

## Guidance Document: Blood Regulations

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**Health Products and Food Branch**

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p><i>Health Canada</i></p>	<p>HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health related to health products and food by:</p> <ul style="list-style-type: none"><li>• Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,</li><li>• Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.</li></ul> <p><i>Health Products and Food Branch</i></p>
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*Également disponible en français sous le titre : Ligne directrice : Règlement sur le sang*

## **FOREWORD**

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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## 1. INTRODUCTION

The *Blood Regulations* are intended to promote the protection of the safety of Canadian blood donors and recipients in connection with the safety of blood for transfusion or for further manufacture into a drug for human use. See section 1, the Interpretation section of this guidance document, for the definition of *safety*.

The *Blood Regulations* contain requirements for human safety and the safety of blood with respect to the following activities related to human blood and blood components *for transfusion*: processing (donor suitability assessment, collection, testing, and blood component preparation); transforming (washing, pooling and irradiating); labelling; storing; record keeping; importing; distributing; and error, accident and adverse reaction investigation and reporting.

The *Blood Regulations* contain requirements for human safety and the safety of blood with respect to the following activities related to human blood and blood components *for further manufacture*: processing (donor suitability assessment, collection, testing, and blood component preparation); labelling; storing; record keeping; distributing; adverse donor reaction investigation and reporting; and error and accident investigation and reporting.

The *Blood Regulations* are administered by the Health Products and Food Branch, Health Canada. Any questions concerning the *Blood Regulations* or this guidance document can be sent to [bgtd.opic@hc-sc.gc.ca](mailto:bgtd.opic@hc-sc.gc.ca).

### 1.1 Policy Objectives

Under the *Food and Drugs Act*, the *Blood Regulations* introduce specific regulations for blood and its components intended for transfusion or for further manufacture into drugs for human use. This guidance document interprets the requirements of the *Blood Regulations* to provide necessary information for establishments that process, label, distribute, transform, or store blood for transfusion or for further manufacture, and establishments that import blood for transfusion, to comply with the requirements of the *Blood Regulations*.

### 1.2 Scope and Application

The *Blood Regulations* only apply to human blood that is collected for transfusion or for further manufacture into a drug for human use. Manufacturing of drug products using blood or blood components is outside the scope of the *Blood Regulations* and is regulated under the *Food and Drug Regulations*. Blood product fabricators are referred to in this guidance in respect of the chain of distribution and for blood safety communication purposes. See 1.5 Definitions, *blood product fabricator*.

The *Blood Regulations* fall under the authority of the *Food and Drugs Act* and apply to all persons or establishments that process, label, store, distribute or transform blood for transfusion or for further manufacture, including establishments that import blood for transfusion. The *Food and Drugs Act* and the current version of the National Standard of Canada, CAN/CSA Z902, *Blood and blood components* (CSA Blood Standard), published by the Canadian Standards Association (CSA), should be read in conjunction with the *Blood Regulations*.

It is the responsibility of the establishment to ensure that they follow the requirements of the most recent version of the *Blood Regulations* and the clauses of the CSA Blood Standard incorporated by reference into the Regulations. The CSA Blood Standard clauses incorporated by reference into the *Blood Regulations* are regulatory requirements that must be met, while CSA Blood Standard clauses that are only referred to in this guidance document are recommended best practices. In the case of a discrepancy between the CSA Blood Standard that is not incorporated into the *Blood Regulations* and a requirement in the *Blood Regulations*, the regulatory requirements take precedence as they are the legislative rules enacted by the Governor in Council.

This guidance document replaces some of Health Canada's blood regulatory guidance documents. See Appendix D. This guidance document should be read in parallel with the *Blood Regulations*. In the event of any perceived inconsistency or conflict, the *Blood Regulations* take precedence over this guidance document.

In this guidance document, “must” is used to express a requirement, i.e. a provision of the *Blood Regulations* that the establishment is obliged to satisfy in order to comply with the regulatory requirements; “should” is used to express a recommendation or that which is advised but not required; and “may” is used to express an option or that which is permissible within the limits of the guidance document.

Where this guidance document indicates number of days for notification or further action required by an establishment or Health Canada, unless it is otherwise specified, the days are counted as calendar days.

### 1.3 Background

The *Blood Regulations* were developed to

- complete Health Canada's response to the Krever Commission recommendations;
- add specific safety requirements for whole blood and its components to the federal regulations;

- consolidate and clarify the existing regulations for blood safety that are contained in various divisions of the *Food and Drug Regulations* into standalone regulations specific to blood safety;
- address the specific needs of blood as a unique therapeutic product rather than applying general drug regulations to blood; and
- deal with fast changing technologies, emerging diseases, and blood shortages in urgent circumstances.

Establishments are regulated, under the new *Blood Regulations*, based on the degree of risk that their activity poses to the safety of Canada's blood for transfusion or for further manufacture.

An establishment must apply to Health Canada for an Authorization and an Establishment Licence if it intends to conduct processing activities described under the *Blood Regulations* with respect to human allogeneic blood for transfusion, including plasma for further manufacture. The preparation of the circular of information of allogeneic blood for transfusion and the labelling of allogeneic units of blood prior to distribution must be conducted in accordance with an Authorization. Blood that is imported for transfusion must be associated with an Authorization and the importing establishment must have an Establishment Licence.

The requirements of the *Food and Drug Regulations* C.04.400-C.04.423 *Human Plasma Collected by Plasmapheresis* are provided in Appendix C. These requirements are the baseline of the authorized criteria for licensed establishments previously held to these requirements prior to the repeal of these sections of the *Food and Drug Regulations*. These baseline requirements will change once an application for an amendment to an Authorization is submitted by an establishment and approved by Health Canada.

An establishment must register with Health Canada if they collect autologous blood, have a Pre-Assessed Donor Program, or transform blood.

All establishments that store and transfuse blood need to meet specific requirements described in the *Blood Regulations*. Note: Labelling, after the blood is determined safe for distribution, is an activity that applies to establishments that transform or transfuse blood.

Some sections of the *Blood Regulations* reference specific clauses in the CSA Blood Standard that are within Health Canada's scope of authority. When a specific section, clause or table in the CSA Blood Standard is incorporated by reference into these regulations, it becomes a mandatory regulatory requirement. The CSA Blood Standard, as amended from time-to-time, is

incorporated in this way. Clauses or tables in the CSA Blood Standard, not referenced in the Regulations, remain voluntary.

### 1.3.1 CSA Blood Standard

The CSA Blood Standard covers the lifecycle of blood for transfusion.

The CSA Blood Standard was developed through a consensus-driven process by a technical committee of experts in the field of hematology, user groups, and federal and provincial and territorial governments. The CSA undertook consultation on the CSA Blood Standard as part of their standard development process.

All establishments require access to the current version of the CSA Blood Standard, since some provisions of the *Blood Regulations* are standards-based. The CSA Blood Standard is available by ordering it through the Canadian Standards Association website ([www.shopcsa.ca/onlinestore/welcome.asp](http://www.shopcsa.ca/onlinestore/welcome.asp)) or by calling 1-800-463-6727. Information on how to receive updates or amendments to the standard is available on the “CSA Standards Update Service” page of the CSA Blood Standard.

All stakeholders play a key role in keeping the CSA Blood Standard up-to-date. The CSA Blood Standard contains a Proposal for Change Form that stakeholders may use to submit proposals for change directly to the CSA. The CSA recommends that stakeholders supply the following information, in addition to the appropriate contact information, to facilitate the evaluation of the proposed changes:

- standard/publication number;
- relevant Clause, Table, and /or Figure number(s);
- wording of the proposed change; and
- rationale for the change.

References to the CSA Blood Standard in the *Blood Regulations* are ambulatory, i.e. as amended from time-to-time. Health Canada will review any changes to clauses of the CSA Blood Standard, referenced in the *Blood Regulations*, with respect to risk and the potential impact on the safety of blood.

## 1.4 Acronyms

BGTD	Biologics and Genetic Therapies Directorate
CMV	Cytomegalovirus
CSA	Canadian Standards Association
HBsAg	Hepatitis B surface antigen

HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HLA	Human leukocyte antigen
HPFBI	Health Products and Food Branch Inspectorate
HTLV I/II	Human T-lymphotropic virus-I/Human T-lymphotropic virus-II
IgA	Immunoglobulin A
PADP	Pre-Assessed Donor Program
US-FDA	United States Food and Drug Administration
WNV	West Nile virus

## **1.5 Definitions**

The additional definitions provided below are to assist in the interpretation of this guidance document.

“apheresis” means the process of withdrawing blood from a donor, separating specific components from the blood, and returning some or all of the remaining blood components to the donor.

“blood product fabricator” refers to the manufacturer of blood products from plasma for further manufacture. Innovation could bring about new blood products, so this term is not restricted to plasma within this guidance document.

“Clarifax” is a communication tool used to request information or to request clarification of information already filed.

“ISBT 128” is an international information standard for use in the labelling of blood for transfusion, blood components intended for use in the manufacture of a drug for human use, and products intended for transplantation that is managed and promoted by the International Council for Commonality in Blood Banking Automation (ICCBBA).

“lookback” is the process of identifying

- previous donations (and related blood components) from a donor who, on subsequent testing, is confirmed positive for a transfusion-transmissible infectious agent; and
- recipients who received blood components from a donor who is confirmed positive for a transfusion-transmissible infectious agent.

