperature of the sensor solution reaches 1.5° C. Adjust the set point and repeat testing if the alarm does not sound at 1.5° C.

5.2.1.1.6 Remove the container with the sensor and thermometer from the slush.

5.2.1.1.7 Document the temperature on the digital and/or continuous temperature recorder and on the thermometer when the alarm stops ringing (it should stop ringing when the temperature of the solution containing the sensing device is above 1.5° C).

5.2.1.1.8 Place the container with the solution, thermometer and sensing device into a container of warm water (12 – 15° C is ideal). Allow the container to remain in the warm water until the alarm sounds.

5.2.1.1.9 When the alarm sounds, read the temperature on the digital and/or continuous temperature recorder and on the thermometer in the sensor container.

5.2.1.1.10 Record the high-activation temperature.

5.2.1.1.11 The alarm should sound when the solution containing the sensing device reaches 5.5° C. Adjust the set point to 5.5° C and repeat testing if the alarm does not sound at 5.5° C.

5.2.1.1.12 Remove the container with the sensor and thermometer from the warm water and return it to the refrigerator.

5.2.1.1.13 Document the temperature on the digital and/or the continuous temperature recorder and on the thermometer when the alarm stops ringing (it should stop ringing when the temperature of the solution containing the sensing device drops below 6° C).

5.2.1.1.14 Record the date the alarm probe was checked.

5.2.1.1.15 Document date of maintenance and explanation for “out of range” on temperature recording chart..

5.2.1.2 Storage Freezers:

5.2.1.2.1 If the temperature sensor is not accessible, follow the manufacturer’s recommendations.

5.2.1.2.2 If the temperature sensor is accessible, place a calibrated thermometer into the same container that the temperature sensor is stored in.

5.2.1.2.3 Place the container with the thermometer and temperature sensor into a container of cold water. Close the freezer door.

5.2.1.2.4 When the alarm sounds, read the temperature indicated on the digital and/or continuous temperature recorder and on the thermometer in the sensor container.

5.2.1.2.5 Record the alarm activation temperature on the appropriate form.

5.2.1.2.6 For most freezers, the alarm should sound at –19° C. Adjust the set point to –19° C and repeat testing if the alarm did not sound at –19° C.

5.2.1.2.7 Remove the container with the sensor and thermometer from the cold water.

5.2.1.2.8 Record the temperature on the thermometer when the alarm stops ringing.

5.2.1.2.9 Record the temperature.

- Document date of maintenance actions on temperature recording chart and explanation of why the temperature is outside the acceptable range.

5.2.1.3 Platelet Incubators:

5.2.1.3.1 Remove platelets from the incubator.

5.2.1.3.2 Remove the temperature sensor probe and place into appropriate temperature solution until the alarm sounds. Check the temperature indicated on the temperature recorder.

5.2.1.3.3 Record the temperature on the digital or continuous temperature recorder on form for semi-annual check or on repair/maintenance form.

5.2.1.3.4 The alarm should have sounded at 23.5° C. Adjust the set point to 23.5° C and repeat testing if the alarm did not sound at 23.5° C.

5.2.1.3.5 Stop heating the incubator; open the door(s) and note the temperature on the digital or continuous temperature recorder at which the alarm stops ringing (it should stop ringing at 24° C).

5.2.1.3.6 Place several freezer packs to cool the temperature of the incubator. Close the door and wait until the alarm sounds.

5.2.1.3.7 When the alarm sounds, check the temperature on the digital or continuous temperature recorder.

5.2.1.3.8 Record the temperature on form.

5.2.1.3.9 The alarm should have sounded at 20° C.

5.2.1.3.10 Adjust the set point to 20° C and repeat testing if the alarm did not sound at 20° C.

5.2.1.3.11 Remove the freezer packs; close the door(s) and note the temperature on the digital or continuous temperature recorder at which the alarm stops ringing (it should stop ringing at 20° C).

5.2.1.3.12 Record the date the alarm probe was checked on form.

5.2.1.3.13 Check the motion alarm indicator if the incubator has one. Follow the manufacturer's instructions. Turn off the agitator. The motion sensor should indicate that the agitator is not moving. If the sensor indicates no motion, record satisfactory on form. If there is no indication, record not satisfactory and initiate a maintenance request (or contact the manufacturer if warranty applies).

5.2.2 Clean dust from compressor and other mechanical parts. Document action and date.

5.2.3 Clean the interior and exterior of the cabinet with a mild detergent. Document action and date.

5.2.4 Check that there is proper air circulation (fan is working, no obstacles preventing the efficient air flow). Document action and date.

5.2.5 Check that the door seals tightly. Adjust gasket as necessary. Document action and date.

5.2.6 Check that the compressor is not leaking. Record that the compressor is not leaking and date checked.

5.2.7 If there are any unexpected findings, record corrective actions. Keep a copy of documentation of the work performed, including work done by the maintenance department or servicing.

