Blood Regulations self-assessment tool for non-registered hospital blood banks

Introduction

Health Canada is pleased to provide you with the "*Blood Regulations* self-assessment tool for non-registered hospital blood banks" to enable you to assess your establishment's compliance with the *Blood Regulations* (the *Regulations*). This tool was specifically developed for hospital blood banks that do not require registration with Health Canada but are still required to comply with some sections of the *Regulations*.

Before completing this self-assessment, it is important to ask yourself, does your blood bank:

- process autologous blood (e.g. collect)?
- have a pre-assessed donor program? or,
- perform blood transformation activities such as pooling (with the exception of pooling of cryoprecipitate), washing and irradiation of blood as per sections 77-78 of the *Regulations*?

If you answered "yes" to any of the above, you are performing an activity or activities that require registration with Health Canada. For any questions or to obtain a copy of the application form, contact roeb.blood-sang.dgoral@hc-sc.gc.ca. Furthermore, the Health Canada website has more information on the registration under the *Blood Regulations*: Blood Establishment Registration Application: Form and Instructions - (FRM-0353) - Canada.ca.

It is strongly recommended that as a blood bank you complete this self-assessment in order to identify deficiencies that you need to address in order to become compliant with the *Regulations*. This tool is intended for your own use and not to be submitted to Health Canada.

Please note that this tool does not supersede the requirements of the *Blood Regulations* or the *Food and Drugs Act*. In the event of any inconsistency or conflict between the *Regulations* and this tool, the *Regulations* take precedence.

When to use this form

The self-assessment tool can be used prior to an inspection by Health Canada or at any time when an establishment wants to evaluate their compliance with the *Blood Regulations*. It can also be used as a training tool for staff so that they may become familiar with the *Regulations.*

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How to complete this form

The questions posed for each of the regulatory sections are typical of what an Inspector would be asking or looking for during an inspection to determine compliance with the *Regulations*. An answer of "No" to any of the questions indicates a practice, procedure, or lack thereof, which may require corrective action on your part in order to be compliant with the *Regulations*.

This document also makes recommendations taken from the Guidance Document intended to promote compliance with the *Blood Regulations*. These will be found throughout this tool clearly identified as recommendations.

Each section of this document should be read in conjunction with the relevant sections of the *Blood Regulations* using the *Guidance Document: Blood Regulations*, as well as sections of the National Standard of Canada *CAN/CSA Z902: Blood and Blood Components* (CSA Blood Standard) incorporated in the *Regulations* by reference.

When completing the questions on error and accident investigation and reporting (S. 103-109 of the *Regulations*), it is strongly recommended that you also read the document titled "Investigating and Reporting Errors & Accidents under the Blood Regulations – Frequently Asked Questions", dated June 2022, that was sent to all hospital blood banks via email on June 29, 2022. If you have not received a copy of this document, or have any questions about this self-assessment tool or the *Regulations*, please contact the Biological Product Compliance Program at bpcp-pcpb@hc-sc.gc.ca.

NOTE: In this document, "blood" includes whole blood, red blood cells, plasma, platelets, and cryoprecipitate (cryo) for transfusion.

Self-assessment tool

BLOOD REGULATIONS SECTION	QUESTIONS	RESPONSE
PROHIBITIONS		
4	Is the blood that you distribute or transfuse processed by a licensed establishment in Canada : either Canadian Blood Services or Héma-Québec?If you distribute or transfuse transformed blood (washed, pooled [except pooled cryoprecipitate], or irradiated) received from another establishment, do you verify it was transformed by an establishment registered with Health Canada?	☐ Y ☐ N
	If you distribute or transfuse autologous blood, do you ensure it was collected and processed by an establishment registered with Health Canada: either Canadian Blood Services, Héma-Québec or a registered hospital blood bank?	☐ Y ☐ N
LABELLING		
60, 61	If you modify or manipulate blood, such as prepare aliquots, perform volume reduction of platelets, pool cryoprecipitate, etc., is the information you add to the labels of the modified component: • in English or French? • accurate, presented clearly and legibly?	 ☐ Y ☐ N ☐ Y ☐ N
	Are the labels made with adhesives and indelible inks that will not permeate the container (e.g. blood bag, syringe)?	☐ Y ☐ N
	Are the labels permanently affixed to the container?	☐ Y ☐ N
	If tags are used, are they firmly attached to the container?	☐ Y ☐ N
	Do you have a written procedure that includes how to label transformed and other modified/manipulated blood? *(S. 95)*	☐ Y ☐ N
65	If your establishment divides blood into aliquots for transfusion, do you ensure that the following appears on the label of each aliquot: • donation code? • name of the blood component? • a code that identifies the aliquot? • when appropriate, the ABO group and Rh factor? • the expiry date?	 ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
	If you aliquot blood using an open system: • Is the expiry date changed according to the storage criteria specified in Table 2 of the CSA Blood Standard?	 ☐ Y ☐ N