The “Medical Devices Bureau” of the Therapeutic Products Directorate (TPD) of Health Canada is the Canadian federal regulator responsible for licensing medical devices in accordance with the *Food and Drugs Act* and the *Medical Devices Regulations*. The Medical Devices Active Licence Listing (MDALL) is a database containing all licensed Class II, III and IV Medical Devices for sale in Canada. It can be found on the Health Canada website at [www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php).

“novel blood component” means a blood component that is not routinely processed or transfused in Canada. A novel blood component either provides a production benefit or is equivalent or superior to a reference product or fulfills an unmet clinical need.

“opportunity to be heard” means that an establishment can respond in writing to Health Canada in response to an action taken by Health Canada regarding the establishment’s Authorization, Establishment Licence or Registration. In some cases, a face-to-face meeting may occur.

“physician” means a person who is entitled to practise the profession of medicine under the laws of the province in which the person provides medical service.

“physician substitute” means a person who

- (a) acts under the general supervision and direction of a physician; and
- (b) is authorized to provide the services that may be provided by a physician according to the applicable laws of the province in which the person provides any of those services.

“pooling” includes mixing.

“quarantine” prevents suspected or confirmed non-conforming units of blood from being used for transfusion, further manufacture or distribution.

The term “senior executive officer” refers to an individual holding a position that has an assigned level of responsibility for activities the establishment conducts under the *Blood Regulations*. The term senior executive officer refers to a function within the establishment and is not necessarily a specific position title.

“traceback” is the process of investigating a report of a suspected transfusion-associated infection in order to identify a potential implicated donor. The purpose of the traceback investigation is to

- determine whether any donor who contributed to the transfusion is infected with, or positive for, serologic markers of the implicated infectious agent;

- trigger a recall of in date blood components contributed by that donor; or
- notify consignees and recipients of components collected from that donor.

## 2. GUIDANCE FOR IMPLEMENTATION

### Chart 1. The application of the *Blood Regulations* to different types of establishments

The purpose of this chart is to identify the sections of the regulations that apply to establishments who must hold an Authorization, Establishment Licence and/or a Registration because of the activities they conduct. See the Authorization (5–16), Establishment Licences (17–29) and Registration (30–37) sections of this guidance to learn more about the level of regulatory oversight required for the types of activities that your establishment conducts.

A	= Establishment holding an Authorization
EL	= Licensed Establishment
R-Auto	= Registered Establishment that conducts autologous activities
R-PADP	= Registered Establishment that has a Pre-Assessed Donor Program
R-TWPI	= Registered Establishment that conducts transformation activities (washing, pooling, irradiating)

<i>Blood Regulations</i> Section	Section Title	A/EL	R-Auto	R-PADP	R-TWPI
1	<b>Interpretation</b>	✓	✓	✓	✓
	<b>Application</b>				
2	Scope of Regulations	✓	✓	✓	✓
3	Non-application	✓	✓	✓	✓
4	Prohibitions	✓	✓	✓	✓
	<b>Authorizations</b>				
5	Authorization	✓			
6	Application for authorization	✓			
7	Issuance	✓			
8	Refusal	✓			
9	Significant changes	✓			
10	Emergency changes	✓			



<b>Blood Regulations Section</b>	<b>Section Title</b>	<b>A/EL</b>	<b>R-Auto</b>	<b>R-PADP</b>	<b>R-TWPI</b>
11	Administrative changes — notice	✓			
12	Other changes — annual report	✓			
13	New or amended terms and conditions	✓			
14	Suspension	✓			
15	Reinstatement	✓			
16	Cancellation	✓			
	<b>Establishment Licences</b>				
17(1)	Establishment licence required	✓			
17(2)	Test Labs		✓ (EL only for PADP)		
18	Application for establishment licence	✓			
19	(1) Inspection (2) Information on request	✓			
20	Issuance	✓			
21	Refusal	✓			
22	Changes requiring application to amend licence	✓			
23	Administrative changes — notice	✓			
24	Changes requiring amendment of licence by Minister	✓			
25	New or amended terms and conditions	✓			
26	Additional information	✓			
27	Suspension	✓			
28	Reinstatement	✓			
29	Cancellation	✓			

<i>Blood Regulations</i> Section	Section Title	A/EL	R-Auto	R-PADP	R-TWPI
	<b>Registration</b>				
30	Requirement to register		✓	✓	✓
31	Application for registration		✓	✓	✓
32	Registration		✓	✓	✓
33	Changes — notice		✓	✓	✓
34	Amendment by Minister		✓	✓	✓
35	Annual statement of compliance		✓	✓	✓
36	Additional information		✓	✓	✓
37	Cancellation		✓	✓	✓
	<b>Processing — Donor Suitability Assessment</b>				
38	Non-application — autologous donations		✓		
39	Licensed establishments	✓			
40	Past unsuitability	✓		✓	
41	Donor screening	✓		✓	
42	Exclusion criteria	✓		✓	
43	When donor determined unsuitable	✓		✓	
44	(1)When donor determined suitable (2) Reassessment (3) Notice	✓		✓	
	<b>Processing — Collection</b>				
45	Licensed establishments	✓			
46	Donor identification code		✓		
47	Donation code	✓	✓		
48	Labelling of containers	✓	✓		

<b>Blood Regulations Section</b>	<b>Section Title</b>	<b>A/EL</b>	<b>R-Auto</b>	<b>R-PADP</b>	<b>R-TWPI</b>
49	Collection procedures	✓	✓	✓	
50	Samples	✓	✓	✓	
51	Autologous donations		✓		
	<b>Processing — Testing</b>				
52	Authorization	✓			
53	Autologous donations — transmissible disease testing		✓		
54	Autologous donations — ABO and Rh		✓		
55	Medical devices		✓	✓ See also S.17(2)	
56(1)	Test results — allogeneic blood	✓			
56(2)	Test results — autologous blood		✓		
	<b>Blood Component Preparation</b>				
57	Licensed establishments	✓			
58	Registered establishments		✓		
	<b>Labelling</b>				
59	Non-application — pre-assessed donors			✓	
60	Language requirement	✓	✓		✓
61	General requirements	✓	✓		✓
62	Circular of information	✓			
63	Donation code	✓	✓		
64(1)	Contents of label — blood for transfusion	✓	✓		

<b>Blood Regulations Section</b>	<b>Section Title</b>	<b>A/EL</b>	<b>R-Auto</b>	<b>R-PADP</b>	<b>R-TWPI</b>
64(2)	Contents of label — Autologous blood		✓		
64(3)	Contents of label — blood for use in manufacture of drug for human use	✓			
66	(1) Designated donations (2) Change of use	✓			
67	Directed donations	✓			
68	Label verification	✓	✓		✓
	<b>Storage</b>				
69(1)(a)	Criteria — collecting establishment, licensed	✓			
69(1)(b)	Criteria — collecting establishment, registered		✓	✓	
69(2)	Criteria — receiving establishment	✓	✓		✓
70	Storage location	✓	✓	✓	✓
71	Segregation — autologous, designated and directed donations	✓	✓		✓
72	Segregation — untested or positive or reactive test results	✓	✓	✓	✓
	<b>Distribution</b>				
73(1)	Determination of safety — allogeneic blood	✓		✓	
73(2)	Determination of safety — autologous blood		✓		
74	(1) Verification (2) Prohibition — distribution	✓	✓	✓	✓

<b>Blood Regulations Section</b>	<b>Section Title</b>	<b>A/EL</b>	<b>R-Auto</b>	<b>R-PADP</b>	<b>R-TWPI</b>
75	Shipping containers	✓	✓	✓	✓
76	Storage during transportation	✓	✓	✓	✓
	<b>Transformation</b>				
77	Transformation methods				✓
78	Washing				✓
79	Pooling				✓
80	Irradiation				✓
	<b>Exceptional Distribution</b>				
81	Conditions	✓			
82	(1) Notice of exceptional distribution (2) Notice in establishment's records	✓			
83	Labelling	✓			
84(1)	Follow-up	✓			
	<b>Pre-Assessed Donor Programs</b>				
86	Program characteristics			✓	
87	Donor identification code			✓	
88	(1) Regular donor assessment and testing (2) Comparison of results (3) Discrepancies			✓	
89	At each collection			✓	
90	Labelling			✓	
91	When blood not transfused			✓	
	<b>Importation in Urgent Circumstances</b>				
92	Importation in urgent	✓			

<i>Blood Regulations</i> Section	Section Title	A/EL	R-Auto	R-PADP	R-TWPI
	circumstances				
	<b>Quality Management System</b>				
93	(1) Organizational structure (2) Oversight (3) Periodic review	✓	✓	✓	✓
94	Requirements	✓	✓	✓	✓
	<b>Operating Procedures</b>				
95	Operating procedures required	✓	✓	✓	✓
96	Requirements	✓	✓	✓	✓
97	Documented evidence	✓	✓	✓	✓
	<b>Personnel, Facilities, Equipment and Supplies</b>				
98	(1) Personnel (2) Competency	✓	✓	✓	✓
99	Facilities	✓	✓	✓	✓
100	Equipment	✓	✓	✓	✓
101	Storage equipment	✓	✓	✓	✓
102	Supplies	✓	✓	✓	✓
	<b>Error and Accident Investigation and Reporting</b>				
103	Error or accident of another establishment	✓	✓	✓	✓
104	Establishment's own error or accident	✓	✓	✓	✓
105	Requirement to cooperate	✓	✓	✓	✓
106	Investigation results	✓	✓	✓	✓
107	Reports to Minister	✓	✓	✓	✓
108	Annual Report	✓	✓	✓	✓