5.2.8 Report any abnormalities found with the refrigerator, freezer or platelet incubator to the supervisor.

5.3 Maintenance following recommendation from service provider that equipment has been repaired or prior to putting into service (following validation), before storing blood products

5.3.1 Blood Component Storage Refrigerators:

5.3.1.1 Place a thermometer in each of 2 containers filled with 10% glycerol. See Procedural Notes 7.1.

5.3.1.2 Place 1 container on the bottom shelf and the other one on the top shelf.

5.3.1.3 Read and record the temperature for 24 – 72 hours on both thermometers and on the recorder. Record the temperatures. See Procedural Notes 7.4.1 and 7.4.2.

5.3.1.4 Test the alarm for sound for 24 – 72 hours. See step 5.1.1. Document response for the "alarm sound test".

5.3.1.5 Test the alarm probe for low and high temperatures. See step 5.2.1. Record the high and low temperatures.

5.3.1.6 Ensure specific instructions in case of equipment malfunction are posted on the refrigerator.

5.3.2 Storage Freezers:

5.3.2.1 Check the temperature of the freezer.

- Place 1 thermometer on the bottom shelf and another one on the top shelf.
- Read and record the temperature for 24 – 72 hours on both thermometers and on the recorder. Record the temperatures. See Procedural Notes 7.4.1 and 7.4.2.

5.3.2.2 Test the alarm for sound for 24 – 72 hours. See step 5.1.1. Document response for the "alarm sound test".

5.3.2.3 Test the alarm probe for high temperature during the week. See step 5.2.1. Record the high temperature.

5.3.2.4 Ensure there are specific instructions in case of equipment malfunction are posted on the freezer.

5.3.3 Platelet Incubators:

5.3.3.1 Check the temperature of the platelet incubator.

5.3.3.2 Place 1 thermometer on the bottom shelf and another one on the top shelf.

5.3.3.3 Read and record the temperature for 24 – 72 hours on both thermometers and on the recorder. Record the temperatures. See Procedural Notes 7.4.1 and 7.4.2.

5.3.3.4 Test the alarm for sound for 24 – 72 hours. See step 5.1.1. Document response for the "alarm sound test".

5.3.3.5 Test the alarm sensor for low and high temperatures. See step 5.2.1. Record the high and low temperatures.

5.3.3.6 Ensure specific instructions in case of equipment malfunction are posted on the incubator.

5.4 Immediate Corrective Action for Alarm Sounding on Storage Equipment

5.4.1 Silence the alarm.

5.4.2 Read and record the temperature of the continuous recording device and internal thermometer/digital readout.

5.4.3 Determine the cause for the alarm: door ajar or incubator malfunction.

5.4.3.1 Document the alarm, the reason and corrective action taken.

5.4.4 Door Ajar Instructions:

5.4.4.1 Close the door and minimize entry.

5.4.4.2 Set a timer for 15 minutes.

5.4.4.3 Check the temperature after 15 minutes.

5.4.4.4 If the temperature remains outside of acceptable temperature range, record the date and immediate action taken.

5.4.5 Malfunction instructions:

5.4.5.1 Remove all blood components or plasma protein products. If there is alternate validated blood storage equipment – consider using as back-up equipment.

5.4.5.2 Read and record the temperature every 4 hours using a calibrated thermometer.

5.4.5.3 Assess need for blood component re-order from Canadian Blood Services (CBS) and inventory impact

5.4.5.4 Call maintenance immediately after ascertaining the safety of the blood components or plasma protein products.

5.4.5.5 If there is an off-site alarm that did not alert someone, determine why there was no response.

5.4.5.6 Record the malfunction and corrective action on form.

6.0 Documentation

6.1 The transfusion service/laboratory shall keep current and accurate records for scheduled monitoring, maintenance and cleaning of storage equipment to ensure conformance to all relevant standards. [CSA 23.3.1/23.4.2]

6.2 Documentation shall include: frequency of checks, check methods, acceptance criteria and corrective actions taken, maintenance schedules, repair activities, calibrations and validations. [CSA 23.3.1]

6.3 A supervisor must review the results of maintenance and any action taken. All corrective action should be documented.

6.4 This review must be documented.

7.0 Procedural Notes

7.1 Follow manufacturer's directions where available.

7.2 Blood Component Storage Refrigerators: Ensure that the glycerol in the container (may be supplied by the manufacturer) is the same volume as the smallest unit.

7.2.1 Prepare 100 mL of 10% glycerol. If additional glycerol is required adjust recipe accordingly.

- Add 10 mL of glycerol in a 100 mL volumetric flask
- Fill with water; mix well

7.2.2 Transfer the 10% glycerol into the container. Use a large syringe if transferring glycerol solution to a donor bag.

7.2.3 Cool the solution before using for temperature calibration.

7.3 Storage Refrigerators: If an interim refrigerator is not equipped with a temperature recorder, record the temperature every four hours. If an interim refrigerator is not available, blood can be stored in the CBS shipping containers for 24 hours. Place completely frozen ice pack(s) in the shipping container(s).