	• Are aseptic techniques being used?	☐ Y ☐ N
	Do you have a written procedure for aliquoting that define the appropriate expiration dates for aliquots? *(S.95)*	☐ Y ☐ N
68	Do you verify that the information that you add to labels is accurate and complete?	☐ Y ☐ N
	Do you have a written procedure for labelling that incorporates all of the requirements mentioned above? *(S. 95)*	☐ Y ☐ N
STORAGE		
69(2)	Do you store blood in accordance with the directions on its label and with any directions that are specified in writing by the establishment that collected it (e.g. in the circular of information or customer letters)?	☐ Y ☐ N
	Do you have a written procedure that describes the action to be taken when you receive blood that does not appear to have been shipped under appropriate conditions (e.g. temperature) or shows evidence of tampering or damage?	☐ Y ☐ N
70	**Note: In this section "storage locations" refers to any/all locations in the hospital where blood is stored (e.g. Operating Room (OR), Emergency Room (ER), patient wards, etc.)**	
	Do your storage locations have appropriate environmental controls to store blood in accordance with the temperature conditions on the labels of the blood?	☐ Y ☐ N
	Are storage locations monitored to ensure those temperature conditions are always maintained?	☐ Y ☐ N
	Note: Temperature monitoring probes or devices should be located at points that represent extreme temperature areas, as determined by a temperature mapping study to assess temperature distribution. When conducting temperature mapping studies, consideration should be given to using empty and full loads, as applicable.	
	Do you maintain documentation (temperature/humidity monitoring records, as applicable) to demonstrate that blood was always maintained under appropriate environmental conditions?	☐ Y ☐ N
	When blood is returned to the lab:	
	• Do you segregate the returned units until these units are deemed suitable for transfusion?	☐ Y ☐ N
	• Do you have a process in place to assess if it is safe to place the blood back into inventory (based on the time it has been out of storage or evidence it continued to be stored at appropriate temperatures)?	☐ Y ☐ N
	In the case of blood units removed and returned to satellite refrigerators, is there a process in place to ensure the blood is returned to the storage device within an appropriate timeframe based on the CSA Blood Standard?	☐ Y ☐ N
	In the event there are temperature excursions beyond acceptable limits:	

	• are these events documented? • is there a documented procedure describing when, and what action is to be taken? • are these events investigated when, or if, there is a potential impact on the safety of blood? *(see also S. 103-108)* In the event stored blood has to be relocated (e.g. fridge malfunction, scheduled maintenance of fridges, etc.) do you have designated alternate storage equipment where you can move the blood inventory? • Are the environmental controls for this equipment also kept at the appropriate temperature range(s) for the types of blood components that may be relocated there? • Have they undergone regular preventive maintenance? • Is the location of the alternate storage equipment documented, or referenced, in a procedure that also describes when blood inventory is to be relocated? Is the access to blood storage location(s) restricted to designated personnel (e.g., authorized card access, lock and key, etc.)? This also applies to locations outside of the transfusion medicine lab (such as the ER, OR, on a ward, etc.), as well as those locations where alternate storage equipment is located. Recommendations: • Parameters such as lighting, humidity and ventilation should be appropriate and controlled to safely store blood and blood components. • If the storage area has an alarm system with audible signals, alarm activation temperatures should be set at temperatures that allow sufficient time for appropriate corrective actions before blood reaches unacceptable temperatures. • Alarm warnings should signal in a location that is continually monitored or staffed and/or alarm notifications should go to designated personnel during and outside of business hours.	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
71, 72	Is blood intended for autologous, designated or directed use segregated from blood intended for other allogeneic use, either by physical segregation (e.g. a labelled shelf or container in fridge) and/or an electronic segregation system? Is blood that is untested, has incomplete testing, or has tested positive for transmissible disease agents or markers, segregated from blood that has been determined safe for distribution or for autologous transfusion? Do you have a written procedure that identifies when and how blood is to be segregated? *(S. 95)* If electronic segregation is used, has the system's performance been validated for this purpose?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
DISTRIBUTION		
74	Before you distribute blood for transfusion, do you examine each blood container (e.g. blood bag, syringe) to verify:	

	• information on the label is legible (including the labels of shipping containers, when applicable)? • the integrity of the container is intact? • there are no signs of deterioration or contamination of the blood? • that blood components that are to be distributed frozen show no signs of thawing? Do you ensure blood is not distributed if: • the donation code is missing or illegible? • any other information required by the *Regulations* to appear on the label is missing or illegible (unless the missing or illegible information can be retrieved from the establishment's records)? • the container is defective or damaged to the extent that it does not protect the blood from external conditions? • there are signs of deterioration or contamination of the blood? Are all of the above steps described in a written procedure? *(S. 95)* Are all employees conducting this verification adequately trained and aware of the required criteria above? *(S.98)* Do your records allow for the rapid identification of units and their location and/or final disposition in the event of a recall?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
75	If you ship blood to another establishment, or between different sites of the same establishment, are: • shipping containers and blood containers (e.g. blood bags, syringes) examined before shipping to verify their integrity and the legibility of the labels? • shipping containers (e.g. coolers, styrofoam containers) capable of resisting damage and maintaining the safety of the blood? • shipping containers maintaining the safety of the blood to ensure no tampering occurred (eg. by use of tamper-evident seals or closures applied to shipping containers) when blood is transported by someone other than an employee of the blood bank? Are the following described in a written procedure: • the packing of blood, including the packing configuration and the use of ice packs etc. (if applicable)? • the examination of the blood containers and their labels prior to packing? • the addition of tamper evident seals (if applicable)? *(S. 95)*	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
76	When shipping blood for transfusion do you ensure that it is being transported in accordance with the criteria specified in Table 2 of the CSA Blood Standard? Have shipping containers been validated for their intended use? Is validation conducted in accordance with a written validation protocol? *(S. 95)*	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N

