Appendix # 2

Glossary of Terms

Term	Definition
Accident	An unexpected or unplanned event, not attributable to a deviation from standard operating procedures or applicable laws or regulations, that could adversely affect: a) the safety, efficacy, or quality of blood components or blood products; or b) the safety of donors, patients, or facility personnel.
Administration	Act of transfusion/infusion of blood components and/or plasma protein products.
Adverse Event	An undesirable and unintended occurrence before, during, or after the administration of blood components or plasma protein products, whether or not considered to be related to the administration.
Adverse Reaction	A type of adverse event, where an undesirable and unintended response develops to the administration of blood components or plasma protein products that is considered to be related to the administration of blood components or plasma protein products.
Associated Blood Component	A blood component that is directly associated in a recall.
Authorized Health Practitioner	Comprehensive term used throughout the Saskatchewan Transfusion Resource Manual to include regulated health professionals that may have a requirement, within their respective scopes of practice set in provincial legislation, regulation or policy, to conduct some activities similar to those of physicians, for a small number of transfusion medicine processes.
Autologous Blood	A term referring to practices in which blood is collected from an individual for the purpose of transfusion back to the same individual at a later time.
Blood Component	Whole blood or a therapeutic component of blood intended for transfusion (e.g., red cells, granulocytes, platelets, plasma, etc.) that can be prepared using the equipment and techniques available in a blood centre.

Term	Definition
Calibration	The comparison of a measurement system or device of unknown accuracy to a measurement system or device of known accuracy (traceable to national standards) to detect, correlate, report, or eliminate by adjustment any variation from the required performance limits of the unverified measurement system or device.
Certified Working Thermometer	Refers to thermometers in regular use which have been calibrated against a reference thermometer.
Circular of Information	An extension of the blood component labelling that provides directions for storage and use, including information on the composition and properties of the product, the indications for use, contraindications, and possible adverse effects of transfusion.
Companion Blood Component	A blood component that has been produced from the same donation.
Course of Treatment	A series or sequence of transfusions administered to a person over a period of time for a particular health problem.
Critical Incident	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 health authority or health care organization.
Directed Donation	A blood donation that is made by a donor who is known by the patient and selected for medical reasons by the patient's physician.
Establishment	Under the Blood Regulations, refers to a person or an organization that imports, processes, distributes, transforms or transfuses blood components.
Error	An unexpected or unplanned deviation from standard operating procedures or applicable laws and regulations, usually attributable to a human or system problem, that could adversely affect: a) the safety, efficacy, or quality of blood components or blood products; or b) the safety of donors, patients, or facility personnel.
Expiry Date	Last date that the blood components or plasma protein products, reagents or supplies shall be used.
Final Disposition	End status of a blood component or plasma protein product.

Term	Definition
Hemoglobin S	The most common type of abnormal hemoglobin and the basis of sickle cell trait and sickle cell disease.
Incident	An accident or error that could lead to an adverse outcome affecting: a) the safety, efficacy, or quality of blood components or blood products; or b) the safety of donors, patients, or facility personnel.
Informed Consent	A patient's authorization to carry out a treatment, surgical procedure, or diagnostic intervention after he or she is provided the information/facts needed to make an informed decision.
Irradiated	Blood components that have been exposed to gamma radiation.
ISBT 128 Donation Identification Number	Comprised of a 13 digit donation identification number and additional elements that are not part of the donation identification number (flag characters and check character).
Issue Voucher	Clerical record containing key identification elements that is presented when a blood component or plasma protein product is released for transfusion.
Laboratory Information System (LIS)	A computer system used in laboratory operations; specifically, the system that generates accession labels.
Large Scale Recall	A recall of a large number of blood components involving multiple provinces or a single province, OR, a recall of a small number of blood components involving multiple provinces or a single province.
Lookback	A procedure in which previous donations (and related blood components) from a donor who is subsequently found to have a transfusion-transmissible infection are identified and follow-up activities are undertaken to notify any involved organizations and affected individuals.
Medical Director	Provincially 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, an infant less than 4 months of age.
Operating Procedure	Thorough, step-by-step documentation of a procedure presented in a standardized format.

Term	Definition
Patient Health Record	The legal record of the patient's diagnostic, treatment and care information.
Plasma Protein Product	Any therapeutic product, derived from blood or plasma, and produced by a manufacturing process that pools multiple units (usually more than 12). Examples of blood products are human serum albumin, immunoglobulin preparations, and coagulation products (factors VIII and IX, fibrinogen, anti-thrombin III, etc.).
Privileges	The authority granted by the Regional Health Authority Board in accordance with these bylaws to a physician, chiropractor, midwife, dentist or nurse practitioner to admit, register, diagnose, treat or discharge patients/clients/residents in respect of a facility, program or service operated or delivered by the regional health authority.
Pre-transfusion Testing	Laboratory testing performed on the patient prior to transfusion to ensure compatibility with the blood component intended for transfusion Pre-transfusion testing generally includes ABO group and Rh type, antibody screening and crossmatching.
Provincial Legislation	The legislation of a province in which a health profession is regulated with respect to registration, education/training/competency, scope of practice, and compliance assurance. In some provinces, a scope of practice may be specified in a regulation or policy.