7.4 All Storage Equipment:

7.4.1 If the three temperatures are not within 1° C, the recorder should be adjusted.

7.4.2 When the temperature readings of the two thermometers agree within 1° C, one thermometer may be used.

7.4.3 Maintenance of equipment may be documented on a computer system, if applicable.

7.4.4 Equipment should be validated when received and following repair prior to being placed into service. Validation should follow an established protocol and must be documented. Validation includes the following:

7.4.4.1 Installation – checks that electrical and special requirements set out by the manufacturer are met.

7.4.4.2 Operational – shows that the equipment functions as intended with respect to temperature range, alarm, temperature monitoring, and shelving

7.4.4.3 Performance – demonstrates that the equipment performs as expected using the established facility processes.

8.0 References

8.1 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services*. Version 3. May 2011.

8.2 Canadian Standards Association. *Blood and blood components.* CAN/CSA-Z902-10. February 2010.

8.3 College of Physicians and Surgeons of Saskatchewan. Laboratory Accreditation Checklist for Transfusion Medicine, 2007.

8.4 Manitoba Health. *Manitoba Transfusion Medicine Best Practice Resource Manual for Nursing.* June 2007.

8.5 Ontario Regional Blood Coordinating Network (ORBCON). Document No: QCA.003, QCA.004, and QCA.005. Ontario Regional Blood Coordinating Network

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Guideline SK 21

Record Retention Requirements

1.0 Principle

1.1 Records shall be such that it is possible to trace blood components and plasma protein products from their source to their final disposition. This guideline outlines the requirements for record retention.

2.0 Scope and Related Policies

2.1 Required

2.1.1 General

2.1.1.1 Records for all facilities shall be such that it is possible to trace blood and blood components from their source to final disposition (i.e., transfusion, further manufacturing, or destruction). The records system shall also provide a means to locate and access all records related to a given unit of blood or blood components. Each facility shall coordinate its record-keeping systems with those facilities that supply it and those that it supplies to maintain the chain of traceability. Each blood centre and transfusion service/laboratory shall develop and maintain records that demonstrate that the quality system has operated effectively. [CSA 20.1.1]

2.1.1.2 There shall be a system developed and maintained to demonstrate that [CSA 20.1.2]:
(a) records are traceable to a location;
(b) obsolete records (i.e., those that have reached their discard date) are withdrawn and accounted for; and
(c) confidentiality of donor and recipient records is ensured.

2.1.1.3 The way in which the record is to be used, and by whom, shall be clearly apparent from the document itself. Each record format shall indicate or include [CSA 20.1.3]:
(a) the name of the facility;
(b) a unique identifying number (where applicable, it should refer to the relevant operating procedure);
(c) the signature(s) of the authorizing person(s); and
(d) page numbers in the format “page x of y”, with “x” being the page number and “y” being the total number of pages.

2.1.1.4 In a paperless system, signatures on records may be recorded electronically; however, the electronic system used to maintain documents and records shall clearly identify the person making

the entry (e.g., by means of individual log-in identification and password). CSA 20.1.4

2.1.1.5 Any correction made to a written record shall be initialled or signed and shall be dated. The correction shall not obscure the original information. Where relevant, the reason for the correction should be recorded. CSA 20.1.5

2.1.1.6 Records of agreements between organizations associated with the manufacture of blood components shall be kept. CSA 20.1.6

2.1.1.7 The storage conditions of records shall prevent tampering and loss. Records to be retained shall be held in a restricted area accessed only by authorized personnel. CSA 20.1.7

2.1.1.8 Records shall be developed and maintained so that the following conditions can be met CSA 20.1.8:
(a) records stored electromagnetically are able to be reproduced as a hard copy at any time during their required storage period;
(b) documents are securely stored to prevent illicit copying; and
(c) distribution records are readily available to expedite recall whenever necessary.

2.1.1.9 Records may be retained on microfilm, microfiche, CD-ROM, or other reliable and easily accessible recording media. CSA 20.1.9

2.1.10 The responsibility for the transfer of data to storage media shall be assigned to a specific position or title in the facility, so that the person holding that position or title can be called upon to attest to the authenticity of the transferred records when necessary. CSA 20.1.10

2.1.11 The following activities and controls shall be adopted when copying records for storage CSA 20.1.11:
(a) a document shall detail the records copied;
(b) an audit on a statistically valid sample of records shall be made to ensure that they are legible and accurate copies, showing all the information present on the originals;
(c) original records relating to a batch shall not be destroyed until the checks described above have been carried out;
(d) all transferred data shall be easily retrievable; and
(e) where records are copied off-site, a contract signed by both parties shall detail specific requirements such as those for transport to that site, copy quality, storage conditions, and, where relevant, destruction of original documents.

2.1.12 Personal health information must be destroyed in a manner that protects the privacy of the patient. Saskatchewan Health Information Protection Act Documents must be shredded or destroyed in an unreadable manner.

2.1.13 The original report of an adverse event (including recommendations for future transfusions) shall become part of the recipients medical record. A copy of the investigators report on the serious adverse event shall be kept of file by the transfusion service. A system shall be in place for checking this information if the recipient requires subsequent transfusion. CSA 18.2.7

2.1.2 Records of Patients

2.1.2.1 The patient transfusion data file in the transfusion service/ laboratory shall be retained indefinitely. Release vouchers shall be retained indefinitely. All transfusion records in the patient's health record, including pre-transfusion serological test results and worksheets for identification of atypical antibodies, shall be retained in accordance with the provincial and Regional Health Authority (RHA) retention policy for health records. CSA 20.6.3.1 Storage methods must ensure that records are protected from degrading or damage.