	Have you taken the following into account as part of validation: • packaging configurations used for the different blood component types, including the number of units packaged in each container? • worst case scenarios involving time (distance travelled) and temperature conditions (weather, type of conveyance used)? If you are not performing validation, do you have some other means of ensuring the criteria specified under Table 2 of the CSA Blood Standard are maintained during transport (e.g. data logger)?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
TRANSFORMATION *Complete this section only if your establishment pools cryoprecipitate (cryo). If your establishment washes, irradiates or pools other components, you are required to obtain a registration. Please refer to the other self-assessment tool for registered blood banks.*		
77, 79	If your establishment pools cryo, is the method you use safe and effective, and documented in a written procedure that includes instructions for: • conducting pooling in an environment suitable for this purpose (i.e. that prevents blood from becoming contaminated)? • the use of aseptic technique used to prevent contamination of ports? • cleaning, disinfection and maintenance of biological safety cabinets or laminar flow hoods used when pooling, including regular certification/preventive maintenance according to the manufacturer's instructions? • examining the units of cryo to be pooled to ensure they have no leaks or other irregularities prior to transformation? Does your blood bank pool cryo in accordance with sections 7.11.1 and 7.11.3 of the CSA Blood Standard? Do you ensure that all the information specified in sections 10.8.2 and 10.8.3 of the CSA Blood Standard appears on the label of the pooled units? Is the pooling method, the steps taken to prevent contamination, storage requirements, labelling, and label verification, included in a written procedure(s)? *(S.95)* Are records of pooling kept in accordance with S. 121 of the *Regulations*?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
EXCEPTIONAL DISTRIBUTION		
81	*An establishment may distribute or transfuse allogeneic blood for transfusion for which the ABO group, Rh factor and transmissible disease or disease agents are not yet available, if both of the following conditions are met:* • *Blood that has been deemed safe for distribution is not immediately available; and* • *The recipient's physician has requested the use of the blood for the emergency treatment of their patient.* Do you have a written procedure in place to handle the release and distribution of blood that you have, or may receive, under exceptional distribution (e.g. granulocytes)?	☐ Y ☐ N

	If you release and distribute blood under exceptional distribution, is it only done for a single patient, on a case-by-case basis, and only where the above-mentioned conditions are met? **Note: You are required to have a procedure in place even if you have not received blood under exceptional distribution. If you do not accept blood under exceptional distribution as a matter of policy, this must be documented.**	☐ Y ☐ N
82(3), (4)	If blood received under exceptional distribution is transfused at your establishment, is a copy of the Notice of Exceptional Distribution placed on the recipient's file? If the blood is sent to another establishment for transfusion, do you ensure a copy of the Notice of Exceptional Distribution is sent to that establishment?	☐ Y ☐ N ☐ Y ☐ N
84(2)	If the blood was sent to another establishment for transfusion, do you send a copy of the test results to that establishment?	☐ Y ☐ N
85	If the blood received under exceptional distribution is not transfused into the intended recipient in the emergency, do you have a procedure in place to ensure it is either: • not transfused into another recipient and is safely and appropriately disposed of? or, • placed into quarantine (and labelled as such) until full test results are available and the blood is deemed safe to put into general inventory for allogeneic use?	☐ Y ☐ N ☐ Y ☐ N
OPERATING PROCEDURES		
95	Do you have written procedures for all regulated activities under the *Blood Regulations* you conduct? This includes, but may not be limited to: *(These are example titles only)* • management of quality documents* • quality control of critical supplies and services • computer system, including management, back-up and authorization of the computer system • document control • record keeping and retention time • equipment calibration and maintenance • management and communication of lab results • error and accident investigation and reporting • adverse reaction investigation and reporting • labelling • label controls and verification • storage • maximum storage periods • packaging according to a package scheme • distribution • exceptional distribution • quarantine and release	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N

	• recall procedure, including action to take when receiving Notices of Component Recalls/Withdrawals • environmental monitoring • training • any other regulated activities, including transformation (pooling cryo) and other blood manipulation activities, such as preparing blood aliquots, etc. * management of quality documents includes a set of procedures that set out the steps for the creation, revision, review, approval, release, implementation and archiving of documents that are part of the Quality Management System, including policies, procedures, forms, job-aids, etc.	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
96	Are your operating procedures: • in a standardized format? • approved by a senior executive officer? • readily accessible, electronically or in hard copy, at all locations where the relevant activities are being conducted? • regularly reviewed at a pre-determined frequency to ensure they are kept up to date (e.g. every 2 years)? • also reviewed, as necessary, outside of the established review frequency when there are regulatory or CSA amendments, changes in processes and changes made as a result of errors/accidents, or deficiencies identified during internal audits? Are hard copies of current procedures necessary to operate during an emergency (i.e. downtime procedures) available to applicable staff?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
97	Do you have documented evidence that the activities, methods and operating procedures used in the pooling of cryo, will consistently lead to the expected results, as determined or supported by, one or more of the following: • your own validation? • verifying the process outcome each time the process is conducted? • use of methods established in standards developed by recognized professional organizations (e.g. AABB)? • current information available in scientific literature?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
PERSONNEL, FACILITIES, EQUIPMENT & SUPPLIES *Note: While sections 99, 100 and 102 of the Regulations do not apply to non-registered blood banks, they are considered best practices and Health Canada strongly recommends that you adhere to the requirements under these sections. We are therefore including them as part of this self-assessment tool.*		
Personnel		
98	Are staff qualified by education, training or experience to perform their respective tasks as they relate to blood safety? Do you have sufficient personnel to conduct all blood safety related activities, based on for instance, the volume or number of activities conducted? Do you have a training program that includes: • a procedure(s) for both initial and on-going training of staff?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N