Term	Definition
Qualified Person	A qualified person is one who is defined by facility policies and procedures to perform specific responsibilities which shall be in accordance with applicable provincial licensing requirements. The facility shall have formal training and competency programs in place to ensure that all qualified persons receive training in and have demonstrated knowledge and competence in the necessary skills related to their specific responsibilities. Examples of responsibilities that a qualified person may be entitled to perform based on defined facility policies/procedures, formal training/competency programs and applicable licensing requirements include: - for the purposes of specimen collection, a qualified person is a trained and 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 to place the band on the patient.
Qualified Transfusionist	Practitioners and regulated health professionals authorized to initiate transfusion of a blood component and/or plasma protein product within their respective scope of practice under applicable provincial legislation, regulations and/or bylaws.
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.
Recall	The removal from further distribution, or use, of a product (blood component) that violates legislation administered by Health Canada (a regulatory requirement).

Term	Definition
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.
Reference Thermometer	Refers to high accuracy thermometers used to check the calibration and accuracy of working thermometers and temperature probes. Reference thermometers are calibrated and traceable per national standards.
Regulated Activity	Under the Blood Regulations, refers to any of the following activities related to blood: processing (donor suitability assessment, collection, testing and blood component preparation); transforming (washing, pooling and irradiating blood intended for transfusion); labelling; storing; record keeping; importing (for transfusion); distributing; and error, accident and adverse reaction investigation and reporting.
Regulated Health Professional	A health professional who is licensed or registered to provide health care under an Act of the Province specific to his or her profession and who provides health care or who is a member of a class of persons prescribed as regulated health professionals.
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.
Safety	In respect of blood, means that the blood has been determined safe for distribution or for autologous transfusion, as the case may be, in accordance with section 73, and includes: a) in the case of blood for transfusion, its quality and efficacy; and b) in the case of blood for use in the manufacture of a drug for human use, its quality.
Saskatchewan Transfusion Service Identification System (SK TSIS)	A provincial blood recipient identification system designed to establish unequivocal identification of the transfusion recipient through the combined use of a transfusion specific identification number and band.

Term	Definition
Serious Adverse Event	An adverse event that meets one or more of the following criteria: a) requires in-patient hospitalization or prolongation of existing hospitalization directly attributable to the event; b) results in persistent or significant disability or incapacity; c) necessitates medical or surgical intervention to preclude permanent damage or impairment of a body function; d) is life threatening; or e) results in death.
Special Transfusion Requirements	Blood components that have attributes or modifications to meet the requirements of a patient's clinical condition. - Modified blood components include irradiated, washed, frozen, pooled or divided components. - Other special transfusion requirements includes, but is not limited to, autologous red blood cells, phenotypically-matched red blood cells, apheresis platelets and HLA or HPA matched apheresis platelets.
Substitute Decision Maker	A person who, pursuant to 'The Health Care Directives and Substitute Decision Makers Act', has the legal authority to make decisions on behalf of an incapable person.
Traceback	The process of investigating a report of a suspected transfusion-associated infection in order to identify a potential implicated donor.
Transfusion	All activities related to the processes of administration of blood components and plasma protein products, regardless of route of administration.
Transfusion Facility	A facility or entity of individual(s) responsible for the administration of blood components and/or plasma protein products to the patient.
Transfusion Service Identification Number (TSIN)	A unique, randomly assigned alphanumeric code (7 character = 3 alpha + 4 numerical) used to establish a continuous, transfusion specific identification link between the patient, their pre-transfusion sample, selected blood components for transfusion and any required forms.
Transfusion Service/Laboratory (TSL)	An entity that performs pre-transfusion serological testing or is involved in the provision of blood components or plasma protein products and their transfusion or administration.

Term	Definition
Transfusion Transmissible Infection (TTI)	Any infection that is transmissible from person-to-person through parenteral administration of blood components or blood products. Examples of known TTIs include: HIV 1 and 2; HBV; HCV; HTLV I/II, West Nile Virus, syphilis, cytomegalovirus and malaria.
Treating Physician	The medical practitioner proposing and responsible for the patient's treatment or treatment plan.
Unexpected Adverse Reaction	An adverse reaction that is not identified among the possible adverse reactions either in the circular of information or in any other information provided to the patient.
Unusual Recall	A recall due to an unanticipated event impacting a large or small number of blood components.
Validation	Documented process to demonstrate that any process, procedure or equipment will consistently provide the expected results.
Withdrawal	The voluntary removal by the manufacturer (blood supplier) of a product (blood component) that does not violate legislation administered by Health Canada.
Wrong-blood-in-tube (WBIT)	Where the blood in the sample tube is not that of the patient identified on the label, and may lead to catastrophic outcomes, such as death from ABO-incompatible red cell transfusion.