2.1.2.2 Records of serious adverse transfusion events shall be retained indefinitely. CSA 20.6.3.2

2.1.2.3 Records of adverse transfusion events shall be retained for 5 years. CSA 20.6.3.3

2.1.2.4 Non-transfusion serological test result records shall be retained for 3 years. CSA 20.6.3.4

2.1.2.5 Transfusion request forms for serological tests shall be retained for 1 month. CSA 20.6.3.5

2.1.3 Other Records

2.1.3.1 All documents related to a lookback or traceback process shall be retained indefinitely CSA 20.6.4.1.

2.1.3.2 Documentation of the qualifications, training, and competency of each employee shall be retained for 10 years after the date the individual ceases to be an employee. The record of each employee's signature, ID, and initials shall be kept for 10 years after the date the individual ceases to be an employee. CSA 20.6.4.2

2.1.3.3 The following records shall be retained for 5 years CSA 20.6.4.3:
(a) temperatures of storage; and
(b) quality control testing of whole blood, blood components, reagents, equipment, and proficiency testing surveys (including dates, tests performed, observed results, interpretations, identification of personnel carrying out the tests, and any appropriate corrective action taken).

2.1.3.4 Records of product complaints shall be retained for 5 years from the date that the complaint is deemed to be closed. CSA 20.6.4.4

2.1.3.5 Quality assurance reports and records of internal audits shall be retained for 5 years. CSA 20.6.4.5

2.1.3.6 Slides from the Kleihauer-Betke Acid-Elution test shall be retained for 3 months. CSA 20.6.4.6

2.1.4 Product complaints, recalls, and corrective action

2.1.4.1 Distribution records should be readily available, complete, and easy to follow, so as to expedite the recall of blood components or materials whenever necessary. CSA 20.7.1

2.1.4.2 Records should demonstrate that corrective action is taken when blood component quality does not meet specifications and that follow-up has taken place. CSA 20.7.2

3.0 Quality Management

3.1 An RHA-based quality improvement system or process shall be in place to monitor compliance with the policies and procedures for record retention. CSA 4.6.1.1

3.2 A formal competency assessment program shall be in place for all personnel involved in the transfusion process. Competency shall be assessed and documented following training and at regular and routine intervals thereafter. CSA 4.3.3.1

4.0 Documentation

4.1 As required by CSA standards CSA Table 4:

Minimum Retention Period	Types of Records
Indefinitely	• Blood component and blood product final disposition • Blood supplier correspondence related to blood components and plasma protein products • Blood supplier packing slips • Directed Donor charts • Donor ABO and Rh groups • Donor testing worksheets and results • Lookback and traceback documents • Serious adverse reactions • Transfusion recipients transfusion service (blood bank) data including serologic test records • Transfusion service packing slips

Minimum Retention Period	Types of Records
10 years	• Donor ABO, RH and blood group determination problems • Employee signature, initials, computer identification (retained for 10 years after last use) • Staff qualification, training, competency (retained for 10 years after employment ceases)
5 years	• Adverse reactions • Autologous donor charts • Blood component and blood product complaints • Inspection of blood prior to use • Internal audits • Proficiency testing reports • Quality assurance reports • Quality control of blood components and blood products reagents and equipment Temperature monitoring of blood storage devices
3 years	• Non-transfusion serologic test records • Validation and operation of computer systems
1 year	• Date and time of specimen collection • Phlebotomists identification
3 Months	• Slides from fetal-maternal hemorrhage • Records of unit phenotyping • ABO reconfirmation of units
1 Month	• Request for serologic tests
In Accordance with Provincial and RHA Guidelines	• Transfusion records in patient's health record

5.0 References

5.1 Canadian Society of Transfusion Medicine. *Standards for Hospital Transfusion Services Version 3.* May 2011.

5.2 Canadian Standards Association. *Blood and blood components* CAN/CSA Z902-10. February 2010.

5.3. Saskatchewan Health Information Protection Act, 1999 Section III Effective September 1, 2003

5.4 Newfoundland Policy for Blood Component and Blood Product Administration (Version 2, Oct 2008)

5.5 Ontario Regional Blood Coordinating Network. (2009). *Standard Work Instruction Manual.*

Facility endorsement if guideline is used as a Standard Operating Procedure (SOP)

Approved by: _____ _____
(Senior Management) (Senior Management)

Facility effective date: _____
(Date of implementation)

Appendix #1

TRANSFUSION GUIDELINE CHANGE REQUEST FORM

Guideline Name:	
Requestor:	RHA:
Version Number:	Date of Request:

Check one: ☐ New Document ☐ Changed Document

Description of Document:

Rationale for New or Changed Document: **New Version Required URGENT** ☐
Suggested Wording for Change
Are any related documents affected? ☐ **Yes** ☐ **No** **If yes, list here. Also prepare additional Document Change Request Forms, if needed.**

Fax changes to: Regina Qu'Appelle Health Region - Transfusion Service
(306) 766-4382