	• identification of the required training for each staff member, including which activities they are responsible for conducting, and their associated processes, procedures and other related quality documents?	☐ Y ☐ N
	• a process for both initial and on-going competency assessment of staff, which sets out:	
	○ which activities require competency assessment?	☐ Y ☐ N
	○ the frequency of assessment?	☐ Y ☐ N
	○ how competency will be assessed?	☐ Y ☐ N
	○ who will conduct the assessment?	☐ Y ☐ N
	○ how the results of the assessments are recorded and assessed? and,	☐ Y ☐ N
	○ what steps are taken in the event a staff member fails his/her assessment?	☐ Y ☐ N
	Note: The evaluation of personnel competency may involve use of one or more of the following methods, and will be dependent on the type of activity/procedure being assessed as well as the judgement of establishment management as to how it is best assessed: ○ direct observation ○ monitoring records that an employee created ○ written tests, including testing of an employee's knowledge of operating procedures and theory ○ assessment of performance through proficiency testing where an employee conducts routine testing ○ other means of assessment as determined by the establishment	
	• training records that include the following:	
	○ when training occurs?	☐ Y ☐ N
	○ what mode of training is being conducted?	☐ Y ☐ N
	○ what procedures and other quality documents were the subject of a training session, including their revision or version number, and their implementation date?	☐ Y ☐ N
	○ which staff were trained during training sessions and who conducted the training?	☐ Y ☐ N
	○ staff competency assessment results, or where there is no assessment or staff are only required to read a new or revised procedure, documentation of their initials or signature acknowledging they have read and understood the procedure/revisions?	☐ Y ☐ N
	• a procedure that ensures all staff responsible for an activity, are trained on/have read and understood (as applicable) a new or revised procedure prior to its implementation date or prior to them conducting the activity?	☐ Y ☐ N
	• where the training does not take place prior to the implementation date, a process to ensure the employee does not conduct the activity prior to the completion of the required training and a rationale for the delay?	☐ Y ☐ N

	Does your training program include a process that requires retraining, or an assessment of re-training needs, for staff returning after an extended leave of absence (e.g. maternity leave, illness, etc.)? Is your training program and all associated processes and procedures, including those for competency assessment, documented? **Recommendation:** All personnel conducting regulated activities should be aware of the requirements in the *Blood Regulations* and the Blood Guidance Document, as applicable to their job responsibilities.	☐ Y ☐ N ☐ Y ☐ N
Facilities *Note: While section 99 of the Regulations does not apply to non-registered blood banks, it is considered best practices and Health Canada strongly recommends that you adhere to the requirements under this section. We are therefore including it as part of this self-assessment tool.*		
99	Is the space used for regulated blood activities of sufficient size and organized, such that: • staff can properly conduct their tasks? • different activities are not crowded in a way that errors or accidents could occur, or that could result in unsanitary conditions? • the space can be easily cleaned to maintain sanitary conditions? Regarding the space where activities are conducted, is it controlled at all times so that only authorized persons have access? This includes access to locations where blood storage devices are used to store blood in satellite locations in the hospital (e.g. OR, Intensive Care Unit, etc.). Where other hospital staff (e.g. biomedical engineering, housekeeping, etc.), third party vendors or other visitors are required to be in spaces where regulated activities are conducted, is their access controlled and also removed once their work is done? Is there a process to ensure that the staff access to databases and/or restricted areas is removed as required? Are environmental controls in place, and are they monitored, where necessary (e.g. where activities that are affected by temperature and/or humidity are conducted, or where supplies are kept that have specific temperature requirements)?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Equipment *Note: While section 100 of the Regulations does not apply to non-registered blood banks, it is considered best practices and Health Canada strongly recommends that you adhere to the requirements under this section. We are therefore including it as part of this self-assessment tool.*		
100	Have you identified all of your critical equipment, including instruments and measuring devices that are critical to ensuring the blood conforms to the *Blood Regulations* (e.g. scales to weigh blood, thermometers, temperature probes, etc.)?	☐ Y ☐ N