<i>Blood Regulations</i> Section	Section Title	A/EL	R-Auto	R-PADP	R-TWPI
	<b>Adverse Reaction Investigation and Reporting</b>				
	<b>Adverse Donor Reactions</b>				
109	Adverse Donor Reactions — Notice to Minister	✓	✓	✓	
	<b>Adverse Recipient Reactions</b>				
110	Required Action	✓	✓	✓	✓
111	Autologous Donations		✓		
112	Requirement to cooperate	✓	✓	✓	✓
113	Notice to Minister	✓	✓	✓	✓
114	(1) Results of investigation (2) Notice to be forwarded	✓	✓	✓	✓
115	Final report to Minister	✓	✓	✓	✓
116	Annual Report	✓	✓	✓	✓
	<b>Records</b>				
117	Record quality	✓	✓	✓	✓
118	Donation code part of all records	✓	✓	✓	✓
119	(1) Retention periods — allogeneic blood (2) Calculation of retention periods	✓		✓	
120	(1) Retention periods — autologous blood (2) Calculation of retention periods		✓		
121	(1) Retention				✓

<b>Blood Regulations Section</b>	<b>Section Title</b>	<b>A/EL</b>	<b>R-Auto</b>	<b>R-PADP</b>	<b>R-TWPI</b>
	periods — transformation (2) Calculation of retention periods				
123	Storage of records	✓	✓	✓	✓
124	<b>Powers of Inspectors</b>	✓	✓	✓	✓
125	<b>Consequential Amendment</b>	✓			
	<b>Transitional Provisions</b>				
126	Deemed authorization	✓			
127	Licence continued	✓			
128	(1) Delayed registration (2) Duration		✓	✓	✓
	<b>Coming Into Force</b>				
129(1)	One year after publication	✓	✓	✓	✓
129(2)	Subsections 4(4) to (6) and paragraph 64(1)(b)		✓	✓	✓

**Chart 2. Application of the *Blood Regulations* to establishments that are not required to obtain an Authorization, an Establishment Licence or a Registration**

Some establishments do not conduct activities for which an Authorization, an Establishment Licence or a Registration is required. However, these establishments must still meet the applicable sections of the *Blood Regulations* for the activities they conduct. These sections are identified in the chart below.

<b>Blood Regulations Section</b>	<b>Section Title</b>
1	<b>Interpretation</b>
	<b>Application</b>
2	Scope of Regulations
3	Non-application
4	Prohibitions



<b>Blood Regulations Section</b>	<b>Section Title</b>
	<b>Labelling</b>
60	Language requirement
61	General requirements
65	Aliquots
68	Label verification
	<b>Storage</b>
69(2)	Criteria — receiving establishment
70	Storage location
71	Segregation — autologous, designated and directed donations
72	Segregation — untested or positive or reactive test results
	<b>Distribution</b>
74	(1) Verification (2) Prohibition — distribution
75	Shipping containers
76	Storage during transportation
	<b>Transformation</b>
77	Transformation methods *applies to establishments that only pool cryoprecipitate
79	Pooling *applies to establishments that only pool cryoprecipitate
	<b>Exceptional Distribution</b>
81	Conditions
82	(3) Notice to be forwarded (4) Notice in recipient's file
84(2)	Results to be forwarded
85	When blood not transfused
	<b>Operating Procedures</b>
95	Operating procedures required
96	Requirements
97	Documented evidence *applies to establishments that only pool cryoprecipitate
	<b>Personnel, Facilities, Equipment and Supplies</b>
98	(1) Personnel (2) Competency
101	Storage equipment
	<b>Error and Accident Investigation and Reporting</b>
103	Error or accident of another establishment
104	Establishment's own error or accident
105	Requirement to cooperate
106	Investigation results
107	Reports to Minister
108	Annual Report

<b>Blood Regulations Section</b>	<b>Section Title</b>
	<b>Adverse Reaction Investigation and Reporting</b>
	<b>Adverse Recipient Reactions</b>
110	Required Action
112	Requirement to cooperate
113	Notice to Minister
114	(1) Results of investigation (2) Notice to be forwarded
115	Final report to Minister
116	Annual Report
	<b>Records</b>
117	Record quality
118	Donation code part of all records
121	Retention Periods - transformation *applies to establishments that only pool cryoprecipitate
122	(1) Retention periods — transfusion (2) Calculation of retention periods
123	Storage of records
124	<b>Powers of Inspectors</b>
	<b>Coming Into Force</b>
129(1)	One year after publication

## Section 1 Interpretation

The statements enclosed in the boxes are sections taken directly from the *Blood Regulations*.

### Definitions

**1.** The following definitions apply in these Regulations.

“accident”  
« *accident* »

“accident” means 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.

“Act”  
« *Loi* »

“Act” means the *Food and Drugs Act*.

“adverse reaction”  
« *effet indésirable* »

“adverse reaction” means an undesirable response that is associated with  
(a) in the case of a donor, the collection of blood; and  
(b) in the case of a recipient, the safety of the transfused blood.

“allogeneic”  
« allogénique »

“allogeneic”, in respect of blood or a blood donation, means that the blood is collected from an individual either for transfusion into another individual or for use in the manufacture of a drug for human use.

The collection of allogeneic blood for distribution into the general blood supply either for transfusion or for use in the manufacture of a drug for human use requires an Authorization and an Establishment Licence.

The collection of allogeneic blood from a pre-assessed donor for an emergency transfusion to a specific patient requires a Registration, while the testing of allogeneic blood from a pre-assessed donor requires an Establishment Licence.

“authorization”  
« homologation »

“authorization”, in respect of any blood or process, means an authorization that is issued under section 7.

“autologous”  
« autologue »

“autologous”, in respect of blood or a blood donation, means that the blood is collected from an individual for transfusion into the same individual at a later time.

Autologous blood must only be used for transfusion to the same individual from whom it was collected.

The scope of autologous blood collection, under the *Blood Regulations*, excludes the following because this type of blood is not considered to be collected for use at a later time:

- peri-operative blood that is collected and remains in the clinical patient care area, for example:
  - collection just prior to surgery (e.g., acute normovolemic hemodilution);
  - collection throughout surgery from the surgical site or an extracorporeal circuit (intraoperative); or
  - collection following surgery or trauma from body cavities, joint spaces, and other closed surgical or trauma sites (post-operative).
- blood that is collected to be radio-labelled for diagnostic purposes.

See section 71 for storage segregation requirements.

“blood”  
« sang »

“blood” means human blood that is collected either for transfusion or for use in the manufacture of a drug for human use, and for greater certainty, it includes whole blood and blood components.

The scope of blood, under the *Blood Regulations*, excludes blood products or blood derivatives.

Examples of blood components include red blood cells, plasma, platelets, and granulocytes. Blood components do not include products manufactured from plasma for further manufacture.

See section 2 of this guidance for the scope of application of the *Blood Regulations*.

“circular of information”  
« document d’information »

“circular of information” means a document that describes all of the following in relation to blood:

- (a) the composition and properties of the blood;
- (b) directions for storage and for use; and
- (c) indications for use, contraindications, warnings and a list of possible adverse reactions.

“critical”  
« essentiel »

“critical”, in respect of equipment, supplies and services, means that the equipment, supply or service could, if it does not meet its specifications, compromise human safety or the safety of blood.

Examples of critical equipment include, but are not limited to, those that are used in the collection of blood, the testing of blood, blood component preparation, storage, and transformation. The following examples are provided for your guidance and are not exhaustive.

### Examples of critical equipment

- a. apheresis equipment;
- b. automated blood extractors/presses;
- c. automated blood processors;
- d. automated blood testing systems and/or transmissible disease test equipment;
- e. automated dockers/sealers;
- f. automated microbial detection systems;
- g. cell counters or hematology analyzers used in blood or blood component assessment;
- h. cell washers/deglycerolization;
- i. centrifuge used for the processing of blood component units;
- j. electrophoresis devices;
- k. fast freezers;
- l. freezers used to store blood (units or samples);

- m. nucleic acid testing (NAT) instruments, including extractors or pipettors;
- n. platelet shakers;
- o. refrigerators; and
- p. thermometers and temperature probes (any type).

Critical equipment also includes critical software.

### **Examples of critical software**

- a. software for transferring data between automated devices; and
- b. software that analyzes data regarding the suitability of blood for transfusion or for further manufacture.

### **Examples of critical supplies**

- a. blood group or phenotype testing reagents;
- b. irradiation indicator labels;
- c. collection sets (bags and tubing);
- d. filters;
- e. labels; and
- f. reagents for transmissible disease test kits.

### **Examples of critical services**

- a. calibration and maintenance of critical equipment;
- b. laboratory testing;
- c. quality control;
- d. quality management;
- e. testing services; and
- f. training on critical equipment by vendor.

### **Examples of non-critical equipment or supplies**

- a. balances (any type);
- b. blood bag shaker;
- c. cell washers of the centrifuge type not used for deglycerolization;
- d. centrifuges not used for component separation or preparation;
- e. circulating bath;
- f. haemoglobinometers;
- g. heating bath;
- h. incubators (except platelet shaker/incubator);
- i. manual extractors for blood component preparation;
- j. microhaematocrit centrifuges;

- k. pipettes (except nucleic acid testing pipettors);
- l. thermosealers for making blood tubing segments for blood sampling;
- m. timers (any type); and
- n. weights (any type).

“designated donation”  
« don désigné »

“designated donation” means a blood donation that is made by a donor who is selected for medical reasons to make the donation for a specific recipient.

“directed donation”  
« don dirigé »

“directed donation” means a blood donation that is made by a donor who is known by the recipient and selected for medical reasons by the recipient’s physician.

“distribute”  
« distribution »

“distribute” does not include to transfuse.