For Document Control Use:
New Document Number and Version_____

Appendix #2

Glossary of Terms

Term	Definition
Administration	Act of infusion of blood components and/or plasma protein products.
Adverse Reaction	Undesirable and unintended response to the transfusion of blood components or plasma protein products that is considered to be definitely, probably, or possibly related to the transfusion.
Autologous Donation	Process in which blood is collected from an individual for the purpose of transfusion back to that individual at a later time.
Blood Component	A therapeutic part of blood intended for transfusion (e.g. red cells, platelets, granulocytes, plasma and cryoprecipitate).
Calibration	Comparison of a measurement system or instrument of unknown accuracy to a system or instrument of known accuracy (established by national standards) to verify the accuracy of the unknown.
Circular of Information	Blood component information which may or may not accompany the blood component that provides information on composition, storage, indications, special precautions, administration, and possible adverse effects of transfusion.
Course of Treatment	A series or sequence of transfusions administered to a person over a period of time for a particular health problem.
Directed Donation	A donation made by a donor chosen for or by the recipient, and who has been identified in advance to be compatible.
Expiry Date	Last date that the blood components or plasma protein products, reagents or supplies shall be used.
Hemoglobin S	The most common type of abnormal hemoglobin and the basis of sickle cell trait and sickle cell disease.
Irradiated	Blood components that have been exposed to gamma radiation.
Issue Voucher	Clerical record containing key identification elements that is presented when a blood component or plasma protein product is released for transfusion.

Term	Definition
Medical Director	Provincially or territorially licensed physician who is responsible for all clinical and laboratory policies, processes and procedures related to transfusion practices within their mandate or jurisdiction.
Neonate	For the purpose of Transfusion Medicine, infant less than 4 months of age.
Nursing Procedures by Transfer of Medical Functions	A policy that applies to RN's, but not RN(NP)s, wherein medical functions primarily performed by physicians and outside the usual scope of nursing practice may be transferred to specific nurses in the interests of client care. The medical authority retains accountability for the decision to transfer the procedure. The SRNA has outlined criteria which must be met (on the part of the RN, the medical authority and the administration) before a procedure can be transferred from medicine to nursing, however this policy is currently under review. The SRNA is exploring alternate mechanisms to replace the "transfer of medical functions" policy.
Plasma Protein Product	A therapeutic product derived from human blood or plasma and produced by a manufacturing process (e.g. Albumin, Immunoglobulin, Coagulation products).
Operating Procedure	Thorough, step-by-step documentation of a procedure presented in a standardized format.
Qualified Person	Qualified person is identified in RHA policy and procedure and may include the following: - for the purposes of specimen collection, a qualified person is a competent individual who can confirm the patient's name, date of birth and address if the patient is not competent or unconscious - for the purposes of placing an identification band on a patient, the qualified person is defined as an individual authorized by the facility or RHA to place the band on the patient. This should be identified in RHA policy and procedure

Term	Definition
Quality Assurance	Actions that are planned and performed to verify that all systems and elements that affect the quality of products and services are working as expected.
Quality System	Organizational structure, responsibilities, policies, processes, procedures, and resources for implementing quality management.
Record	Information captured in writing or through electronic media providing evidence that an activity has been performed. Examples include logs, completed forms, test results and audit results.
Request Form	Request for preparation or transfusion of a blood component or plasma protein product generated in response to an order written by a physician.
Serious Adverse Reaction	Adverse reaction that meets at least one of the following: - requires in-patient hospitalization or prolongation of existing hospitalization - results in persistent or significant disability or incapacity - necessitates medical or surgical intervention to preclude permanent damage or impairment of a body function - is life-threatening - results in death
Scope and Related Policies	Required - statements in accordance with CSA Z902-10 standards. Best Practice- additional information to enhance quality and safety.
Transfusion	All activities related to the processes of administration of blood components and plasma protein products.

Term	Definition
Transfusionist	The qualified person who initiates the transfusion of blood components and/or plasma protein products. In accordance with applicable provincial legislation, regulations and/or bylaws, it is within the scope of practice for a physician, Registered Nurse, Nurse Practitioner (RN (NP)), Registered Nurse (RN), Registered Psychiatric Nurse (RPN) or Licensed Practical Nurse (LPN) who has completed the IV Therapy/Blood and Blood Products Completer Course to transfuse blood components and plasma protein products. Graduate RN, RPN and LPN must be supervised by a licensed professional.
Transfusion Service (TS)	Department or facility that performs transfusion related serological testing and/or is involved in the provision of blood components and/or plasma protein products and their transfusion or administration..
Validation	Documented process to demonstrate that any process, procedure or equipment will consistently provide the expected results.

Appendix #3

Nurse Practitioner Primer

1.0 Background

The Saskatchewan Registered Nurses' Association (SRNA) is the professional regulatory body for the registered nursing profession, including nurse practitioners, or RN(NP)s. In 2003, amendments were made to *The Registered Nurses Act, 1988*[i] and to seven regulations to support the practice of RN(NP)s in the province.[ii] On April 30, 2004 the SRNA began licensing RN(NP)s for practice in Saskatchewan.