	Does your establishment perform validation/qualification of critical equipment upon installation or before first use?	☐ Y ☐ N
	Is revalidation/requalification conducted as appropriate (e.g. after significant repairs or changes to the equipment)?	☐ Y ☐ N
	Is critical equipment calibrated and maintained according to the manufacturers' instructions?	☐ Y ☐ N
	• Are manuals consulted for critical equipment to verify the preventive maintenance frequency and tasks are consistent with the manufacturer's instructions?	☐ Y ☐ N
	Are the instruments used to calibrate and test equipment also calibrated and maintained according to manufacturers' instructions?	☐ Y ☐ N
	Do you have a preventive maintenance schedule for all your critical equipment, even where the maintenance is conducted by a third party, either internal or external?	☐ Y ☐ N
	Do you receive and review the results of all validation, calibration and preventive maintenance records for your critical equipment to ensure they continue to operate in accordance with their specifications?	☐ Y ☐ N
	Is the computer system used in the conduct of regulated activities validated?	☐ Y ☐ N
	Are controls in place to limit access to the computer system data to ensure unauthorized changes or deletions are not made to software or data?	☐ Y ☐ N
	Is there a way to track changes made to the electronic data (i.e. audit trails must be enabled and reviewed)?	☐ Y ☐ N
	Recommendation: There should be processes and operating procedures to support the maintenance and security of computer systems and their data.	
Storage equipment		
101	Does the equipment* you use to store blood, including blood stored in satellite locations such as the OR, allow compliance with the storage requirements of sections 69-72 of the *Regulations*? For example:	
	• Is storage equipment validated/qualified prior to use?	☐ Y ☐ N
	• Is revalidation/requalification performed as appropriate (e.g. after significant repairs or changes)	☐ Y ☐ N
	• Are temperature monitoring devices (e.g. temperature probes and thermometers) qualified, calibrated and maintained according to manufacturers' instructions?	☐ Y ☐ N
	• Are continuous monitoring measures in place for temperature as well as agitation (platelet incubators)?	☐ Y ☐ N

	• If temperature monitoring is not continuous, are temperatures manually recorded at regular intervals? *This includes transport containers in which blood could be stored temporarily. Do you have written procedures for the maintenance and calibration of storage equipment, including temperature monitoring devices, that includes: • the frequency of maintenance and calibration, including alarm checks? • actions to be taken if maintenance and/or calibration exceeds its due date? • tolerances for test specifications? • actions to take when test specifications exceed tolerances? • alarm set points within critical limits? (*see also S. 69-72)*	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Supplies *Note: While section 102 of the Regulations does not apply to non-registered blood banks, it is considered best practices and Health Canada strongly recommends that you adhere to the requirements under this section. We are therefore including it as part of this self-assessment tool.*		
102	Have you identified the supplies that you use for transformation and other blood manipulation procedures that are considered critical? Have you qualified your critical supplies, to ensure they are suitable for their intended purpose? Does your establishment conduct a documented quality check of each incoming shipment of critical supplies to verify they: • are without damage? • are shipped under the correct environmental conditions? • are within their expiry date? • are consistent with what was ordered and for which qualification was performed? • have passed manufacturer's test specifications (e.g. by reviewing Certificates of Analysis)? Are records of the lot numbers of critical supplies used for each transformation and blood manipulation activities recorded and retained? Are critical supplies stored under the storage conditions stated on their label? Do you have a written procedure(s) to monitor and strictly follow expiry dates and that describe all of the above? *(S.95)*	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
ERROR & ACCIDENT INVESTIGATION & REPORTING *If upon review of sections 103-108, incidents are identified that meet the criteria of a reportable error or accident, they should be reported to Health Canada.*		
103 -108	Do relevant staff understand the requirements for error and accident (E/A) investigation, and when they need to be reported to Health Canada?	☐ Y ☐ N

	Have staff read the document titled *Investigating and Reporting Errors & Accidents under the Blood Regulations – Frequently Asked Questions* that was provided to blood banks in June 2022? Health Canada recommends this document become part of staff training.	☐ Y ☐ N
	Does your establishment have written procedures that include the requirements set out in sections 103-108? *(S.95)*	☐ Y ☐ N
	Do you maintain records of all E/A investigations, including: • description of the E/A and the reason the safety may be compromised? • donation codes, and types of blood components implicated? • details of the investigation, including root cause of the E/A? • copies of notices to other establishments, or notices received from other establishments, if applicable? • copy of preliminary, follow-up and final reports to Health Canada, if applicable? • records of disposition of units, if applicable? • records of corrective and preventive actions taken?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Error or accident occurs at another establishment		
103	Do you have a procedure to ensure that the following actions immediately take place when you have reasonable grounds to believe the safety of blood may have been compromised during an activity conducted by another establishment: • determination of the donation codes of all blood that could be implicated? • identification and quarantine all of the implicated blood still in your possession? • notification of the establishment that collected the implicated blood? • notification of the establishment you received the blood from, if different from the establishment that collected it? • notification of all establishments to whom you distributed implicated blood?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
	When sending a notification to an establishment, does the notice include: • the donation codes of the implicated blood? • a statement of whether the implicated blood is whole blood or blood components, and the name of the implicated blood components? • the reason you believe the safety of the blood may have been compromised?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
	If you are notified by another establishment to whom you sent blood, that they suspect the safety of the blood you sent them has been compromised by an activity conducted by your establishment, do you immediately notify every other establishment to whom you sent implicated blood, and instruct them to quarantine all of the implicated blood in their possession?	☐ Y ☐ N
	If you notify establishments verbally, do you confirm it in writing as soon as possible afterwards?	☐ Y ☐ N

