Blood Regulations Tool

PROMOTING EXCELLENCE IN TRANSFUSION MEDICINE

Nova Scotia Provincial Blood Coordinating Program

Self-Assessment Tool
To Support Compliance

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Version 2.0

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NOVA SCOTIA

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1. Introduction

The Nova Scotia Provincial Blood Coordinating Program (NSPBCP) is a provincial program of the Acute and Tertiary Care branch of the Nova Scotia Department of Health and Wellness. The NSPBCP was created in January 2003 and provides leadership in promoting excellence in transfusion medicine. The NSPBCP collaborates with health care providers in the DHAs/IWK and Canadian Blood Services (CBS) in order to support the appropriate management and safe administration of blood and blood products to patients in Nova Scotia.

Health Canada published new Blood Regulations on October 23, 2013 which provide Health Canada's final response to the Krever Commission recommendations. These Regulations regulate the processing, labeling, storage, distribution, and importation of blood and its components intended for transfusion. The Regulations apply to all establishments that handle blood; the level of oversight corresponds to the level of risk of the activity being performed by each establishment. The Regulations will come into force on October 23, 2014.

The NSPBCP developed the *Blood Regulations Self-Assessment Tool* in 2014 to aid hospital Blood Transfusion Services in achieving compliance with the new Health Canada Blood Regulations by the coming-into-force date. The tool highlights the sections of the Blood Regulations that are relevant to Nova Scotia establishments and, where applicable, cross references these sections to related clauses in the CSA-Z902 Blood and Blood Components Standards.

This tool is intended for use by all those who work in Blood Transfusion Services in Nova Scotia, as well as clinical staff who label, store, distribute, or transfuse blood. It is intended to supplement the Blood Regulations and the Guidance Document introduced by Health Canada. Revisions to the tool will be made on an "as-needed" basis, in response to feedback/requests from users and interested parties.

The Regulations are only applicable to blood components; blood products are not in the scope of the Blood Regulations

2. Labeling

Applicable Blood Regulations pertaining to labeling include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
60-68	1. Does your facility affix labels at any time to blood components (i.e. after transformation, or changing expiry date prior to issuing)?		Yes ☐ No ☐ If no proceed to next section
	2. Do you have a mechanism to control the label and ensure all labels are consistent?		Yes ☐ No ☐
	Indicate the SOP # which clearly identifies the steps to take when labeling a blood component.	8.6.1.2	SOP # _____
	I. Does your SOP clearly state that a label must include: donation code, name of component, aliquot code if applicable, ABO, Rh and expiry date and must be presented clearly and legibly?	8.6.1.7 8.6.1.8	Yes ☐ No ☐
	II. Does your SOP indicate verification is needed to confirm the correct ABO/Rh, expiration date and blood component name if re-labeling a product or preparing aliquots?	8.6.1.2	Yes ☐ No ☐
	III. Does your SOP clearly indicate that the label must be permanently affixed to the container?	8.6.12	Yes ☐ No ☐
	IV. Does your SOP clearly define steps to take if changes need to be made on the primary label?	8.6.1.2	Yes ☐ No ☐
	V. Does your SOP contain instructions on what type of ink should be used to ensure it will not leach through the label if making changes to the primary label?	8.6.1.2	Yes ☐ No ☐
	VI. Does your SOP contain information on what to do if a blood component or blood component label comes in contact with a pen or other marking device?		Yes ☐ No ☐
	VII. Does your SOP state only adhesives that will NOT permeate the container must be used?		Yes ☐ No ☐

60-68	3. Does your facility attach supplemental tags to blood/blood components prior to distribution (cross match tag, thawed plasma tag, supernatant reduced platelet, etc)? **Indicate the SOP # which clearly identifies the steps to take when attaching a supplemental tag.**		Yes ☐ No ☐ If no proceed to next section SOP # _____
	I. Does your SOP clearly state when a supplemental tag must be used?	8.6.1.8	Yes ☐ No ☐
	II. Does your SOP clearly state that supplemental tags must be firmly attached?		Yes ☐ No ☐
	III. Does your SOP clearly indicate that supplemental tags must contain product name, expiration date and other information based on what the supplemental tag is for? (i.e. patients ABO/Rh if a crossmatch tag)	8.1.1 (c) 8.6.1.8	Yes ☐ No ☐
	IV. Does you SOP have a verification step to ensure that all information contained on a supplemental tag is accurate and complete?		Yes ☐ No ☐

