

## Appendix # 2

### Glossary of Terms

Term	Definition
<b>Accident</b>	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.
<b>Administration</b>	Act of transfusion/infusion of blood components and/or blood products.
<b>Adverse Event</b>	An undesirable and unintended occurrence before, during, or after the administration of blood components or blood products, whether or not considered to be related to the administration.
<b>Adverse Reaction</b>	A type of adverse event, where an undesirable and unintended response develops to the administration of blood components or blood products that is considered to be related to the administration of blood components or blood products.
<b>Associated Blood Component</b>	A blood component that is directly associated in a recall.
<b>Autologous Blood</b>	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.
<b>Blood Component</b>	A therapeutic component of blood intended for transfusion, namely red cells, platelets and plasma.
<b>Blood Product</b>	Any therapeutic product, derived from blood or plasma, and produced by a manufacturing process that pools multiple units (usually more than 12). Note: Examples of blood products are human serum albumin, immunoglobulin preparations, and coagulation products (factors VIII and IX, fibrinogen, anti-thrombin III, etc.).
<b>Calibration</b>	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.
<b>Certified Working Thermometer</b>	Refers to thermometers in regular use which have been calibrated against a reference thermometer.
<b>Circular of Information</b>	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.

<b>Term</b>	<b>Definition</b>
<b>Companion Blood Component</b>	A blood component that has been produced from the same donation.
<b>Course of Treatment</b>	A series or sequence of transfusions administered to a person over a period of time for a particular health problem.
<b>Critical Incident</b>	An incident that arises as a result of the provision of a health service provided by the Saskatchewan Health Authority or a health services provider; means the incident is a serious adverse health event, including but not limited to, the actual or potential loss of life, limb or function related to the health service provided.
<b>Direct Antiglobulin Test (DAT)</b>	This test is performed to determine whether a patient's red blood cells have been coated with immunoglobulins or complement or both. The immunoglobulins and/or complement can cause hemolysis in some situations. Hence, the DAT is utilized to investigate hemolysis/risk of hemolysis due to transfusions (AHTR), drugs, maternal alloantibodies (hemolytic disease of fetus/newborn) and autoimmune hemolytic anemia.
<b>Directed Donation</b>	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.
<b>Establishment</b>	Under the Blood Regulations, refers to a person or an organization that imports, processes, distributes, transforms or transfuses blood components.
<b>Error</b>	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.
<b>Expiry Date</b>	Last date that the blood components or blood products, reagents or supplies shall be used.
<b>Females of Childbearing Age</b>	For the purposes of transfusion medicine in Saskatchewan, a female of child bearing age is defined as less than 50 years of age.
<b>Fetal Maternal Hemorrhage (FMH) Screen</b>	This test is utilized to determine if a 'sensitizing' event in pregnancy caused fetal red cells to enter maternal circulation. A sensitizing event is an event leading to mixing of larger quantities of fetal blood with maternal circulation (e.g. placental abnormalities, intrauterine instrumentation, abdominal trauma, delivery). This can cause the maternal immune system to form antibodies against fetal red cell antigens which can cross the placenta and lead to HDFN. This screen is of particular importance in Rh negative pregnancies as it determines the optimal dose of Rhlg required to prevent alloimmunization against anti-D. Of note, this test is only ordered after 20 weeks gestation as fetal blood volume is not large enough to require an increase in Rhlg dose before that.