Establishment's own error or accident		
104	When you know or suspect an E/A has occurred as a result of an activity carried out by your own establishment, do you have a written procedure to ensure the following actions are immediately carried out: • determination of the donation codes of all blood that could be implicated? • identification and quarantine of all implicated blood still in your possession? • determination as to whether or not there is sufficient evidence to warrant an investigation of the E/A? • if an investigation is warranted, the notification of every establishment to which you distributed implicated blood? When sending a notification to an establishment, does the notice include: • the donation codes of the implicated blood? • a description of the suspected E/A? • an explanation of how the safety of the implicated blood may have been compromised? Does the documented investigation include: • a root cause analysis? • consideration of the potential impact of the E/A on the safety of the blood and the recipient? • development of appropriate corrective actions? If an establishment to whom you sent blood sends you a notice indicating they have reasonable grounds to believe an E/A occurred during an activity carried out by another establishment (maybe you), do you immediately carry out the same actions listed above? If you receive a notice of a suspected E/A from an establishment to whom you sent blood, and you decide an investigation is not warranted, do you immediately notify that establishment that you will not be conducting an investigation, and your reasons for that decision?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Requirement to cooperate		
105	Are staff aware that they must cooperate and provide information requested by other establishments in support of E/A investigations those establishments may be conducting? Is this documented in a procedure?	☐ Y ☐ N ☐ Y ☐ N
Investigation results		
106	Following the investigation of an E/A, do you issue a written notice of the results of the investigation to all establishments to whom you distributed implicated blood, including any actions to be taken?	☐ Y ☐ N

	Does your establishment have a system in place to verify implicated blood is not distributed or transfused if the result of an E/A investigation confirms the safety of the blood is compromised, or if the results of the investigation are inconclusive? *[S. 4(7)(b)]*	☐ Y ☐ N
	If your establishment is notified of the results of an investigation of an E/A pertaining to implicated blood you have further distributed, do you send a copy of the notice to each of those establishments?	☐ Y ☐ N
Reports to the Minister		
107	Do you have a process in place to ensure your establishment reports all errors and accidents to the Biological Product Compliance Program (BPCP) of Health Canada when **all** the following criteria are met: • the E/A is known or suspected to have occurred during a regulated activity your establishment conducted; **and** • the E/A was identified after the blood was distributed or transfused; **and** • there is a reasonable probability the E/A could have led to a serious adverse reaction?	☐ Y ☐ N
	Do your reports sent to the BPCP include the following information, and are sent within the stated timeframes: • a preliminary report, including all relevant information available at the time, within 24 hours of the start of your investigation?	☐ Y ☐ N
	• a written update on the progress of the investigation, including any new information and steps taken to mitigate further risks: o within 15 days after the start of the investigation? and o at any time after the preliminary report at the request of the BPCP?	☐ Y ☐ N ☐ Y ☐ N
	• a final report at the conclusion of the investigation that includes: o the results of the investigation, including the root cause of the E/A? o the final disposition of the blood that was the subject of the investigation and the reason for the disposition? and o the corrective and preventive actions taken, including any changes made to processes and/or procedures in order to prevent recurrence of the E/A?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
	If a serious adverse reaction is suspected to have occurred as a result of an E/A, do you ensure that the adverse reaction is also reported to the Minister (i.e. the Canada Vigilance Program at the Marketed Health Products Directorate (MHPD) of Health Canada) in accordance with section 113 of the *Regulations*?	☐ Y ☐ N
Annual report		
108	Do you prepare an annual report that summarizes all the error and accident investigations you conducted in the previous 12 months, identified before and after distribution or transfusion, including those that you have reported to the BPCP?	☐ Y ☐ N
	Does the report include a concise, critical analysis of the investigations, including:	

	• ensuring errors and accidents that were required to be reported to the BPCP were, and that reporting was done in accordance with the *Regulations*? • Identifying recurring issues and trends that may require additional corrective and preventive action? Is the preparation of this annual report described in a written procedure? **Note: It is not required to send this annual report to the BPCP unless requested.**	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
ADVERSE RECIPIENT REACTION INVESTIGATION & REPORTING *Note: These Regulations apply only if your preliminary investigation of an adverse reaction leads you to suspect the reaction may be the result of the compromise of the safety of the blood during a regulated activity you conducted (not a practice of medicine error) or a regulated activity conducted by the supplier or establishment you received the blood from.*		
110-116	Have relevant staff read and understood the requirements of adverse reaction investigation, and when adverse reactions are required to be reported to Health Canada? Do you have a procedure(s) for conducting investigations and reporting of unexpected and serious adverse reactions that includes the requirements set out in S. 110-116 of the *Regulations*? *(S. 95)* Do you maintain records of all investigations of serious and unexpected adverse reactions, including: • description of the reaction that occurred? • donation codes and types of blood component involved? • details of the investigation, including root cause? • copies of notices to other establishments, or notices received from other establishments, if applicable? • copy of preliminary, follow-up and final adverse reaction reports to Health Canada, when applicable? • records of corrective and preventive actions taken? • copies of, or reference numbers, for any error or accident reports associated with adverse reactions?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Required action		
110	When your establishment has reasonable grounds to believe a recipient of blood has experienced an unexpected or serious adverse reaction, do you do all of the following: • determine the donation codes of all implicated blood? • identify and quarantine any implicated blood in your possession? • perform a preliminary inquiry into the root cause of the adverse reaction? If your preliminary inquiry suggests the root cause of the adverse reaction is attributable to a regulated activity you carried out, do you: • conduct an investigation into the adverse reaction? and, • notify any establishment you distributed implicated blood to?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N