3. Storage and Storage Equipment

Applicable Blood Regulations pertaining to storage include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
69-72	1. Does your facility store blood components on site?		Yes ☐ No ☐ If no proceed to next section
	Indicate the SOP # which clearly identifies the requirements needed for the storage of blood components.		SOP # _____
	I. Does your SOP clearly state that blood components must be stored in accordance with the directions on its label and with any other directions that are specified in writing by the establishment that collected it (CBS)?	9.4.1	Yes ☐ No ☐
	II. Does your SOP indicate storage condition requirements for all blood components held at your facility? See Table 1 for requirements.	9.4.1	Yes ☐ No ☐
	III. Does your storage location(s) have temperature monitoring probes or devices in place to ensure temperatures of the components?	9.4.3	Yes ☐ No ☐
	IV. Are your temperature monitoring probes or devices located at points that represent extreme temperature areas, as determined by a temperature mapping study?	9.4.3	Yes ☐ No ☐
	V. Is your storage location(s) clearly labeled with the status of the blood? This must include:	9.4.2	Yes ☐ No ☐
	a. Untested or incompletely tested autologous units		Yes ☐ No ☐
	b. Non-conforming/repeat reactive or positive autologous units of blood and		Yes ☐ No ☐
	c. Tested autologous units of blood suitable for transfusion.		Yes ☐ No ☐
	VI. Is your storage location(s) secure against the entry of unauthorized persons?		Yes ☐ No ☐

69-72	VII.	Does your SOP clearly identify who would be considered designated personnel and would have access to areas where blood components are stored?	9.4.3	Yes ☐ No ☐
	VIII.	Does your storage location(s) have a means by which the environmental conditions are controlled and monitored using calibrated monitoring devices?	9.4.5	Yes ☐ No ☐
	IX.	Does your storage area(s) have an audible alarm which signals in a location that is continuously monitored or staffed so that corrective action can be taken immediately?	9.4.5	Yes ☐ No ☐
	X.	Does your SOP state that your storage area(s) must be continuously monitored and recorded using an automated continuous monitoring system or monitored every 4 hours manually?	9.4.3	Yes ☐ No ☐
	XI.	Does your SOP explain the process in place to ensure the above?	9.4.4	Yes ☐ No ☐
	XII.	Are parameters such as lighting, humidity and ventilation controlled in your storage location(s) to the extent necessary to safeguard blood?	9.4.5 9.4.8	Yes ☐ No ☐
	XIII.	Does your SOP indicate that temperature documentation must be kept as evidence that units of blood were maintained under the appropriate environmental conditions at all times?	9.4.7	Yes ☐ No ☐
	XIV.	Does your SOP describe procedures for corrective action to be taken in the event of a deviation from established storage criteria?	9.4.7	Yes ☐ No ☐
	XV.	Do you have a designated storage area for quarantining blood components if need be?	9.4.7	Yes ☐ No ☐
	XVI.	Does your SOP clearly indicate that quarantined components must be marked appropriately and have a designated storage area?	9.4.7	Yes ☐ No ☐
	XVII.	Do you have a designated storage area for autologous, designated or directed use?		Yes ☐ No ☐
	XVIII.	Does your SOP clearly indicate that blood intended for autologous, designated or directed use must be clearly labeled and segregated from blood that is intended for other allogeneic use?		Yes ☐ No ☐
	XIX.	Do you have a designated storage area for blood components which are: a. untested b. testing is incomplete or all results are not yet available and	9.4.7 9.4.8	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐

	c. positive or repeat reactive for transmissible disease agents or markers?		Yes ☐ No ☐
69-72	XX. Does your SOP clearly indicate where blood components are stored which are:		
	a. untested		Yes ☐ No ☐
	b. testing incomplete or all results are not yet available and		Yes ☐ No ☐
	c. positive or repeat reactive for transmissible disease agents or markers		Yes ☐ No ☐

4. Distribution

Applicable Blood Regulations pertaining to distribution include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
	1. Does your facility distribute blood? Distribution is the action of releasing product outside of the control of the transfusion service.		Yes ☐ No ☐ If no proceed to next section
	Indicate the SOP # which clearly identifies the requirements needed for the distribution of blood components.		SOP # _____
	I. Does your SOP clearly state that before distribution the units must be examined and verified for the following:	9.5.2.5	
	a. information on the label is legible;		Yes ☐ No ☐
	b. integrity of the container is intact;		Yes ☐ No ☐
	c. there are no signs of deterioration or contamination of the blood;		Yes ☐ No ☐
	d. frozen blood components show no signs of thawing.		Yes ☐ No ☐
74-76	II. Does your SOP clearly state not to distribute if:	9.5.2.5	
	a. the donation code is missing or illegible;		Yes ☐ No ☐
	b. any information-other than the donation code-that is required by the Blood Regulations (see labeling section above for requirements) to appear on the label of blood is missing or is illegible, unless missing or illegible information can be retrieved from the establishments records		Yes ☐ No ☐
	c. the container is defective or damaged to the extent that it does not protect the blood against external conditions		Yes ☐ No ☐
	d. there are signs of deterioration (hemolysis and discoloration) or contamination (clots, fibrin strands, cellular aggregates,		Yes ☐ No ☐