Many requirements throughout the *Blood Regulations* are associated with the distribution of blood. This guidance document further explains the activity of distribution in various instances. Also refer to section 4, Prohibitions; section 73, Determination of safety; sections 81–85, Exceptional Distribution; section 92, Importation in Urgent Circumstances.

The following are some examples of distribution of blood under the *Blood Regulations*. In each of these instances, when blood is to be distributed to another establishment or to the operating theatre or the ward, the establishment must perform the additional verification steps required by section 74 of the *Blood Regulations*.

### **Example 1, Distribution of allogeneic blood for transfusion**

Allogeneic blood is processed by a licensed establishment for transfusion. After determining the blood is safe for transfusion, it is placed into inventory. Distribution occurs when the establishment sends the blood to another establishment. Distribution also occurs when the transfusion medicine laboratory sends the blood to the operation theatre or the ward.

Distribution can also occur if Hospital A receives a request for allogeneic units of blood for transfusion from Hospital B. Distribution occurs when Hospital A sends the blood to Hospital B.

### **Example 2, Distribution of autologous blood**

Autologous blood is processed for transfusion by a registered establishment. Before the autologous units of blood can be distributed, they must be determined safe for autologous transfusion. Distribution occurs when the establishment sends the autologous unit(s) of blood to the hospital.

Distribution can also occur within the same establishment if a registered establishment processes autologous blood for transfusion at the same establishment where it will be transfused. Before the autologous units of blood can be distributed, they must be determined safe for autologous transfusion. Distribution occurs when the transfusion medicine laboratory sends the blood to the operation theatre or the ward.

If an establishment sends blood from a mobile clinic to the processing facility, distribution has not taken place because the blood has not yet been declared safe for distribution for transfusion or for further manufacture.

### **Example 3, Distribution of blood for further manufacture**

Blood (plasma) is processed by a licensed establishment for the purpose of manufacturing into a drug for human use. After determining the blood is safe for distribution for further manufacture, it may be stored at the collection site. Distribution occurs when the establishment sends the blood to the blood product fabricator.

### **Example 4, Distribution of Red Blood Cells for immunization (iRBCs)**

Blood is processed by a licensed establishment for the purpose of immunization. Before the iRBCs are placed into inventory they must be determined safe for distribution. Distribution occurs from the location where the inventory is stored to the location where the immunization of the donor occurs. This can be within the same establishment.

“donation code”  
« code d’identification du don »

“donation code” means the unique group of numbers, letters or symbols, or combination of any of them, that an establishment assigns to a unit of blood at the time of collection.

“donor identification code”  
« code d’identification du donneur »

“donor identification code” means the unique group of numbers, letters or symbols, or combination of any of them, that an establishment assigns to a donor.

“donor suitability assessment”  
« évaluation de l’admissibilité du donneur »

“donor suitability assessment” means an evaluation of a donor that is based on all of the

following criteria:

- (a) the donor's medical history;
- (b) the results of any donor tests and physical examination; and
- (c) the donor's social history, to the extent that it is relevant in determining the presence of risk factors for diseases transmissible by blood.

- a. A donor's medical history refers to
  - conditions that could pose a risk to the donor; and
  - vaccinations, medications and transmissible diseases that could pose a risk to the recipient.
- b. A physical examination is one of the methods of qualifying a donor as acceptable for donating blood and is based on the establishment's authorized criteria.
- c. A donor's social history refers to the prior activities of a donor that could put the donor and recipient(s) at risk for infection with transmissible disease(s).

"error"  
« manquement »

"error" means a deviation from the operating procedures or applicable laws that could compromise human safety or the safety of blood.

"establishment"  
« établissement »

"establishment" means a person that conducts any of the following activities in respect of blood:

- (a) importation;
- (b) processing;
- (c) distribution;
- (d) transformation; or
- (e) transfusion.

**(e) transfusion**

Although blood transfusion itself is not regulated under the *Blood Regulations*, establishments that transfuse blood must meet the requirements of the *Blood Regulations* that apply to the activities that they conduct, such as storing blood.

"human safety"  
« sécurité humaine »

"human safety" means the safety of donors and recipients of blood, in so far as it relates to the safety of the blood.



Whenever the *Blood Regulations* or this guidance document refer to human safety, this means the safety of blood donors, or the safety of recipients of blood as long as human safety is associated with the safety of the blood processed and distributed under these *Blood Regulations*.

“medical director”  
« directeur médical »

“medical director”, in respect of an establishment, means a physician who is entitled under the laws of a province to practise the profession of medicine and who is responsible for all medical procedures carried out by the establishment and for the application of the operating procedures that relate to them.

“operating procedures”  
« procédures opérationnelles »

“operating procedures”, in respect of an establishment, means the component of the establishment’s quality management system that is composed of instructions that set out the processes to follow in conducting its activities.

“pre-assessed donor”  
« donneur pré-évalué »

“pre-assessed donor” means a donor who has been accepted into a pre-assessed donor program described in sections 86 to 91 from whom blood is taken in an emergency to be transfused before completion of the testing.

The term *pre-assessed donor* is used in the *Blood Regulations* to describe what was formerly referred to as a “walking donor.” See sections 86–91 of the *Blood Regulations* for requirements.

“processing”  
« traitement »

“processing” means any of the following activities:

- (a) donor suitability assessment;
- (b) collection;
- (c) testing; or
- (d) blood component preparation.

An establishment processes blood for transfusion or for further manufacture if it carries out any of the following activities: donor suitability assessment, collection, testing, blood component preparation. The scope of processing cannot extend beyond this interpretation.

Blood component preparation does not include transformation or dividing blood into aliquots.

“safety”  
« sécurité »

“safety”, in respect of blood, means that the blood has been determined safe for distribution or for autologous transfusion, as the case may be, in accordance with section 73, and includes

- (a) in the case of blood for transfusion, its quality and efficacy; and  
(b) in the case of blood for use in the manufacture of a drug for human use, its quality.

Whenever the *Blood Regulations* or this guidance document refer to the safety of blood, this means (a) the safety, quality and efficacy of blood for transfusion; and (b) the safety and quality of blood for use in the manufacture of a drug for human use.

Blood safety and quality, in the case of blood for transfusion or for further manufacture, are determinants of whether the blood is safe for distribution. Blood safety is the degree to which the blood for transfusion or for use in the manufacture of a drug for human use is free of harmful substances or infectious agents. Blood quality is defined by quality assurance procedures and is determined by the specifications set for blood and blood components. Blood safety and quality includes policies for mandatory testing, donor selection, collection procedures, testing methods, donation handling, storage, transportation, and distribution.

Blood efficacy, in the case of blood for transfusion, is a determinant of whether the blood is safe for distribution. Blood efficacy is the capacity to produce a desired or intended result or effect in blood recipients.

“serious adverse reaction”  
« *effet indésirable grave* »

“serious adverse reaction” means an adverse reaction that results in any of the following consequences for the donor or recipient:  
(a) their in-patient hospitalization or its prolongation;  
(b) persistent or significant disability or incapacity;  
(c) medical or surgical intervention to preclude a persistent or significant disability or incapacity;  
(d) a life-threatening condition; or  
(e) death.

“standard”  
« *norme* »

“standard” means National Standard of Canada CAN/CSA-Z902 published by the Canadian Standards Association and entitled *Blood and blood components*, as amended from time to time.

Throughout this guidance document, the *standard* is referred to as the CSA Blood Standard.

“transformation”  
« *transformation* »

“transformation”, in respect of blood components, means washing, pooling and irradiation that are performed after blood has been determined safe for transfusion.

The definition of *transformation* states activities included within its scope: washing, pooling, and irradiation. The scope cannot extend beyond this interpretation.

The definition of *transformation* in the *Blood Regulations* does not include pathogen reduction technologies. Transformation does not include dividing blood into aliquots.

“unexpected adverse reaction”  
« effet indésirable imprévu »

“unexpected adverse reaction” means an adverse reaction that is not identified among the possible adverse reactions either in the circular of information or in any other information provided to the recipient.

*Unexpected adverse reaction* means an adverse reaction whose nature, severity or outcome is not consistent with the circular of information or in any other information provided to the recipient.

## Sections 2–3 Application

### Section 2 Scope of the Regulations

Scope of Regulations

**2.** These Regulations apply to blood that is collected for transfusion or for use in the manufacture of a drug for human use.

The scope of the *Blood Regulations* applies to human blood that is collected from donors

- for the purpose of transfusion;
- as a raw material for further manufacture into blood products; and
- for the immunization of donors of plasma for further manufacture (e.g., red blood cells for immunization).

Included within this scope is

- the safety of blood donors;
- the safety of the blood collected and processed from these donors; and
- the safety of blood recipients.

### Section 3 Non-application

Non-application — various therapeutic products

**3.** (1) These Regulations do not apply to any of the following therapeutic products:

(a) cord blood and peripheral blood that are for use in lymphohematopoietic cell transplantation and that are regulated under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*;

- (b) blood that is the subject of clinical trials under Division 5 of Part C of the *Food and Drug Regulations*; or  
(c) blood that is imported for use in the manufacture of a drug for human use.

Non-application — regulations

(2) Except for section A.01.045 of the *Food and Drug Regulations*, no other regulation made under the Act applies to blood that is the subject of these Regulations.

Non-application — imported rare phenotypes

(3) Sections 4 to 124 do not apply to blood that is of a rare phenotype if it is imported pursuant to a prescription.