	If your preliminary inquiry suggests the root cause of the adverse reaction is attributable to an activity carried out by another establishment, do you immediately notify all of the following: • the establishment that collected the blood? • the establishment you received the blood from, if different from the establishment that collected it? • any establishment to which you distributed implicated blood? When notifying establishments, does your notice include: • a description of the adverse reaction? • an explanation of how the safety of the implicated blood may have been compromised, if known? • the donation codes of all implicated blood? • a statement indicating whether the implicated blood is whole blood or blood components, including the names of the implicated blood components? Refer to section 110(2) of the Blood Guidance Document for additional information that should be included in the notice. If your blood bank is notified by another establishment that a serious or unexpected adverse reaction may be attributable to a regulated activity you carried out, do you immediately do the following: • quarantine any implicated blood in your possession? • notify every establishment or other person that you distributed implicated blood to? • conduct an investigation into the adverse reaction? If you verbally notify other establishments to inform them they have received blood implicated in a serious or unexpected adverse reaction, or that a serious or unexpected adverse reaction may be attributable to an activity they carried out, do you send a written confirmation as soon as possible afterwards?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Requirement to cooperate		
112	Are staff aware that they must cooperate with other establishments that may request information in support of adverse reaction investigations those establishments are conducting? Is this requirement documented in a procedure?	☐ Y ☐ N ☐ Y ☐ N
Notice to the Minister		
113	When your establishment conducts an investigation of a serious or unexpected adverse reaction where the root cause is thought to be a result of an activity your establishment carried out, and it is suspected to be associated with the safety of the transfused blood, do you notify the Minister (i.e. the Canada Vigilance Program at the Marketed Health Products Directorate (MHPD) of Health Canada): • within 24 hours of becoming aware of the death of a recipient? or,	☐ Y ☐ N

	• in the case of any other serious or unexpected adverse reaction, within 15 days after you are made aware of it?	☐ Y ☐ N
	If reporting the preliminary notification of a death, do you send a follow-up report to the Canada Vigilance Program without delay containing the additional information?	☐ Y ☐ N
	When notification is given to the Canada Vigilance Program verbally, do you send confirmatory written notice as soon as possible afterwards?	☐ Y ☐ N
	If a serious or unexpected adverse reaction is suspected to have occurred as a result of an error or accident, do you ensure that the error or accident is also reported to the Biological Product Compliance Program of Health Canada in accordance with section 107 of the *Regulations*?	☐ Y ☐ N
Results of investigation		
114	When you are conducting an investigation into a serious or unexpected adverse reaction do you notify, in writing, every establishment you may have distributed implicated blood, of the results of your investigation?	☐ Y ☐ N
	Do you inform those establishments of the action to be taken, if any?	☐ Y ☐ N
	If your establishment is notified of the results of an investigation by another establishment, do you pass on that notice to establishments that you distributed implicated blood to?	☐ Y ☐ N
	Do you retain copies of notices you send to other establishments?	☐ Y ☐ N
Final report to the Minister		
115	After completing an investigation of a serious or unexpected adverse reaction, do you send a final report to the Canada Vigilance Program containing the following:	
	• the results of the investigation, including root cause?	☐ Y ☐ N
	• the final disposition of the implicated blood and the reasons for the disposition?	☐ Y ☐ N
	• any corrective actions taken and any recommended changes to relevant processes and procedures as a result of the adverse reaction?	☐ Y ☐ N
Annual report		
116	Does your establishment prepare an annual report at the end of each year that summarizes all of the final adverse reaction reports that were submitted to the Canada Vigilance Program within the previous 12 months?	☐ Y ☐ N
	Does the report include a critical analysis of the investigations that were the subject of those reports?	☐ Y ☐ N
	Is the preparation of this annual report described in a written procedure?	☐ Y ☐ N
	Recommendation: The annual report should include the following:	