The SRNA has identified core competencies that are expected of each RN(NP). These competencies are in addition to the entry level competences of all Registered Nurses (RNs) in Saskatchewan. As such, all RN(NP)s are bound to practice within the:

- *The Registered Nurses Act 1988* ;
- The Saskatchewan Registered Nurses' Association Bylaws 2009;
- The *Registered Nurse (Nurse Practitioner) RN(NP) Standards & Core Competencies 2011;* and
- The Canadian Nurses Association *Code of Ethics for Registered Nurses*, 2008.

RN(NP)s are integral members of the health care team who provide and coordinate initial, continuing and comprehensive advanced nursing services in rural, remote and urban areas of the province. RN(NP)s serve ethnoculturally diverse populations of Saskatchewan across the continuum of healthcare throughout the lifespan. The spectrum of health services that RN(NP)s provide encompass health promotion and maintenance of wellness; illness and injury prevention; health condition, and health care management of common acute and chronic illness, including ordering diagnostic investigations and prescribing treatments including medications.[iii]

The SRNA currently recognizes 4 specialty categories of RN(NP)s: Primary care(family /all ages), Neonatal, Adult and Pediatric. Nurse Practitioners possess and demonstrate competencies to autonomously perform four new areas of activity as it relates to their specialty:

1. Ordering, performing, receiving and interpreting reports of screening and diagnostic tests;
2. Prescribing and dispensing drugs;
3. Performing minor surgical and invasive procedures; and
4. Diagnosing and treating common medical disorders.[iv]

Although transfusion medicine is not identified as a specialty area, there are occasions where medical conditions requiring transfusions, may be a regular part of a specific RN(NP)'s practice. As a guiding principle, the SRNA recognizes that the scope of practice of the RN(NP) encompasses the activities for which the RN(NP) is competent

to perform, and is influenced by the setting in which they practice, and the needs of the clients.

2.0 Autonomy of the Nurse Practitioner vs. Transfer of Medical Functions

2.1 Autonomy of Nurse Practitioner

The nurse practitioner functions both autonomously and collaboratively within the scope of RN and RN(NP) practise. According to the *RN(NP) Standards and Core Competencies 2011*, the nurse practitioner accepts sole responsibility and accountability for all actions taken within the scope of RN(NP) practice. This accountability cannot be altered or lessened by employer policies and each individual nurse practitioner is responsible for maintaining his/her own level of competence (knowledge, skills and judgement) in his/her practice as a RN(NP).

Nurse practitioners are accountable to refer patients to physicians or other health professionals to assess or manage patients' health/illness status when the patients' condition requires care beyond the RN(NP)s scope of practice and/or competence, or when specialized knowledge, skills and judgement of a specific care provider is required.

Consultations with a primary team physician are required when: the RN(NP) approaches or reaches the limit of his/her scope of practice; when signs, symptoms, diagnosis or plans/treatments are unclear or beyond the RN(NP)s scope of practice; or when the client's health condition destabilizes or a potentially life-threatening situation arises. However, the RN(NP) remains accountable for treatment decisions made on the basis of these consultations.

The SRNA emphasizes that the RN(NP) must have reasonable access to the primary physician for the purposes of consultation with respect to any client.

2.2 Nursing Procedures by Transfer of Medical Functions

Conversely, the SRNA's "nursing procedures by transfer of medical functions" policy[v] applies to RNs as opposed to RN(NP)s, wherein medical functions primarily performed by physicians and outside the usual scope of nursing practice may be transferred to **specific** nurses in the interests of client care. Transfer of medical function is linked to a specific nurse. However, it is different from the accountabilities of the RN(NP)s, in that the physician retains accountability for the decision to transfer the procedure.

The SRNA has outlined criteria which must be met (on the part of the RN, the medical authority and the administration) before a procedure can be transferred from a physician to a nurse, however this policy is currently under review and alternate mechanisms are being explored to facilitate this capability.

3.0 Responsibility of the Employer

In addition to the individual RN(NP) and the SRNA responsibilities, the employers also have an obligation to provide essential support systems, including human and material resources, so that the RN(NP)s are able to meet the minimum standards of practice and defined in the *Standards and Foundation Competencies for the Practice of Registered Nurses in Saskatchewan (2000) and* the *Registered Nurse (Nurse Practitioner) RN(NP) Standards and Core Competencies, 2011.* Employers are also responsible for developing and maintaining care and accreditation standards of their employing agency.

4.0 Responsibility of the Regional Health Authorities

In Saskatchewan, the regional health authorities are responsible for the day to day operations and delivery of health services, and RN(NP)s must practice within the applicable regulations. In accordance with *The Attending Health Professional Regulations*, RN(NP)s may do the following, as an employee of the RHA or as a non-employee once they have gone through the RHA privileging process:

- Register a client for out-patient treatment and diagnostic services;
- Attend on a client, diagnose and treat common medical disorders in out-patient facility;
- Collaborate with attending physicians, to treat in-patients of a facility operated by the RHA;
- Discharge an out-patient whom he/she is attending.

unless otherwise specified in their appointment to the nurse practitioner staff.[vi]

RN(NP)s cannot admit a client to an in-patient facility or for in-patient treatment and services.

As is the case for physicians who are privileged and credentialed to provide services within an RHA, the RHA should make sure that they are in compliance with the *Model Practitioner Staff Bylaws* (2010) as they reflect the process for the review and resolution of adverse events.