**3(1)** Table 1 describes blood that the *Blood Regulations* do not apply to.

**Table 1. Non-application — various therapeutic products**

1. Cord blood and peripheral blood for use in lymphohematopoietic cell transplantation	See the <i>Safety of Human Cells, Tissues and Organs for Transplantation Regulations</i>
2. Blood that is the subject of a clinical trial	See sections C.04.230– C.04.241 and Division 5 of Part C of the <i>Food and Drug Regulations</i>
3. Plasma for further manufacture <i>after</i> an establishment distributes the plasma to the blood product fabricator	See Part C, Divisions 1, 1A, 2, C.04.001. – C.04.020., C.04.230.–C.04.241. and 8 of the <i>Food and Drug Regulations</i>
4. Blood products, such as plasma derivatives, and blood product manufacturing	See the <i>Food and Drug Regulations</i>
<p>- examples of blood products include: coagulation factors, immune globulins, hyperimmune globulins, and albumin</p>	
5. Blood for further manufacture collected outside Canada	Regulated by the foreign jurisdiction from which it is imported
	See the <i>Food and Drug Regulations</i> for the importation of blood for further manufacture

6. Blood that is of a rare phenotype — not available in Canada — and that is imported in accordance with a prescription      Proof of prescription must be provided at port of entry

## Section 4 Prohibitions

### Allogeneic blood

**4.** (1) Subject to subsections (2) and (3), an establishment must not import, distribute or transfuse allogeneic blood unless it is processed by an establishment in accordance with an authorization and determined safe for distribution under subsection 73(1).

### Exception — pre-assessed donor programs

(2) Subsection (1) does not apply if the processing is conducted as part of a pre-assessed donor program.

### Exception — urgent circumstances

(3) An establishment may, in urgent circumstances,  
(a) import, in accordance with section 92, allogeneic blood that has not been processed in accordance with an authorization; and  
(b) distribute or transfuse such blood if the importer imported it in accordance with section 92.

### Pre-assessed donors

(4) An establishment must not transfuse allogeneic blood that is collected from a pre-assessed donor unless the establishment has complied with the requirements of sections 86 to 91.

### Transformations

(5) An establishment must not distribute or transfuse blood that has been transformed unless the transformation is conducted by a registered establishment.

### Autologous blood

(6) An establishment must not distribute or transfuse autologous blood unless it has been processed by a registered establishment and determined safe for autologous transfusion under subsection 73(2).

### Investigations

(7) An establishment must not distribute or transfuse blood in either of the following circumstances:  
(a) while the blood is in quarantine; or  
(b) when the results of an investigation into a suspected error or accident or an unexpected adverse reaction or serious adverse reaction are inconclusive or indicate that there has been a compromise to the safety of the blood.

**4(1)** Allogeneic blood must be processed in accordance with an Authorization, in order for an establishment to import, distribute or transfuse the blood.

When allogeneic blood is the subject of exceptional distribution, establishments must comply with the requirements in sections 81 through 85 of the *Blood Regulations*. Exceptional distribution is not the same as importation in urgent circumstances.

See subsection 4(2) for the exception concerning allogeneic blood collected from pre-assessed donors.

See subsection 4(3) for the exception concerning the importation of blood in urgent circumstances.

**4(2)** If an establishment conducts processing on allogeneic blood as part of a Pre-Assessed Donor Program, an Authorization is not required. See subsection 4(4) for the requirement to register.

**4(3)** In urgent circumstances, a licensed establishment may import blood that has not been processed in accordance with an Authorization. The establishment must have a licence to import blood in urgent circumstances as required in paragraph 18(1)(l) and subsection 92(1).

See section 92 regarding the information a licensed establishment must provide the Minister before Health Canada will allow the importation of blood in urgent circumstances.

**4(4)** In order to operate a Pre-Assessed Donor Program, an establishment must register under subsection 30(1) of the *Blood Regulations* and comply with specific requirements in sections 86 to 91.

An establishment that tests blood collected in a Pre-Assessed Donor Program must hold an Establishment Licence as required by subsection 17(2) of the *Blood Regulations*.

**4(5)** The *Blood Regulations* list specific transformation activities that may be conducted within the scope of a Registration. See section 1 (Interpretation, *transformation*), subsection 30(1) and sections 77 through 80 of the *Blood Regulations*.

**4(6)** An establishment must not process autologous blood unless it is registered under subsection 32(1) of the *Blood Regulations*.

**4(7)(a)** An establishment must quarantine blood as stated in the requirements in section 56, paragraphs 103(1)(b), 104(1)(b), 110(1)(b), subsection 110(3) and section 111. See sections 70 through 72 of this guidance document for guidance concerning the segregation of blood.

**4(7)(b)** An establishment must consider the prohibition in paragraph 4(7)(b) when notifying other establishments of the results of an investigation into a suspected error or accident or an unexpected adverse reaction or serious adverse reaction and any action required to be taken. See subsections 106(1) or 114(2).

## Sections 5–16 Authorizations

### Section 5 Authorization

Authorization — processing

**5.** (1) Except for an establishment that only tests blood, an establishment that processes allogeneic blood must have an authorization to do so.

Exception — pre-assessed donor programs

(2) Subsection (1) does not apply if the processing is conducted as part of a pre-assessed donor program.

Authorization — importation

(3) Subject to section 92, an establishment that imports blood must have an authorization to do so, unless the blood is already the subject of another establishment's authorization.

#### 5(1)

#### What is an Authorization?

An Authorization is permission from Health Canada for an establishment to process allogeneic blood: i.e. conduct donor suitability assessments, collect blood from donors, test blood, and prepare blood components.

A new establishment obtains an Authorization by applying to the Biologics and Genetic Therapies Directorate (BGTD) for an Authorization and filing information for review. Licensed establishments apply for an amendment to their Authorization whenever they intend to make a significant change to their processing activities.

See section 1, the Interpretation section of this guidance document, for the definitions of “allogeneic” and “processing.”

Establishments previously licensed under the *Food and Drug Regulations* should refer to the Transitional Provisions in sections 126–128 of the *Blood Regulations* to understand how their Establishment Licence under the *Food and Drug Regulations* will transition to an Authorization under the *Blood Regulations*.

#### What is the difference between an Authorization and an Establishment Licence?

##### *Authorization*

An Authorization gives an establishment the authority to process blood by describing

- the processes related to blood at the establishment; and
- the blood components prepared using these processes.

The BGTD reviews the evidence and the information provided by the establishment on the processes that the establishment intends to conduct. An on-site evaluation may complement the review process. An on-site evaluation confirms that the documents filed for review correspond with what the establishment proposes to implement. A Notice of Authorization or a Notice of Authorization Amendment with or without Terms and Conditions is issued if the Minister, as represented by Health Canada's BGTD, is satisfied that the processes do not pose an unacceptable risk to human safety or the safety of the blood.

### ***Establishment Licence***

An Establishment Licence (EL) is a licence issued to an establishment in Canada allowing them to conduct activities requiring a licence in a building which has been assessed and is compliant with the *Blood Regulations* and the Authorization.

Most establishments requiring an Establishment Licence will also require an Authorization. An exception is an establishment that only tests allogeneic blood. See subsections 5(1) and 17(2) of the *Blood Regulations*.

The Minister, as represented by Health Canada's Health Products and Food Branch Inspectorate, issues the Establishment Licence. See sections 17–29 for Establishment Licence requirements.

**5(2)** An Authorization is not required to process blood from pre-assessed donors. An establishment must have a Registration to process allogeneic blood in a Pre-Assessed Donor Program. See sections 30–37 for requirements specific to Registration. Chart 1 — The application of the *Blood Regulations* to different types of establishments — provides information about which sections of the regulations would apply to pre-assessed donor programs.

**5(3)** The term “import” in this and other sections applies only to the importation of blood for transfusion.

Blood imported into Canada for transfusion falls within the scope of an Authorization. The importer or the foreign establishment can apply for the Authorization. See paragraph 18(1)(k) for licensing requirements with respect to the importation of blood for transfusion.



## Section 6 Application for an authorization

### Application for authorization

**6. (1)** An establishment must file with the Minister an application for an authorization in the form established by the Minister. The application must be dated and signed by a senior executive officer and contain all of the following information:

- (a) the applicant's name and civic address, and its postal address if different, and the civic address of each building in which it proposes to conduct its activities;
- (b) 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;
- (c) the name and telephone number of a person to contact in an emergency, if different from the person mentioned in paragraph (b);
- (d) a statement of whether the establishment proposes to import whole blood or blood components;
- (e) a list of the whole blood and blood components that the establishment proposes to process or import;
- (f) a list of the processing activities that are proposed to be conducted in each building;
- (g) a description of the establishment's facilities, including its buildings and all critical equipment, supplies and services that it proposes to use in the conduct of its activities;
- (h) a description of the processes that the establishment proposes to use or to have used on its behalf in respect of blood and each blood component in the conduct of its activities;
- (i) a draft of each proposed label and circular of information;
- (j) evidence that any foreign establishment that it proposes to have conduct any of its processing activities is licensed in the foreign jurisdiction; and
- (k) sufficient evidence to demonstrate that the proposed processes will not compromise human safety and will result in blood that can be determined safe for distribution.

### Site inspection

**(2)** During the review of an application, the Minister may inspect the establishment's facilities to evaluate on site the information provided in the application.

### Information on request

**(3)** An establishment must provide the Minister, on written request, with any information that the Minister determines is necessary to complete the Minister's review of the application, by the date specified in the request.