	particulate matter and discoloration) of the blood		
	III. Does your SOP clearly indicate if any defect, improper labeling or abnormal appearance is observed, the component should be quarantined immediately and discarded?	9.5.2.5 10.10.5	Yes ☐ No ☐
	IV. Does your SOP clearly indicate that returned units of allogeneic blood should be quarantined until the blood is deemed suitable for transfusion?	10.10.5 20.5.2	Yes ☐ No ☐
	V. Does your SOP clearly state that blood components which have been returned to the blood transfusion service shall not be re-released unless:	10.10.5	
	a. there is at least one remaining sealed segment of donor tubing attached to the blood bag		Yes ☐ No ☐
	b. there is documentation with the blood component to indicate that it is being re-released and to confirm that it has been visually inspected before release		Yes ☐ No ☐
74-76	c. a suitable temperature monitoring system indicates that the blood component has not reached an unacceptable temperature since being released or, in the absence of a temperature monitoring system, the blood component has not been outside of a controlled environment for more than 30 minutes		Yes ☐ No ☐
	d. the blood bag closure is undisturbed		Yes ☐ No ☐
	VI. Does your SOP clearly state that you must examine the blood container before shipping to verify the integrity of the container and the legibility of the labels? As well the container must be capable of resisting damage and maintaining the safety of the blood	9.5.2.5	Yes ☐ No ☐
	VII. Does your SOP clearly indicate that a tamper proof seal must be applied to the container to ensure no tampering can occur that could affect the safety of the blood during transport?		Yes ☐ No ☐
	VIII. Does your SOP clearly indicate storage requirements for blood components during storage? See table 2 for requirements	9.5.2.2 9.5.2.3	Yes ☐ No ☐

74-76	IX.	Does your SOP take into account the above requirements and have validated packing schemes to adhere to the requirements?	9.5.2.4	Yes ☐ No ☐
	X.	Does your SOP clearly indicate:	9.5.2.6	
		a. the origin of the shipment (issuing facility)		Yes ☐ No ☐
		b. the destination for the shipment (receiving facility) and		Yes ☐ No ☐
		c. a notice that it contains human blood components must be clearly labeled on the container?		Yes ☐ No ☐
	XI.	Does your SOP indicate a release voucher with the following information:	9.5.2.7	
		a. the name of the site receiving blood components		Yes ☐ No ☐
		b. the unique serial number of the voucher		Yes ☐ No ☐
		c. a description of the type of blood and blood components being shipped, including notice if quarantined products have been included		Yes ☐ No ☐
		d. the donation numbers of the blood components		Yes ☐ No ☐
		e. the total number of items		Yes ☐ No ☐
		f. the date and time of shipping and		Yes ☐ No ☐
		g. the signature(s) of the designated person(s) responsible for the packing		Yes ☐ No ☐

5. Transformation

Applicable Blood Regulations pertaining to transformation include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
	1. Does your facility transform blood? (Pool Cryoprecipitate) **Indicate the SOP # which clearly identifies the requirements needed for the transformation of blood components.**		Yes ☐ No ☐ If no proceed to next section SOP # _____
	I. Does your SOP clearly indicate that cryoprecipitate should be visually inspected to determine the units are acceptable for transfusion prior to use?		Yes ☐ No ☐
	II. Does your SOP clearly state that pooling must occur in an environment that is specifically set up for this purpose?		Yes ☐ No ☐
77-79	III. Does your SOP indicate that pooling cryoprecipitate using an open system will change the expiry to whichever comes first; 4 hours from start of pooling process or the expiration date of the oldest unit and storage must occur between 20^0C and 24^0C?	10.8.3	Yes ☐ No ☐
	IV. Does your SOP indicate that only units of the same ABO blood group shall be pooled?	10.8.1	Yes ☐ No ☐
	V. Does your SOP for pooling cryoprecipitate include what the label for the pooled component shall include:	10.8.2	
	a. the name of the blood component?		Yes ☐ No ☐
	b. the number of units contained in the component?		Yes ☐ No ☐
	c. the name of the facility preparing the component?		Yes ☐ No ☐
	d. the unique numeric or alphanumeric identification of the component?		Yes ☐ No ☐
	e. the approximate volume of the blood component?		Yes ☐ No ☐

77-79	f. the ABO/Rh groups of the blood components in the pool, or the final ABO and Rh group of the pooled component?		Yes ☐ No ☐

6. Exceptional Distribution

Applicable Blood Regulations pertaining to exceptional distribution include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
81-85	1. An establishment may distribute or transfuse allogeneic blood for transfusion for which the test results for ABO group, Rh factor and transmissible diseases or disease agents are not yet available if both of the below conditions are met: a. blood that has been determined safe for distribution is not immediately available; and b. the recipient's physician requests the blood for use in the emergency treatment of their patient	8.4.7 9.3 10.9.3.5	
	Indicate the SOP # which clearly identifies your process for exceptional distribution.		SOP # _____
	I. Does your SOP clearly indicate that the above two conditions need to be met before issuing?		Yes ☐ No ☐
	II. Does your SOP clearly state that a notice of exceptional distribution must be received when receiving the blood from CBS and contain the following:	8.4.7	Yes ☐ No ☐
	a. the name of the establishment and the signature of the medical director		Yes ☐ No ☐
	b. the donation code		Yes ☐ No ☐
	c. a statement of whether the blood was whole blood or a blood component, and if it was a component, its name		Yes ☐ No ☐
	d. a list of the results that were not available at the time of the distribution		Yes ☐ No ☐
	e. the name and signature of the recipients physician		Yes ☐ No ☐
	f. the justification for the distribution		Yes ☐ No ☐