<b>Term</b>	<b>Definition</b>
<b>Final Disposition</b>	End status of a blood component or blood product.
<b>Health Service Number (HSN)</b>	A unique nine-digit numeric identifier assigned to every Saskatchewan resident registered for health insurance in the province; equivalent to personal health number (PHN) from other provinces/territories.
<b>Hemoglobin S</b>	The most common type of abnormal hemoglobin and the basis of sickle cell trait and sickle cell disease.
<b>Hemolytic Disease of the Fetus and Newborn (HDFN)</b>	Is a disorder where the pregnant person is exposed to fetal blood and develops antibodies against fetal red cell antigens. These red blood cell or blood group antibodies cross the placenta during pregnancy and cause fetal red cell destruction. Effects of HDFN range from mild anemia to hydrops fetalis in the fetus and hyperbilirubinemia and kernicterus in the newborn.
<b>Incident</b>	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.
<b>Informed Consent</b>	Is a discussion within a shared decision-making process between the patient or substitute decision maker and the Most Responsible Practitioner (MRP), resulting in the patient or substitute decision maker's decision regarding the proposed health care.
<b>Irradiated</b>	Blood components that have been exposed to gamma radiation.
<b>Issue</b>	Release of blood components or blood products from the transfusion medicine laboratory (TML) or a temperature controlled environment.
<b>Laboratory Information System (LIS)</b>	A computer system used in laboratory operations; specifically, the system that generates accession labels.
<b>Large Scale Recall</b>	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.
<b>Lookback</b>	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.
<b>Lot Number</b>	The unique number assigned by the manufacturer when preparing a blood product. The number is located on both the box and the vial.
<b>Manufacturer Label</b>	A label permanently attached to a blood component or blood product as part of the manufacturing release process that provides information about the contents.

<b>Term</b>	<b>Definition</b>
<b>Medical Record Number (MRN)</b>	A facility or program generated number for the client's medical chart, also referred to as health record number (HRN).
<b>Most Responsible Practitioner</b>	The physician/practitioner/nurse practitioner with the overall responsibility for directing and coordinating the care of a patient at the specific point in time.
<b>Neonatal Patient</b>	For the purpose of Transfusion Medicine, an infant less than 4 months of age.
<b>Operating Procedure</b>	Thorough, step-by-step documentation of a procedure presented in a standardized format.
<b>Patient Health Record</b>	The legal record of the patient's diagnostic, treatment and care information.
<b>Patient Identity Verification</b>	The process by which a patient's identity is confirmed. The process requires engaging the patient in identifying themselves whenever possible and using at least two (2) person-specific identifiers to confirm the patient receives the service or procedure intended for them.
<b>Pediatric Patient</b>	For the purpose of transfusion medicine, a pediatric patient is defined as an infant or child between 4 months and 17 years of age.
<b>Pickup Slip</b>	A written record or form containing key identification elements that is presented when a blood component or blood product is released (issued) for transfusion.
<b>Pre-transfusion Independent Double Check</b>	Process whereby two (2) regulated health care professionals with required competencies independently check the blood component or blood product and verify the patient identification on the product to the patient prior to blood administration. All identifying information linking the patient to the blood component or blood product must be matched.
<b>Pre-transfusion Testing</b>	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.
<b>Privileges</b>	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.
<b>Provincial Legislation</b>	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.

<b>Term</b>	<b>Definition</b>
<b>Qualified Person</b>	<p>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.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>- 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</li> <li>- 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.</li> </ul>
<b>Qualified Transfusionist</b>	Regulated health professionals authorized to initiate transfusion of a blood components and/or blood products within their respective scope of practice under applicable provincial legislation, regulations, and/or bylaws, and who have successfully completed outlined training that includes transfusion administration, recognition, and management of adverse transfusion reactions.
<b>Quality Assurance</b>	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.
<b>Quality System</b>	Organizational structure, responsibilities, policies, processes, procedures, and resources for implementing quality management.
<b>Recall</b>	The removal from further distribution, or use, of a product (blood component) that violates legislation administered by Health Canada (a regulatory requirement).
<b>Record</b>	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.
<b>Reference Thermometer</b>	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.