**6(1)** The application for an Authorization must contain sufficient information to enable the Minister to assess human safety and to demonstrate that the processes will result in blood that can be determined safe for distribution. An establishment must send their application for an Authorization, evidence requirements, and questions concerning the Authorization to the BGTD's Blood Establishment Regulation Unit:

Blood Establishment Regulation Unit  
Office of Regulatory Affairs  
Biologics and Genetic Therapies Directorate  
Address Locator #0601C  
100 Eglantine Driveway  
OTTAWA ON K1A 0K9

Tel (613) 957-1722  
Fax (613) 948-3564  
Email [bgtd.ora@hc-sc.gc.ca](mailto:bgtd.ora@hc-sc.gc.ca)

## The Application Process

### *Pre-Application Blood Establishment Meetings*

Prior to applying for an Authorization, an establishment should consider a meeting or teleconference to discuss application requirements with the BGTD. Meetings or teleconferences provide an opportunity to define the purpose of the application and to discuss various application requirements.

A written request for a pre-application meeting should be received by the BGTD no less than 1 month prior to the proposed meeting date and should include the following information:

- the purpose of the meeting;
- a brief description of the issues to be discussed at the meeting;
- two or more proposed dates and times for the meeting; and
- a note indicating if participation by other areas of Health Canada might facilitate the discussion (e.g., Medical Devices Bureau or Health Products and Food Branch Inspectorate).

In preparation for a pre-application meeting, the establishment must provide a meeting package two weeks prior to the date of the meeting containing the following:

- i. purpose of the meeting;
- ii. agenda;
- iii. list of establishment participants;
- iv. background information;
- v. presentation to be made, if applicable; and
- vi. a list of any questions/issues to be discussed with Health Canada.

It is recommended that the meeting package be provided electronically to the Blood Establishment Regulation Unit for distribution within Health Canada.

### ***Receipt of Application***

The BGTD acknowledges receipt of the application in writing. The date of the acknowledgement letter denotes the start of the screening period. The BGTD assigns a control number to each application. A *control number* is a unique tracking number that is assigned by the BGTD to each application at the time it is initially received. This number is referenced in all correspondence concerning the application.

The BGTD assigns a document number to the initial application package and to each additional instalment of information. Document numbers are also assigned to letters and other correspondence related to an application issued by the BGTD to the establishment.

A teleconference or meeting can be requested by either the BGTD or the establishment to discuss the application at any point during the application process.

### ***Screening of Application***

The BGTD screens all application-related materials for acceptability including, but not limited to, quality and completeness and to determine if the proposed processes or changes to processes are in compliance with the *Blood Regulations*. The screening process is separate from the review process and occurs prior to the review process. During the screening process, the BGTD also identifies the type of application:

#### *Types of applications*

*Regular* — not a rolling or accelerated application

*Rolling* — an application with multiple parts that the establishment files at different times; generally, a rolling application is required when the need for a pilot project and/or production trial is anticipated. All applications for the authorization of a new establishment are rolling applications.

*Accelerated* — accelerated applications are those where the establishment and the BGTD agree that the application will be screened and reviewed in a shortened time frame due to safety or operational concerns. The establishment must communicate these concerns and the critical timeline for implementation in writing to the BGTD. The establishment must provide adequate rationale for the accelerated status and the critical timeline.

In the case where Health Canada issues a directive requiring the rapid implementation of a change, the accelerated status is assumed and no written rationale is required.

The BGTD reviews accelerated applications ahead of others already filed or under review. Review times will depend upon the circumstances and the BGTD will communicate the review timeline to the establishment in a timely manner.

### ***Solicited Information During Screening***

The BGTD may request additional information or clarification from the establishment through various forms of communication, including information requests known as *screening clarifaxes*. The establishment must provide a rationale if they do not deem it necessary to provide a response. The response to the clarifax (*solicited information*) must be provided by the date indicated in the clarifax; however, the establishment may request an extension.

### ***Screening Deficiencies***

The BGTD may also issue a Screening Deficiency Notice (SDN) if there are significant omissions or inadequacies that prevent a review from being performed. The Screening Deficiency Notice outlines the deficiencies and indicates the date after which the BGTD will not accept a response to the Screening Deficiency Notice. The establishment may

1. withdraw the application; or
2. provide a response to the Screening Deficiency Notice, containing the identified information, by the indicated response date:
  - after receipt of the response to the Screening Deficiency Notice, a new screening period commences;

If the establishment fails to provide all requested information by the indicated response date, a Notice of Refusal to Issue an Authorization or a Notice of Refusal to Amend an Authorization may be issued.

Following a withdrawal or a Notice of Refusal, the establishment may re-file the entire application.

- This application will be processed as a new application and assigned a new control number.
- The re-filed application must cross-reference the original control number.

- Information and material filed in the original application, and that remains unchanged, should be clearly identified.

If the application is found to be acceptable for review, the BGTD issues an Acceptable Screening Letter to the establishment confirming the date the application becomes part of the review workload.

### ***Review of Application***

Once the BGTD accepts an application for review, the BGTD evaluates the information and supporting evidence to determine if there is an unacceptable risk to human safety or the safety of blood.

In cases where the BGTD receives extensive information (e.g. evidence of successful validation) from the establishment, either as an instalment in a multipart application or as solicited information, the review period begins on the day the last such information is screened and deemed acceptable for review by the BGTD.

Once all the necessary information and material has been received and reviewed, the BGTD's decision to accept or reject the application is issued. See section 7 for guidance on Issuance of an Authorization.

## **Content — Application for an Authorization**

An application for an Authorization must contain sufficient information and evidence to enable the Minister to assess the risk to human safety and to demonstrate that the proposed processes will result in blood that can be determined safe for distribution.

### ***6(1)(a), (b) and (c) Administrative Information***

The establishment must provide the administrative information in paragraphs 6(1)(a)–(c). The person named as a contact concerning the application in paragraph 6(1)(b) may be the same person to contact in an emergency in paragraph 6(1)(c).

### ***6(1)(d) Importation***

The establishment must state whether they are proposing to import whole blood or blood components, as applicable.

**6(1)(e) List of blood components**

The establishment must provide a list of the names of the allogeneic blood and blood components that they propose to process (including blood for use in the manufacture of a drug for human use) and a list of allogeneic blood for transfusion the establishment is proposing to import. The names must fully describe listed components, e.g., Platelets (leukoreduced)-apheresis-CMV negative-IgA deficient.

**6(1)(f) List of processing activities**

The establishment must provide a list of the processing activities with respect to allogeneic blood that it proposes to conduct in each building. These activities must correspond to the activities that are listed on the establishment's licence.

Examples of processing activities include the following:

- donor suitability assessment of donors of blood for transfusion;
- apheresis collection of plasma for the manufacture of a drug for human use;
- nucleic acid testing of whole blood for viral transmissible disease agents; and
- blood component preparation by the Buffy Coat method.

**6(1)(g) Facilities — Buildings and Critical Equipment, Supplies, and Services**

The establishment must provide the following:

- (i) for each building the establishment must provide
  - a building floor plan, including locations of built-in equipment such as walk-in freezers; and
  - evidence that all facility systems (e.g. electrical, ventilation, water, security, temperature monitoring, etc.) are commissioned or validated successfully.
- (ii) a description of all critical equipment, supplies, and services, including the functions of each.

See section 1, the Interpretation section of this guidance, for the definition of *critical* and for examples of critical equipment, supplies, and services.

The application must contain adequate evidence of successful validation of the equipment performed at the establishment, including installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ), as applicable.

Equipment used in the processing of blood is often a medical device requiring a medical device licence issued by the Medical Devices Bureau (MDB) of the Therapeutic Products Directorate at Health Canada. The applicant should contact the MDB if they have any questions concerning the licencing of medical devices. The establishment should include in their application evidence of a current, valid medical device licence for all critical equipment and supplies that are also medical devices.

### ***6(1)(h) Proposed processes***

An establishment's application for an Authorization must include a description of and all relevant evidence for the processes that the establishment proposes to implement in order to process allogeneic blood, from the time the establishment assesses the donor until the establishment determines that the unit of blood is safe for distribution. This includes the storage and labelling of allogeneic blood components during processing activities but prior to and at the point of determination that the blood is safe for distribution. See subsection 73(1) for the determination of safety of allogeneic blood for distribution.

Allogeneic blood processed in accordance with an Authorization must have the processing establishment's licence number on its label (see paragraph 64(1)(b)). See section 1, the Interpretation section of this guidance document, for the definition of *processing*.

Note: An establishment must apply for a registration if they conduct autologous blood processing activities, transformation activities or have a Pre-Assessed Donor Program. See section 30.

*Contract Establishments:* An establishment that holds an Authorization may contract out processing activities to an establishment in Canada licensed under the *Blood Regulations* for those activities; for example, testing of blood samples for viral markers.

A contract establishment that *only* tests blood samples and does no other processing activities under the *Blood Regulations* does not have to apply for an Authorization if they are under contract to an establishment that holds an Authorization for testing. See subsection 5(1). The tests on blood samples performed by the contract establishment must accord with those specified in the Authorization. The establishment that holds the Authorization assumes the responsibility for testing and is required to apply to Health Canada for Authorization amendments for any significant changes to that process.

For contracts with foreign establishments, see paragraph 6(1)(j).

### **6(1)(i) Labels**

For each allogeneic blood component that the establishment proposes to process, the establishment must provide Health Canada with the proposed final blood container label. In the case of allogeneic blood for transfusion, the establishment must provide the draft text of the circular of information. Labels for autologous blood, labels added to units of blood following transformation (transformation labels) and labels for blood collected in a Pre-Assessed Donor Program do not need to be provided to Health Canada for review.