5.0 Common Medical Disorders

According to SRNA Bylaw VI, Section 3(3)(a), and the *RN(NP) Standards and Core Competencies (2011)* (and/or as amended from time to time), common medical disorders shall be interpreted to mean health problems, conditions, diseases or disorders that the RN(NP) sees with regularity within the context of their practice.

Further, educational curriculum from an approved and/or accredited program shall be used as a guide for the determination of appropriate problems, conditions, diseases or

disorders diagnosed and/or treated by the RN(NP). The RN(NP) shall maintain current competence within their chosen area of practice and may only independently diagnose or treat common medical disorders for which they are currently competent. When the client's condition requires the care beyond the RN(NP)'s scope of practice and/or competence, the appropriate consultation will be initiated.

Accordingly, the RN(NP) will not consider the following as being within their independent scope of practice:

1. Independently manage atypical or complex health problems (e.g. Diabetes Type 1 for Primary Care RN(NP)s, or discontinuation of resuscitation situations for Neonatal RN(NP)s).
2. Any health problem requiring diagnostic contrast medium radiography.
3. Any health problem that requires imminent surgical intervention.
4. Any health problem that becomes unstable requiring further consultation (e.g. hospitalization required).
5. Perform an internal biopsy.

It is NOT considered independent practice when a RN(NP) is practising in accordance with agreed upon, evidence based nurse-physician client care protocols.

6.0 References

[i] Government of Saskatchewan. (2003) *The registered nurses act, 1988.* Regina, SK: Queen's Printer.
[ii] Saskatchewan Registered Nurses' Association. (2004) Orientation information for RN(NP)s: The laws as they apply to RN(NP)s. Regina SK: SRNA. See SRNA website at: http://www.srna.org/images/stories/pdfs/nurse_practitioner/2004_orientation_information.pdf
[iii] Saskatchewan Registered Nurses' Association. (2011) *Registered nurse (nurse practitioner) RN(NP) standards & core competencies*. Regina SK: SRNA.
[iv] See interpretations of Common Medical Disorders for Primary Care, and Neonatal RN(NP)s on the SRNA website at http://www.srna.org/nurse-practitioner/common-medical-disorders
[v] Saskatchewan Registered Nurses' Association. (1993). The *registered nurse scope of practice: Special nursing procedures and nursing procedures by transfer of medical functions*. Regina, SK: SRNA.
[vi] Saskatchewan Ministry of Health (2010). *Model practitioner staff bylaws*. Regina SK.

Appendix #4

Blood Transfusion Patient Handbook

See the Saskatoon Health Region's patient handbook on the following website:
http://www.health.gov.sk.ca/transfusion-medicine

Canadian Blood Services
it's in you to give

Saskatchewan Hospital Customer Feedback Form

Section 1: CUSTOMER CONTACT INFORMATION

Name/Position:

Facility: | Phone #:

Section 2: DESCRIPTION OF OCCURRENCE

Date of Report: (YYYY/MM/DD)	**Date Event Occurred:** (YYYY/MM/DD)	**Date Event Discovered:** (YYYY/MM/DD)

Type:

Communication	Packaging	Quality	Labelling	Delivery
☐ Thank you	☐ Incorrect Product Issued	☐ Clot	☐ Incorrect Label Information	☐ CBS-Incorrect Destination
☐ Delayed Response	☐ Order vs Issue Mismatch	☐ DAT Positive	☐ Missing Label(s)	☐ CBS – Late
☐ Inappropriate Response	☐ Packing Slip Incorrect	☐ Damaged/Broken	☐ Missing Tag(s)	☐ External Carrier Late
☐ Not Properly Informed	☐ Packing Slip Missing	☐ Expired Product	☐ Incomplete/Incorrect Tag	☐ External Carrier Lost
☐ PN/XM Report Incomplete	☐ Tamper Seal Missing	☐ Product Unavailable		☐ External Carrier Incorrect Destination
☐ PN/XM Report Incorrect	☐ Incorrect Packing Config.	☐ Seal/Segment Issue		
☐ Other	☐ Temperature at Receipt	☐ Hemolyzed		

Product Type: ☐ RBC ☐ APLT ☐ Pooled Platelets ☐ FP ☐ AFFP ☐ CRYO ☐ CSP
☐ Other Product ☐ N/A (Product not Involved)
☐ Plasma Protein Product (Specify)

Description:

- For blood components, please provide the donation number and date collected below (or attach a copy of the packing slip)
- For plasma protein products, please include manufacturer's name, lot # and expiration date of the product

Disposition of Product: ☐ Returned to CBS on (YYYY/MM/DD) ☐ Discarded at Facility ☐ Transfused/Available for Transfusion at Facility ☐ Quarantined at Facility ☐ Not Applicable

Response Required from CBS? ☐ Yes ☐ No

Please forward completed form/supporting documents to CBS:
FAX: (306) 347-1551 OR EMAIL: skdistribution@blood.ca