	g. the name of the establishment to which it is distributed; and		Yes ☐ No ☐
	h. the date and time of the distribution		Yes ☐ No ☐
	III. Does your SOP indicate that the notice of exceptional distribution must be kept in the recipients file?		Yes ☐ No ☐
81-85	IV. Does your SOP indicate that subsequent test results must be forwarded to your facility from CBS which are then forwarded to the patients file?	8.4.7	Yes ☐ No ☐
	V. Does your SOP clearly indicate that if the blood is not used it is to be quarantined until all testing is complete or discarded?		Yes ☐ No ☐

7. Operating Procedures

Applicable Blood Regulations pertaining to operating procedures include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
95-97	1. Does your facility have operating procedures for ALL activities the establishment conducts with respect to human safety and the safety of blood?		Yes ☐ No ☐
	2. Do your operating procedures meet the following requirements:		
	I. Are they in a standardized format which should include:	4.2.2.3	
	a. the title and purpose of the procedure		Yes ☐ No ☐
	b. the unique number or code identifying the document and indicating the version		Yes ☐ No ☐
	c. the date of implementation and last revision date		Yes ☐ No ☐
	d. the signature of the authorizing person and the date of authorization		Yes ☐ No ☐
	e. appropriate page numbers		Yes ☐ No ☐
	f. clear instructions to be followed that correspond to the tasks required to perform the activity		Yes ☐ No ☐
	g. the responsible department for performing the operating procedure		Yes ☐ No ☐
	h. references to publications cited, if applicable		Yes ☐ No ☐
	II. Are they approved by a senior executive officer?	4.2.1.2	Yes ☐ No ☐
	III. Are they readily accessible at all locations where the relevant activities are conducted?	4.2.2.4	Yes ☐ No ☐
	IV. Are they up-to-date (reviewed at a minimum every 2 years)?	4.2.2.4	Yes ☐ No ☐
	V. Are previous versions of the SOPs removed and archived to ensure they are not in use?	4.2.3.4	Yes ☐ No ☐
	VI. Do you have an SOP which clearly	4.2.1.5	Yes ☐ No ☐

95-97		indicates the procedure for deviating from a current operating procedure if permitted by a senior executive officer or designate in an urgent situation?	4.2.1.6	
	VII.	Do you have documented evidence that demonstrates your operating procedures for processing and transforming blood consistently lead to expected results? (validation)		Yes ☐ No ☐

8. Personnel

Applicable Blood Regulations pertaining to personnel include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
98-101	1. Does your facility have sufficient personnel, who are qualified by their education, training or experience to perform their respective tasks, to conduct the establishment's activities? (The number of personnel shall be based on size and complexity of the facility and number of units of blood components it normally handles)	4.3.1.4 4.3.1.5	Yes ☐ No ☐
	2. Does your facility have an SOP which describes your organizational structure, staffing requirement and qualifications of all personnel?	4.3.1.1	Yes ☐ No ☐ SOP # _____
	I. Does your SOP include clearly defined lines of authority and specify individual responsibilities and qualifications required?	4.3.1.6	Yes ☐ No ☐
	II. Does your SOP clearly indicate that records of the qualifications, training and continuing competency of all personnel must be maintained?	4.3.2.1	Yes ☐ No ☐
	III. Does your SOP state that training must be documented and include:	4.3.2.1	Yes ☐ No ☐
	a. the date on which training was conducted		Yes ☐ No ☐
	b. signature of employee		Yes ☐ No ☐
	3. Does your facility have a program for the orientation and training, both initial and ongoing for the evaluation of staff competencies?	4.3.2.1	Yes ☐ No ☐
	4. Does your facility have a formal competency/evaluation program to assess the effectiveness of the training provided?	4.3.2.3	Yes ☐ No ☐
	I. Does the program include the assessment of the effectiveness of continuous training and on-going competency evaluation		Yes ☐ No ☐

98-101	program for all personnel conducting activities? This may include: a. direct observation of performance b. monitoring of recording and reporting c. written tests d. assessment of knowledge of operating procedures and theory e. assessment of performance through proficiency tests.		Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐

9. Error and Accident Investigation and Reporting

Applicable Blood Regulations pertaining to Errors/Accidents include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
103-108	The *Blood* Regulations define **accident** as an unexpected event that is not attributable to a deviation from the operating procedures or applicable laws and that could compromise human safety or the safety of blood. An **error** is defined as a deviation from the operating procedures or applicable laws that could compromise human safety or the safety of the blood.	4.6.2.1 to 4.6.2.5	
	1. Indicate the SOP # which clearly indicates the steps to take when an accident or error occurs.		SOP # _____
	I. Does your SOP indicate how important it is to communicate between establishments when an accident or error occurs to ensure **all** establishments which may be affected are aware?		Yes ☐ No ☐
	* All establishments which were sent potentially affected unit(s) must be contacted. If these establishments further redistributed, they are responsible for contacting the establishment(s) which they sent the unit(s) to. The discovering establishment must also notify the establishment from which the unit(s) was received. This chain of communication must repeat until all establishments receiving potentially affected unit(s) have been notified. *		Yes ☐ No ☐ Yes ☐ No ☐
	II. Does your SOP state that you MUST, on request provide any establishment that is conducting an investigation in regards to a transfusion reaction or an error/accident which a. Occurred during a regulated activity; b. Was identified after the blood was distributed or transfused; and c. Have reasonable probability that it could lead to a serious adverse reaction with any relevant information in your possession in a timely matter?		Yes ☐ No ☐ Yes ☐ No ☐
	III. Does your SOP indicate that all verbal communications must be documented and written notices must be sent as soon as possible?		Yes ☐ No ☐

103-108	IV. Does your SOP indicate that all affected products must be quarantined until a decision is made which deems the units to be safe for transfusion or that units should be discarded?		Yes ☐ No ☐
	V. Does your SOP indicate where distribution records can be found to ensure if distributed from one establishment to another, affected units can be easily located and notification sent?		Yes ☐ No ☐
	VI. Does your SOP clearly state the following actions must immediately be taken if a facility has reasonable grounds to believe that the safety of the blood may have been compromised by an error or accident during an activity **conducted by another facility:** a. determine donation codes of the implicated units. b. identify and quarantine any implicated blood in its possession c. Notify: i. the establishment that collected the implicated units ii. the establishment from which it received the implicated units, if different from (i). iii. any establishment to which it distributed implicated units. d. The notice must include: i. donation codes of implicated blood ii. name of implicated units iii. reason for the establishments' belief that the safety of the blood may have been compromised.		Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
	VII. Does your SOP clearly state the following actions must immediately be taken if a facility has reasonable grounds to believe that the safety of the blood may have been compromised by an error or accident during an activity **it conducted or receives notice that another facility has reason to believe an error or accident occurred at your facility**: a. Determine donation codes of the implicated units. b. Identify and quarantine any implicated blood in its possession c. Determine whether there is sufficient evidence to warrant proceeding to an investigation in the suspected error or accident i. if facility determines an investigation is not warranted it		Yes ☐ No ☐ Yes ☐ No ☐

103-108	must notify facilities that it will not be conducting an investigation and provide reasons for decision. ii. if facility determines that an investigation is warranted, it must begin the investigation, notify every establishment and other person to whom it distributed implicated units and include donation codes and a description of the suspected error or accident as well as an explanation of how the safety of the implicated unit may have been compromised and to quarantine these units. VIII. Does your SOP clearly indicate that all implicated establishments must be notified of the results of investigation if warranted as well as disposition of units? IX. Does your SOP clearly state that if you receive a notification for a unit of blood which was sent to you establishment and you in turn distributed this unit to another establishment, it is your responsibility to follow up with the facility you distributed to? X. Does you SOP state that all establishments are required to keep record of investigations and reports of all errors and accidents whether they are serious or not. These must include corrective and/or preventive actions taken. XI. Does your SOP clearly state the establishment conducting the investigation into a suspected error or accident that is a. thought to have occurred during an activity that was conducted by them **and** b. that is identified after the blood is distributed or transfused **and** c. there is a reasonable probability that the error or accident could lead to a serious adverse reaction **must file reports with Health Canada's Inspectorate Regional Program. Atlantic Region Inspectorate Program 1625-1505 Barrington Street. Halifax NS B3J 3Y6** (this may initially be verbal but must be followed up with a written report) **Tel: (902) 426-5350 Fax: (902) 426-6676** XII. Does your SOP state that the above reports must include: a. A preliminary report that includes all		Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐

		relevant information that is available, within 24 hours of the start of the investigation		Yes ☐ No ☐
		b. A written update on any new information about the suspected error or accident, on the progress made in the investigation since the last report and on steps taken to mitigate further risks: i. within 15 days after the start of the investigation, and ii. on request of the Minister at any time after the preliminary report.		Yes ☐ No ☐ Yes ☐ No ☐
		c. On completion of an investigation, the establishment must file a final report with the minister that contain all of the following: i. the results of the investigation ii. the final disposition of the units that was the subject of the investigation and the reasons for the disposition iii. any corrective actions taken and other changes that are recommended to be made to relevant processes		
	XIII.	Does your SOP state that an annual report must be prepared which summarizes all of the final reports that you filed in the year (includes all error/accidents not just those which were reportable to Health Canada), including a concise critical analysis of the investigations that were subject to those reports.		
	XIV.	Do you have a mechanism in place which would allow you to pull the above report at anytime if requested?		