### **6(1)(j) Foreign establishment: contracted processes**

An establishment that proposes to contract out any of its activities to a foreign establishment must provide evidence to Health Canada that the foreign establishment has a current licence in the foreign jurisdiction. The establishment in Canada that holds the Authorization for the contracted processes assumes the responsibility for these processes and is required to apply to Health Canada for Authorization amendments for that activity.

Paragraph 6(1)(j) also applies if an establishment imports blood from a foreign establishment. If an establishment imports blood for transfusion — including the importation of red blood cells for the immunization of source plasma donors — the blood must meet the importation requirements described in the establishment's Authorization. See also section 92, Importation in Urgent Circumstances.

### **6(1)(k) Sufficient evidence**

An establishment must provide sufficient evidence to Health Canada when applying for an Authorization, including the following:

1. all required data and information about the safety of each type of allogeneic blood component that it proposes to process;
2. all required data and information to demonstrate that the processes it uses will result in allogeneic blood that is safe, including:
  - a. donor suitability assessment
  - b. post-donation information
  - c. testing
  - d. blood component preparation
  - e. labelling prior to distribution



- f. circular of information
  - g. storage prior to distribution
  - h. exceptional distribution
3. evidence of successful validation of equipment including documented executed protocols; the validation of equipment should include the validation of any software associated with the equipment;
4. evidence that the components of its computer system are validated and that it has operating processes in place.

## On-site evaluation

**6(2)** Health Canada may carry out an on-site evaluation (OSE) to complement the review of an application. The scheduling of the on-site evaluation will be done in consultation with the establishment and documented in writing. One or more staff members from Health Canada may participate in the OSE.

The issuance of an Authorization may be conditional on a successful on-site evaluation. An on-site evaluation may be used to

- review evidence, documentation or data;
- observe processes;
- view a demonstration of new equipment.

The blood establishment should make every effort to make available all relevant documents and materials and ensure that subject specialists are available to answer questions.

Results of the on-site evaluation will be verbally summarized for the establishment prior to completing the visit. All actions to be taken by the establishment will be documented in writing at the close of the OSE, if possible, or within 15 days subsequent to the OSE. Time frames for responses will be identified.

## Solicited information during review

**6(3)** During the review of an application, the BGTD may request that the establishment provide additional information if the information provided is found to be insufficient or unclear. This type of information is referred to as *solicited information* and is used to determine human safety or the safety of the blood.

The BGTD may request solicited information during a teleconference or meeting; through a clarifax; or in the form of a Notice of Deficiency. A clarifax may be transmitted by facsimile or by email in standard format. An establishment must provide the BGTD with the solicited information by the date specified in the request; however, the establishment may request an extension. The establishment must provide a rationale if they decide it is not necessary to provide a response.

### **Notice of Deficiency**

If an application has deficiencies precluding further evaluation or if an establishment's response to a review clarifax is inadequate, the BGTD issues a Notice of Deficiency (NOD). The NOD identifies the deficiencies and indicates the date after which the BGTD will not accept a response to the Notice of Deficiency. The establishment may provide a response to the Notice of Deficiency referencing the original application control number and containing the identified information. The establishment may also choose to file a letter to cancel the application; the BGTD will issue a Cancellation Acknowledgement Letter.

The establishment has 90 days to respond to the Notice of Deficiency. The review is inactive until the BGTD receives a response. Following receipt of the response to the NOD, a new screening period commences.

If the establishment does not provide a response to the Notice of Deficiency within the specified time frame and does not cancel their application, or if the application remains deficient, the BGTD will issue a NOD-Withdrawal Letter.

If the establishment is unable to meet the response date specified in the Notice of Deficiency, they should provide the BGTD with a written request and justification for an extension prior to the end of the 90 day period.

Following a cancellation of an application by the establishment or when a NOD-Withdrawal Letter is issued by the BGTD, the establishment may re-file the application (see section 8).

## **Section 7 Issuance**

### **Issuance**

**7.** On completion of the review of an application, the Minister must issue an authorization, with or without terms or conditions, if she or he determines that the establishment has provided sufficient evidence to demonstrate that issuance of the authorization will not compromise human safety or the safety of blood.

## Notice of Authorization

When the BGTD completes the review of the information and evidence in the establishment's application and finds it acceptable, the BGTD issues a Notice of Authorization that allows the establishment to proceed with implementation and summarizes the following information:

- a. name of the establishment;
- b. blood components that the establishment may process;
- c. processing activities that the establishment may perform;
- d. civic address of each building and the processing activities to be conducted at each location; and
- e. any terms and conditions on the Authorization.

The Notice of Authorization may also list the following:

- f. laboratories or other facilities with whom the establishment has contracted processing activities:
  - i. domestic; or
  - ii. foreign;
- g. approved control documents;
- h. establishment computer systems and major software applications and their version numbers, such as electronic donor screening software applications, donor or blood management systems, or laboratory information systems;
- i. test kits used to qualify donors, e.g. transmissible disease, blood group or red blood cell antibodies (including the Medical Devices Bureau licence number and the date approved); and
- j. medical devices in use, e.g. major testing platforms (including the Medical Devices Bureau licence number and the date approved).

The BGTD issues a Notice of Authorization or a Notice of Authorization with Terms and Conditions following the review and approval of an establishment's original application for an Authorization. All subsequent notices following review and approval of applications to amend an

Authorization are Notices of Authorization Amendment (section 9) or Notices of Authorization Amendment with Terms and Conditions (section 13).

## Section 8 Refusal

Refusal

**8.** The Minister may refuse to issue an authorization if she or he determines that the information provided by the establishment in its application is inaccurate or incomplete.

### Notice of Insufficient Information

During the review, if the BGTD finds that the establishment's information in the application is insufficient to demonstrate that issuance of the Authorization will not compromise human safety or the safety of blood, the BGTD may issue a Notice of Insufficient Information explaining why the information in the application is insufficient.

The establishment has 90 days to respond to the Notice of Insufficient Information. The review is inactive until the BGTD receives a response to the Notice of Insufficient Information. Following receipt of the response, a new screening period commences.

If the establishment fails to respond within 90 days, or the BGTD determines that the application remains non-compliant, the BGTD will issue a Notice of Insufficient Information Withdrawal Letter. The establishment may also choose to file a letter to cancel the application in which case the BGTD will issue a Cancellation Acknowledgement Letter.

If the establishment is unable to respond within the 90 day period, they should provide the BGTD with a written request and justification for an extension prior to the end of the 90 day period.

Following cancellation of an application by the establishment or when a Notice of Insufficient Information Withdrawal Letter is issued by the BGTD, the establishment may re-file the application.

### Notice of Refusal

The BGTD may issue a Notice of Refusal to Issue an Authorization or a Notice of Refusal to Issue an Authorization Amendment in any of the following circumstances:

- if the establishment provided inadequate evidence to support the proposed processes;
- if there were inaccuracies in the application;
- if false or misleading statements were made; or

- if the processes reviewed were found to pose an unacceptable risk to human safety or to the safety of blood.

The Notice of Refusal delineates the reasons for the refusal and provides the establishment with the opportunity to be heard in writing. The establishment may choose to re-file the application.

## Re-filing

When an application is re-filed

- the re-filed application will be processed as a new application and assigned a new control number;
- the application should cross-reference the original control number; and
- the information and material filed in the original application, and that remains unchanged, should be clearly identified.

## Section 9 Significant Changes

Significant changes

**9.** (1) Before making a significant change, an establishment must file with the Minister an application to amend its authorization and include with it all relevant information to enable the Minister to determine whether the change or the way in which it is implemented could compromise human safety or the safety of blood.

Applications to amend

(2) Sections 6 to 8 apply to an application to amend an authorization, with any necessary modifications.

Meaning of “significant change”

(3) In this section and sections 10 and 12, “significant change” means any of the following changes:

- (a) the addition of blood or a blood component to the list required by paragraph 6(1)(e);
- (b) the deletion of or a change to any authorized process;
- (c) the addition of a process described in paragraph 6(1)(h); or
- (d) a change to the description of the establishment’s facilities referred to in paragraph 6(1)(g).

**9(1)** An establishment must file an application with the BGTD to amend their Authorization if they intend to make a significant change to their Authorization. The meaning of *significant change* is described in subsection 9(3) of the *Blood Regulations*.

## Application to amend an Authorization — Minimum requirements

Applications for all significant changes have the same minimum information requirements:

- detailed description of the proposed changes;
- rationale for the proposed changes;
- risk assessment; and
- contact information, as required by paragraphs 6(1)(b) and 6(1)(c) of the *Blood Regulations*.

### **Additional requirements, where applicable**

- Medical Device Bureau approval for medical devices;
- clinical data;
- scientific or technical data;
- a detailed description of new or modified critical equipment, supplies, or services if its operation or function differs from its authorized approval;
- impact on the blood management computer system;
- a description of changes to blood labels, including the Circular of Information (include new or revised labels);
- training plan;
- validation plan;
- validation results; and
- implementation schedule.

The application to amend the Authorization must be dated and signed by the senior executive officer stating that all of the information in the application is accurate and complete. See Subsection 6(1).

Questions regarding significant changes, new information that could trigger an amendment, and the Authorization amendment process should be directed to the Blood Establishment Regulation Unit at the BGTD. See subsection 6(1) of this guidance for contact information.

**9(2)** When an establishment applies to amend an Authorization, sections 6 through 8 of the *Blood Regulations* apply. See sections 6 through 8 of this guidance.

The BGTD may require an on-site evaluation of the establishment following a review of the submitted documentation, depending on the nature of the change and the supporting evidence. See subsection 6(2).