Section 3: FOR CBS USE ONLY

Date & Time Received: _____ Initials: _____

NCR Initiated ❑ # _____

Original attached to NCR ❑

Copy to HLS ❑

Appendix #6

Transfusion Transmitted Injuries Surveillance System

1.0 Background

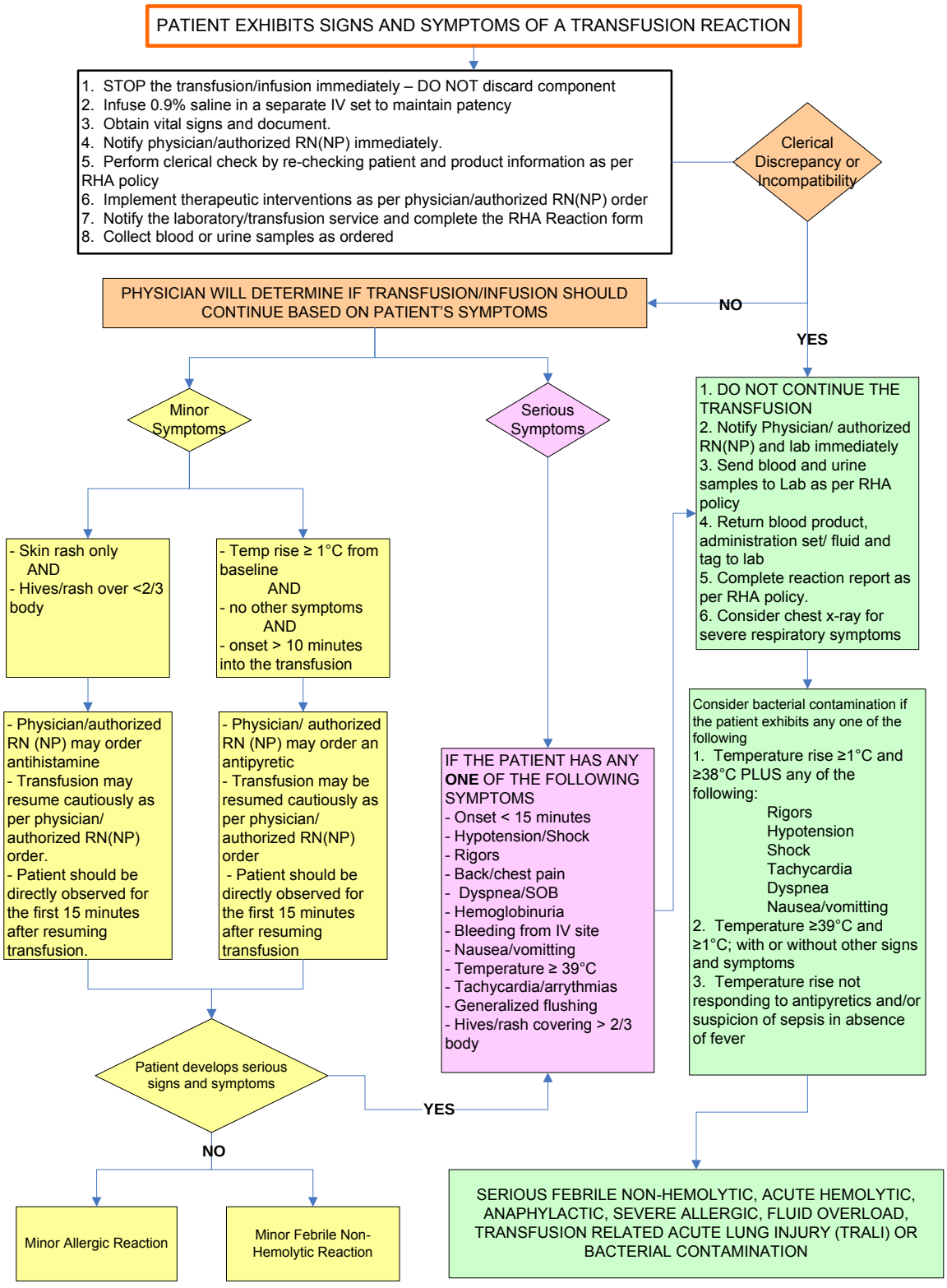
In the 1997 *Report of the Commission of Inquiry on the Blood System in Canada*, Justice Horace Krever emphasized the importance of surveillance and tracking of blood, blood components, or blood products (plasma derivatives), referring to the concept of vein-to-vein management of blood.

In response to this report the federal government launched a series of initiatives and provided additional funds to improve the safety of Canada's blood system. One such initiative is the Transfusion Transmitted Injuries Surveillance System (TTISS). TTISS is a national surveillance and monitoring system for reporting of adverse reactions to blood, blood components, or blood products (plasma derivatives). It provides data that will be used for managing the risks related to the transfusion of these products in Canada.

The Canadian Transfusion Adverse Event Reporting Form and User's Manual have been developed by a National Working Group consisting of representatives from the provinces/territories, manufacturers of blood components and Health Canada and Public Health Agency of Canada personnel. This manual is to be used as a resource for completing the Canadian Transfusion Adverse Event Reporting Form or TTISS database.

Appendix #7

TRANSFUSION REACTION ALGORITHM



Production of this Transfusion Reaction Algorithm has been made possible through a financial contribution from the Public Health Agency of Canada