<b>Term</b>	<b>Definition</b>
<b>Regulated Activity</b>	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.
<b>Regulated Health Care Professional</b>	A health professional who is a member of a regulated health profession and is licensed or registered to provide health care under provincial legislation specific to his or her profession.
<b>Safety</b>	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.
<b>Saskatchewan Transfusion Service Identification Number System (SK TSIN System)</b>	A blood recipient identification system endorsed within Saskatchewan, designed to establish unequivocal identification of the transfusion recipient through to transfusion administration with the combined use of a transfusion specific identification number and band.
<b>Satellite Blood Refrigerator</b>	A temperature controlled blood refrigerator located outside the lab but still maintained by the transfusion medicine laboratory (TML).
<b>Serious Adverse Event</b>	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.
<b>Special Transfusion Requirements</b>	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.
<b>Traceback</b>	The process of investigating a report of a suspected transfusion-associated infection in order to identify a potential implicated donor.
<b>Transfusion</b>	All activities related to the processes of administration of blood components and blood products, regardless of route of administration.

<b>Term</b>	<b>Definition</b>
<b>Transfusion-associated circulatory overload (TACO)</b>	An adverse transfusion reaction characterized by acute or worsening respiratory compromise and/or evidence of pulmonary edema during or up to 12 hours after transfusion.
<b>Transfusion-related acute lung injury (TRALI)</b>	Development of new, acute hypoxemia with a chest x-ray showing bilateral infiltrates in the absence of circulatory overload, occurring during or within six hours from the time the blood transfusion is discontinued or completed.
<b>Transfusion Facility</b>	A facility or entity of individual(s) responsible for the administration of blood components and/or blood products to the patient.
<b>Transfusion Label/Tag</b>	A laboratory generated label or tag attached to the blood component/blood product that contains key identifiers and links the intended patient to the blood component or blood product.
<b>Transfusion Medicine Laboratory (TML)</b>	An entity that performs pre-transfusion serological testing or is involved in the provision of blood components or blood products and their transfusion or administration.
<b>Transfusion Medicine Physician (TMP)</b>	A licensed physician, qualified by Transfusion Medicine training and/or experience, with assigned responsibility within the Saskatchewan Health Authority (SHA) to provide advice and direction regarding policies, processes and procedures related to the care and safety of transfusion recipients in Saskatchewan.
<b>Transfusion Order</b>	The paper or electronic documentation required by the transfusion medicine laboratory providing the details of the request or prescriber's order for blood components or blood products.
<b>Transfusion Service Identification Number (TSIN)</b>	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.
<b>Transfusion Transmissible Infection (TTI)</b>	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.
<b>Transporter (also known as a blood porter)</b>	A health care worker qualified by training and competency assessments to pick up and transport blood components and/or blood products internally within a facility. Transporters may include regulated health care professionals or unregulated health care workers such as porters, nursing students, health care aides and unit clerks.

<b>Term</b>	<b>Definition</b>
<b>Two-person Check</b>	A cooperative process whereby two (2) health care professionals or a health care professional and health care provider verify patient/product/documentation identification details <u>during collection</u> of pre-transfusion samples and <u>blood component or product issue/sign out</u> from the blood storage location. The first person leads and verbalizes all of the necessary elements and the second person verbally confirms after each element is checked, utilizing at least two (2) unique person-specific identifiers.
<b>Unexpected Adverse Reaction</b>	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.
<b>Unique Identification Number</b>	Any number used to uniquely identify a patient within a health registry or a health records system. The Health Service Number (HSN) is the preferred unique patient identification number in Saskatchewan. Other acceptable forms of unique identifiers include a Medical Record Number (MRN) or a government-issued ID number (e.g. valid driver's license, passport, Canadian military identification card, government-issued identification card, etc.).
<b>Unusual Recall</b>	A recall due to an unanticipated event impacting a large or small number of blood components.
<b>Validation</b>	Documented process to demonstrate that any process, procedure or equipment will consistently provide the expected results.
<b>Withdrawal</b>	The voluntary removal by the manufacturer (blood supplier) of a product (blood component) that does not violate legislation administered by Health Canada.
<b>Wrong-blood-in-tube (WBIT)</b>	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.