	• an executive summary • a detailed analysis and assessment of any new safety signals • an overall summary analysis of the adverse reactions reported in the period that considers blood or blood component use • a cumulative analysis of the adverse reactions reported that includes an analysis of trends over time • traceback and lookback annual summary statistical reports • overall conclusions and opportunities for improvement	
RECORDS		
Record quality		
117	Are all records accurate, complete, legible, indelible and readily retrievable:	
	• pens with indelible ink are used for handwritten entries?	☐ Y ☐ N
	• white-out is not permitted?	☐ Y ☐ N
	• corrections and entries of information or notations after the original date of the record are clearly crossed out, initialed or signed, and dated to indicate a change has been made to the original entry?	☐ Y ☐ N
	• manual transcriptions of test results are independently verified in cases where the transcribed document is the permanent record?	☐ Y ☐ N
	• records maintained concurrently with the performance of each step in processing, transformation, manipulation, storage, distribution (including exceptional distribution), investigation of errors/accidents and adverse reactions, so that all steps can be clearly associated with the person that conducted the step, the time/date, and if applicable, the location of the activity?	☐ Y ☐ N
	• records associated with the processing, transformation and manipulation include the lot numbers of the critical supplies used, and the unique identifier of the critical equipment, documented as part of each process?	☐ Y ☐ N
	• all records are readily retrievable to enable quick and efficient retrieval of blood traceability information including records of transfusion?	☐ Y ☐ N
	• preserved in a manner to ensure their integrity over time?	☐ Y ☐ N
	If your establishment keeps electronic records, is the electronic system validated?	☐ Y ☐ N
	If original records are scanned and stored electronically to a format other than the original, does your establishment have a written procedure for ensuring the accuracy of the transferred information?	☐ Y ☐ N
	• Is the accuracy of the transfer verified by someone other than the individual that transferred the information?	☐ Y ☐ N
	Where records are stored electronically or digitally, are they easily retrieved?	☐ Y ☐ N
	Can a hard copy of the information on electronic or digital media be printed, if necessary?	☐ Y ☐ N
	Does your establishment use a standardized date format for all records?	☐ Y ☐ N

Donation code part of all records		
118	Are blood donation codes a component of all records related to the processing, distribution, transformation (pooled cryoprecipitate) and transfusion of blood by your establishment? If a new code is assigned for a pooled unit, is the donation code of all pooled components traceable in the records?	☐ Y ☐ N ☐ Y ☐ N
Retention periods – transformation		
121	If your establishment pools cryoprecipitate, are the types of records identified in the table to section 121 retained for the stated period? *Refer to Appendix A.* Are the types of records to be retained, and their associated retention times written in a procedure? Does your procedure specify that the retention period for personnel records begin on the last day on which they were employed by your establishment? Does the retention period for all other records begin on the day the record was created?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Retention periods – transfusion		
122	Does your establishment maintain the different types of records for the indicated periods of time set out in the table to Section 122? *Refer to Appendix B.* Are the types of records to be retained, and their associated retention times, written in a procedure? Does your procedure specify that the retention period for personnel records begin on the last day on which they were employed by your establishment? Does the retention period for all other records begin on the day the record was created?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N
Storage of records		
123	Are records: • stored under appropriate environmental conditions to ensure their integrity is maintained for the duration of their retention period? • secure against the entry of unauthorized persons? This includes password protection of electronic systems. If third parties are used to copy and/or store records, does your establishment have a signed contract with the party that clearly outlines copy procedures and quality of copies, transport conditions, security conditions, including who has access, retrieval information, storage conditions, and specific requirements for destruction, if applicable?	☐ Y ☐ N ☐ Y ☐ N ☐ Y ☐ N

Appendix A – Table to Section 121 of the *Regulations*

Records and Retention Periods – Transformation		
Item no.	Records	Retention Period
1	Donation code	10 years
2	Records of washing, pooling and irradiation of blood	10 years
3	Lot # and name of manufacturer of critical supplies for each transformation	1 year
4	Complaints and their investigation	5 years
5	Internal audit reports	5 years
6	Quality control testing	5 years
7	Maintenance, validation, qualification and calibration of critical equipment	3 years
8	Critical supplies, including their qualification	3 years
9	Every version of the operating procedures that was implemented	10 years
10	Personnel qualifications, training and competency evaluation	10 years
11	Investigations and reports of errors and accidents	10 years
12	Investigations and reports of adverse reactions	10 years

Appendix B – Table to Section 122 of the *Regulations*

Records and Retention Periods – Transfusion		
Item no.	Records	Retention Period
1	Donation code – allogeneic blood	50 years
2	Donation code – autologous blood	10 years
3	Shipping documents	1 year
4	Blood storage temperature monitoring	5 years
5	Distribution	50 years
6	Exceptional Distribution	50 years
7	Record of transfusion or disposition of allogeneic blood, including identification of recipient	50 years
8	Record of transfusion or disposition of autologous blood	10 years
9	Complaints and their investigation	5 years
10	Every version of the operating procedures that was implemented	10 years
11	Personnel qualifications, training and competency evaluation	10 years
12	Investigations and reports of errors and accidents	10 years
13	Investigations and reports of adverse reactions	10 years

Appendix C – References

Food and Drugs Act
https://laws-lois.justice.gc.ca/eng/acts/f-27/

Blood Regulations
https://laws-lois.justice.gc.ca/eng/regulations/SOR-2013-178/index.html

Guidance Document: Blood Regulations
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/blood-regulations/guidance-document-blood-regulations.html

CSA Group National Standard of Canada: CAN/CSA-Z902: Blood and Blood Components
https://www.csagroup.org/store/product/CAN-CSA-Z902%3A20/
View Access to the CSA Blood Standard is available by registering with the CSA Communities website.

Pre-inspection package for blood establishments (FRM-0414)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/blood-donor/pre-inspection-package-for-blood-establishments-0414-summary.html *(document available upon request)*

Investigating and Reporting Errors & Accidents under the Blood Regulations – Frequently Asked Questions, June 2022. *(document available upon request)*