10. Adverse Reaction Investigation and Reporting

Applicable Blood Regulations pertaining to Adverse Reactions include:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
109-116	**Indicate SOP #(s) which contains all information on Adverse reaction investigation and reporting**		SOP # _____
	1. Does your SOP clearly state all actions which must be promptly taken if you have reasonable grounds to believe that a recipient has experienced an unexpected adverse reaction or a serious adverse reaction? These must include	18 to 19 inclusive	Yes ☐ No ☐
	i. Determine the donation codes of all implicated blood		Yes ☐ No ☐
	ii. Identify and quarantine any implicated blood in your possession		Yes ☐ No ☐
	iii. If preliminary inquiry indicates that the root cause of the adverse reaction is attributable to an activity that is carried out, conduct an investigation into the adverse reaction and notify any establishment to which it distributed implicated blood; and		Yes ☐ No ☐
	iv. If preliminary inquiry indicates that the root cause of the adverse reaction is attributable to an activity carried out by another establishment, notify all of the following establishments:		
	a. the establishment that collected the implicated blood		Yes ☐ No ☐
	b. the establishment from which it received the implicated blood, if different from above, and		Yes ☐ No ☐
	c. any establishment to which it distributed implicated blood		Yes ☐ No ☐
	v. When notifying the above does your SOP indicate that the notification must contain all of the following information:		
	a. a description of the adverse reaction		Yes ☐ No ☐
	b. an explanation of how the safety of the implicated blood may have been compromised, if known		Yes ☐ No ☐
	c. the donation codes of all implicated blood		Yes ☐ No ☐
	d. the names of the implicated blood components, and		Yes ☐ No ☐

109-116	e. the name of any suspected transmissible disease or disease agent, if known.		Yes ☐ No ☐
	vi. Does your SOP clearly state that if you receive a notification for a unit of blood which was sent to you establishment and you in turn distributed this unit to another establishment, it is your responsibility to follow up with the facility you distributed to?		Yes ☐ No ☐
	vii. Does your SOP state that when reporting an adverse reaction it must contain all information as (e) as well as:		Yes ☐ No ☐
	a. recipients date of birth and sex		Yes ☐ No ☐
	b. hospital identification		Yes ☐ No ☐
	c. diagnosis, medical history		Yes ☐ No ☐
	d. blood group, antibody screen		Yes ☐ No ☐
	e. date, time, and place of transfusion		Yes ☐ No ☐
	f. component transfused, donation code(s), blood group, collection date/pooling date, infusion start/stop time		Yes ☐ No ☐
	g. description of reaction, investigation, vital signs, treatment, culture of the recipients blood and of the component transfused		Yes ☐ No ☐
	h. assessment by transfusing establishment physician		Yes ☐ No ☐
	i. establishment physician		Yes ☐ No ☐
	j. outcome, and		Yes ☐ No ☐
	k. further information		Yes ☐ No ☐
	viii. Does your SOP state that if conducting an investigation CBS must be notified with 24 hours of learning of a death or within 15 days after it learns of any other adverse reaction?		Yes ☐ No ☐
	ix. Does your SOP state that all serious or unexpected reactions due to a. The product quality, or b. A Canadian Blood Services (CBS) activity, or c. An Error or accident of a regulated activity performed at the hospital site Must be reported **the Canada Vigilance Program of the Marketed Health products Directorate** (this may initially be verbal but must be followed up with a written report) **Tel: (613) 957-0337 or Fax: (613) 957-0335**		

11. Records

Applicable Blood Regulations pertaining to Records:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
117-118	1. Do you have an SOP for records and record retention which makes it possible to trace blood and blood components from their source to final disposition?	20.1.1-20.7.2	SOP # _____
	I. Does your SOP indicate that records must be accurate, complete, legible, indelible and readily retrievable?		Yes ☐ No ☐
	II. Is the donation code a component of all the records related to distribution, transformation and transfusion of blood?		Yes ☐ No ☐
	III. Does your SOP state that records must be stored in a location that has appropriate environment conditions (a temperature appropriate to safeguard the integrity of the records as well as humidity) and is secure against the entry of unauthorized persons.		Yes ☐ No ☐
	IV. Does your SOP include the necessary Record Retention Periods? (see table 3)		Yes ☐ No ☐

In addition to the previous sections, Blood Transfusion Services undergoing Registration need to confirm the following:

12. Registration

Applicable Blood Regulations pertaining to Registration:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
30-37	**An establishment that process autologous blood, which transforms blood or that, has a pre-assessed donor program must be registered under the Health Canada Blood Regulations.** In order to do so: An establishment must file with the Minister an application for registration in the form established by the Minister. The form can be found at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index-eng.php The form must contain all of the following: I. The applicants name and civic address, and its postal address if different II. In the case of an establishment that previously conducted its activities under these regulations under another name, that other name III. The name and telephone number, fax number, email address or other means of communication of a person to contact for further information concerning the application IV. The name and telephone number of a person to contact in an emergency, if different from the person above V. A list of the processing activities that establishment proposes to conduct in respect of autologous blood and a list of the whole blood and blood components that it proposes to process VI. A list of transformation activities that the establishment proposes to conduct and list of all the whole blood and blood components that it proposes to transform VII. A statement of whether the establishment has a pre-assess donor program VIII. The civic address of every building in which it proposes to conduct its activities and a list of the activities that are proposed to be conducted in each		

	building IX. The name and civic address of any other establishment that it proposes to have conduct any of its activities X. A statement, dated and signed by a senior executive officer, that certifies both of the following: a. The establishment has sufficient evidence to demonstrate that it is in compliance with these regulations, and b. That all of the information in the application is accurate and complete		
	Did you file with the Minister?		Yes ☐ No ☐
30-37	You must provide the Minister, on written request, any information that the Minister determines is necessary to complete the Minister's review of the application, by the date specified in the request. On completion of reviewing the application for registration, if the Minister determines that the information provided in the application is complete, the Minister must register the establishment and issue a registration number. The Minister may refuse to register an establishment if he/she determines that the information provided by the establishment in its application is incomplete or if he or she has reasonable grounds to believe that issuance of the registration could compromise human safety or the safety of blood. You must notify the minister in writing of any change to the information provided in your application within 30 days after the day on which the change is made The Minister may amend an establishment's registration to remove it from any activity if she/he has reasonable grounds to believe that it is necessary to do so to prevent a compromise to human safety or the safety of blood. You must provide the Minister with a statement dated and signed by a senior executive officer that certifies the establishment has sufficient evidence to demonstrate that it is in compliance with these Regulations by April 1 each year.		
30-37	The Minister may cancel a registration in any of the following circumstances: I. The minister receives notice that the establishment has ceased all of its activities that are the subject of registration II. The information provided by the establishment proves to be false or misleading III. The establishment has not complied with a request for		

	additional information IV. The establishment fails to take corrective action within the required period V. The minster has reasonable grounds to believe that the establishment is not in compliance with these Regulations or that human safety of blood could be compromised		

13. Transformation

Applicable Blood Regulations pertaining to Transformation:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
77-79	1. Do you have an SOP for the transformation of blood?		SOP # _____ Yes ☐ No ☐
	I. Does your SOP clearly state that you must transform blood using safe and effective methods?		Yes ☐ No ☐
	II. Do you have an environment that is specifically set up for the pooling process?		Yes ☐ No ☐
	III. Is it clearly indicated in your SOP where transformation should be performed?	7.11.1	Yes ☐ No ☐
	IV. Does your SOP clearly state that only units of the same ABO blood group shall be pooled?	10.8.2	
	V. Does your SOP state that the label for a pooled component must include:		Yes ☐ No ☐
	a. the name of the components		Yes ☐ No ☐
	b. the number of units contained in the component		Yes ☐ No ☐
	c. the name of the facility preparing the blood component		Yes ☐ No ☐
	d. the unique numeric or alphanumeric identification of the blood component		Yes ☐ No ☐
	e. the approximate volume		Yes ☐ No ☐
	f. the ABO and Rh groups of blood components in the pool, or the final ABO and Rh group of the pooled component		
	VI. Does your SOP state that the expiration date cannot exceed the expiration date of the oldest component in the pool	10.8.3	Yes ☐ No ☐

14. Quality Management System

Applicable Blood Regulations pertaining to Quality Management Systems:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
93-94	1. Do you have an organizational structure that sets out the responsibility of management for all activities that the establishment conducts?	4.6.1.5	Yes ☐ No ☐ SOP # _____
	2. Do you have an effective quality management system?	4.6.1.4	Yes ☐ No ☐
	What is the name of the individual who has responsibility for it?	4.6.1.1	_____
	Does your Quality Management system encompass the following:	4.6.1	Yes ☐ No ☐
	I. Defined, documented, implemented and maintained		Yes ☐ No ☐
	II. Include elements that enable the prevention, detection and correction of deficiencies that may compromise the safety of blood		Yes ☐ No ☐
	III. An organizational structure that defines and documents the personnel responsible for all activities under these regulations		Yes ☐ No ☐
	IV. Ensure that written policies, processes and procedures that cover the regulated activities are available and communicated to all relevant personnel		Yes ☐ No ☐
	3. Do you review all elements of the quality management system at specified intervals to ensure its continuing suitability and effectiveness?	4.6.1.4	Yes ☐ No ☐
	4. Are the above results assessed and any deficiencies or areas requiring improvement addressed and corrected?		Yes ☐ No ☐
	5. Do you have a plan that includes goals, objectives and action plans developed and utilized? Your quality management system must		Yes ☐ No ☐

93-94	include the following: I. a quality assurance unit II. a quality control program III. a change control system IV. a process control program V. a system for process improvement through complaint monitoring and the implementation of corrective and preventive actions VI. a system for the identification and investigation of post-donation information, errors, accidents and adverse reactions, including the implementation of corrective action and the conduct of recalls VII. a program for the training and competency evaluation of personnel VIII. a proficiency testing program for the evaluation of the accuracy and reliability of test results IX. a document control and records management system X. an internal audit system XI. emergency contingency plans XII. a system that uniquely identifies all critical equipment and supplies XIII. Written specification for all critical equipment, supplies and services XIV. a program for the preventative maintenance of critical equipment XV. a program for process validation ** Each of the above is defined in the Guidance Document of the Blood Regulations pgs 130-137**		Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐

15. Personnel, Facilities, Equipment and Supplies

Applicable Blood Regulations pertaining to personnel, facilities, equipment and supplies:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
99-100, 102	1. Does your facility permit all of the following: I. The conduct of all your activities II. The performance by personnel of the respective tasks using proper hygiene III. The cleaning of the facilities in a way that maintains sanitary conditions IV. Environmental controls that are appropriate to all areas where its activities are conducted V. Controlled access to all areas where its activities are conducted	22.1.1	SOP # _____ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
	2. Do you have a procedure which ensures that the critical equipment you use is cleaned and maintained and validated for its intended purposes and calibrated?	23.1.1-23.5.2	Yes ☐ No ☐
	3. Do you have an SOP which states that whenever necessary after a repair or any critical change to equipment, it must be revalidates and recalibrated as appropriate?	23.4.2-23.5.2	Yes ☐ No ☐
	4. Does your SOP state that the critical supplies that it uses must be validated or qualified, as applicable, for their intended use and must store them under appropriate environmental conditions?		Yes ☐ No ☐

16. Records

Applicable Blood Regulations pertaining to Records:

Blood Regulation Section	Requirements	CSA Cross-Reference	Assessment
121	1. Does your SOP clearly state the retention periods for the transformation procedures? (see Table 4) The retention period begins on the day on which the record is created, except for the personnel records set out in item 10 of the table, in which case the period begins on the last day on which the employee was employed by the establishment.	20.3.2 20.4	SOP # _____ Yes ☐ No ☐

Table 1: Blood Component Storage Requirements

Component	Storage Requirement
Red Blood Cells	1^{O}C to 6^{0}C
Platelets (Apheresis and Pooled)	20^{0}C to 24^{0}C
Plasma (Frozen Plasma and Apheresis)	≤-18^{0}C
Cryoprecipitate	≤-18^{0}C
Cryosupernatant Plasma	≤-18^{0}C

Table 2: Blood Component Storage Requirements During Transport

Component	Storage Requirement
Red Blood Cells	1^{0}C to 6^{0}C or 1^{0}C to 10^{0}C if under 24 hours
Platelets (Apheresis and Pooled)	20^{0}C to 24^{0}C
Plasma (Frozen Plasma and Apheresis)	Keep Frozen
Cryoprecipitate	Keep Frozen
Cryosupernatant Plasma	Keep Frozen

Table 3: Records and Retention Periods – Transfusion

Records	Retention Period
Donation code – allogeneic blood	50 years
Donation code – autologous blood	10 years
Shipping documents	1 year
Blood storage temperature monitoring	5 years
Distribution	50 years
Exceptional distribution	50 years
Record of transfusion or disposition of allogeneic blood, including identification of recipient	50 years
Record of transfusion or disposition of autologous blood	10 years
Complaints and their investigation	5 years
Every version of the operating procedures that was implemented	10 years
Personnel qualifications, training and competency evaluation	10 years
Investigations and reports of errors and accidents	10 years
Investigations and reports of adverse reactions	10 years

Table 4: Records and Retention Periods – Transformation

Records	Retention Period
Donation Code	10 years
Records of pooling	10 years
Lot number and name of manufacture of critical supplies for each transformation	1 year
Complaints and their investigation	5 years
Internal Audit reports	5 years
Quality control testing	5 years
Maintenance, validation, qualification and calibration of critical equipment	3 years
Critical supplies, including their qualification	3 years
Every version of the operating procedure that was implemented	10 years
Personnel qualification, training and competency evaluation	10 years
Investigations and reports of errors and accidents	10 years
Investigations and reports of adverse reaction	10 years

References

Blood and Drug Act: Blood Regulations. (2013). *Canada Gazette Part II*, Vol. 147, No. 22. Retrieved from: http://www.gazette.gc.ca/gazette/home-accueil-eng.php

Health Canada Guidance Document: Blood Regulations. Health Canada 2014.

Canadian Standards Association. Blood and Blood Components Z902-10. Canadian Standards Association 2010.

Canadian Blood Services Circular of Information: Red Blood Cells, Leukocyte Reduced (LR). Canadian Blood Services 2013.

Canadian Blood Services Circular of Information: Pooled platelets LR CPD, apheresis platelets. Canadian Blood Services 2012.

Canadian Blood Services Circular of Information: Plasma components (FFPA, FP, CPD, Cryosupernatant CPD, Cryoprecipitate CPD). Canadian Blood Services 2012.