The BGTD aims to screen an application to amend an Authorization within 15 days and to review the application within 90 days following the date the application is accepted into review. An establishment is prohibited from implementing changes filed in an application to amend an Authorization prior to approval from Health Canada, even though the review may extend beyond 90 days.

### **Division of an application to amend an Authorization**

Occasionally, an establishment files an application pertaining to two or more unrelated topics. The BGTD may divide the original application into two or more applications and assign a separate control number to each application. This may occur during the screening or review of the application. When the BGTD divides an application, the establishment will receive notice of the division in writing.

### **Notice of Authorization Amendment**

When the BGTD completes the review of an application to amend an Authorization and finds it acceptable, the BGTD issues a Notice of Authorization Amendment that allows the establishment to proceed with implementation of the significant change. Any significant changes approved in the Authorization amendment will be indicated in the Notice.

The sum of the Notice of Authorization and all of the Notices of Authorization Amendment constitutes the establishment's Authorization.

### **9(3)(a) Addition of blood or a blood component**

A significant change includes the addition of blood or a blood component or a novel blood component to the list of blood or blood components that the establishment proposes to process or import. See 1.5 Definitions, *novel blood component*.

It is strongly recommended that an establishment consult with the BGTD prior to applying for an amendment to an Authorization when the establishment proposes to introduce

- a medical device that has the potential to produce an effect on a blood component; or

- a novel blood component developed in conjunction with a medical device manufacturer.

### **9(3)(b) Deletion or change to any authorized process**

The meaning of *significant change* includes deleting or changing any authorized process.

### **9(3)(c) Addition of a process**

An establishment must file an application with a detailed description of any new process that the establishment proposes to use in respect of each type of blood and blood component in the conduct of its activities.

### **9(3)(a), 9(3)(b) and 9(3)(c) Pilot studies and/or production trials**

Pilot studies or production trials are sometimes required to provide the necessary evidence to demonstrate that changes to processes or blood components do not negatively impact human safety or the safety of blood. When an establishment wishes to implement a new or amended process or a new blood component, they should make their application to amend their Authorization for this change before they start the pilot study or production trial. Having prior input on the design of the study from the BGTD is strongly recommended to facilitate the application process.

The establishment is encouraged to contact the BGTD for any questions about pilot studies or production trials.

### **9(3)(d) Changes to facilities (buildings and critical equipment, supplies, and services)**

#### ***New or renovated buildings***

If an establishment proposes to add or renovate a building where processing (donor suitability assessment, collection, testing or blood component preparation) will take place, it must file an application to amend its Authorization.

It is not necessary for an establishment to include in their application information and evidence for processes and equipment that have already been validated by the establishment and approved by the BGTD as long as a similar validation approach is being used.

If applicable, the application should include a statement indicating that there are no changes to the previously authorized processes and equipment, that these have been validated, and that a similar validation approach will be used for processes and equipment already authorized by the BGTD. This statement will confirm that the new facility will operate in compliance with the currently approved processes.



In addition to the minimum information requirements in subsection 9(1) above, the application for a change to the establishment's facilities should include the following information:

1. The civic address of the facility where the significant change is proposed to take place.[Paragraph 6(1)(a)]
2. A list of the processing activities proposed to be conducted in each building where the significant change is proposed to take place.[Paragraph 6(1)(f)]
3. A detailed description of changes to the facility, including
  - a. a building floor plan, including the locations of built-in equipment such as walk-in freezers; and
  - b. a list of all critical equipment, supplies, and services that it proposes to use in the conduct of its activities.[Paragraph 6(1)(g)]
4. A detailed description of any new or modified critical equipment, supplies or services if its operation or function differs from its authorized approval. [Paragraph 6(1)(g)]
5. Evidence that all new processes related to facility systems (e.g. electrical, ventilation, water, security, temperature monitoring, etc.) and equipment are commissioned/validated successfully.

As per section 22, an establishment must apply for an amendment to its Establishment Licence when proposing to add or make a change to a building in its list of facilities. Health Canada may inspect a new building after all changes have been made but prior to the start of operations (i.e. the establishment has not begun to accept donors for blood collection).

### ***Critical equipment, supplies, and services***

Significant changes to critical equipment are determined based on evaluating the impact to authorized processes and the subsequent impact on human safety or the safety of blood. Equipment includes software. See the definition of *critical* in section 1, the Interpretation section of this guidance, for examples of critical equipment, supplies, and services.

#### ***A new device or technology***

An establishment must apply for an authorization amendment for significant changes to medical devices or for a new device or technology that has the potential to have an impact on human safety or the safety of blood.

In the following examples of changes, the establishment should consider these changes to be significant if they have the potential to have an impact on human safety or the safety of blood:

- i) Replacement of a device with another device that has the same indication or functionality but not the same make;
- ii) Replacement of a device with another device that has a different indication or functionality;
- iii) Replacement of a device with a new or different model from the same manufacturer;  
or
- iv) Upgrade to a part of the device with new software or functionality.

#### *Changes to a medical device licensed by Health Canada*

Changes made to medical devices by the device manufacturer are deemed either significant or non-significant by Health Canada as per the *Guidance for the Interpretation of Significant Change of a Medical Device*. If an establishment intends to use a device that has had a change made to it, they should evaluate the impact of the change on human safety or the safety of blood and follow the reporting structure in the following 3 points:

1. If Health Canada has determined the change to the device as “non-significant,” and there is no potential impact on human safety or the safety of blood, the establishment is not required to file this change either as an annual report or as an application to amend an Authorization.
2. If the change is “non-significant” but there is a potential impact on safety, then the blood establishment should file this change in an annual report.
3. If the change is “significant” and there is a potential impact on safety, the establishment should file the change as an application to amend their Authorization.

#### ***Information Technology***

When an establishment that holds an Authorization plans to make changes to processes that have a significant information technology component, the establishment should contact the BGTD.

Examples of significant changes to information technology include the following:

- adding a computerized system, such as:
  - a new donor management system,

- a new electronic questionnaire platform,
- a new laboratory information system; or
- migrating to a newer version of the application software or data management system currently installed and validated;
- corresponding changes to operating processes when making significant changes to a computerized system;
- changes to the software configuration currently installed and validated; and
- additions to the functionality of the software application already installed and validated — including additions introduced in the course of system maintenance.

If an establishment is unsure whether a change to any validated components of a currently installed computerized system is considered significant, it is strongly recommended that the establishment consult with the BGTD for guidance.

Guidance is essential when an establishment implements a *new* computerized system that performs one or more of the following functions:

- use of software for transferring data between automated devices where translation and/or reformatting is required;
- use of data to make decisions regarding the suitability of blood or blood components for transfusion or for further manufacture; or
- use of data to trace a unit of blood or a blood component from the source to its final disposition.

An establishment should direct questions about proposed changes to an existing computer system to the Blood Establishment Regulation Unit at the BGTD. See subsection 6(1) of this guidance for contact information.

See section 12 of this guidance for changes to be filed in an annual report.

## Section 10 Emergency Changes

### Emergency changes

**10. (1)** In an emergency, if it becomes necessary for an establishment to implement a significant change before filing an application to amend its authorization, the establishment may do so if the change is necessary to prevent a compromise to human safety or the safety of blood.

Notice and application

(2) The establishment must notify the Minister in writing of any significant change that it implements under subsection (1) no later than the day after implementing it and file an application to amend its authorization within 15 days after the day on which that notice is given.

## 10(1) Emergency Changes

Section 10 allows an establishment to make a significant change to an authorized process in an emergency situation. For example, an emergency situation may necessitate emergency changes to work around (i) an error in blood management software or (ii) a malfunction in equipment used in testing.

## 10(2) Notice and application

In an emergency, if it becomes necessary to implement a significant change to prevent a compromise to human safety or the safety of blood, the establishment must provide a written initial report to the BGTD within a day of implementing the emergency change. The initial report should contain the following information:

- definition of the issue and the emergency;
- decisions made;
- actions taken; and
- significant change made or that will be made by the establishment.

Within 15 days of notifying the BGTD, the establishment must apply to amend its Authorization with respect to these changes. The BGTD may apply additional terms and conditions to the Authorization as a result of emergency changes. (See section 13.)

## Section 11 Administrative changes — notice

Administrative changes — notice

**11.** An establishment must notify the Minister in writing of any change to the information provided under paragraphs 6(1)(a) to (c) as soon as possible after the change is made, and the Minister must amend the authorization accordingly.

An establishment must notify the BGTD in writing of any change to information in the establishment's application for an Authorization provided under paragraphs 6(1)(a) to (c). See subsection 6(1) of this guidance for contact information.

The BGTD will revise the establishment's Authorization upon receipt of the notification and issue a Notice of Authorization Amendment.

## Section 12 Other changes — annual report

Other changes — annual report

**12. (1)** An establishment must file with the Minister an annual report that describes any changes made in the year that are not described in section 9 or 11 and that could compromise human safety or the safety of blood.

Amendment by Minister

**(2)** On receipt of the report, the Minister must amend the establishment's authorization accordingly.

When changes determined significant

**(3)** If the Minister determines that a change that was included in a report under subsection (1) is a significant change, the Minister must notify the establishment in writing to that effect and may require the establishment to cease or reverse the implementation of the change.

Application to amend authorization

**(4)** On receipt of the notice, the establishment must file an application to amend its authorization.

**12(1)** When an establishment makes other changes to its processes that were not filed under section 9 (significant) or section 11 (administrative) — and these changes could compromise human safety or the safety of blood — the establishment must describe these changes in an annual report to Health Canada.

An establishment should contact the BGTD if there is any question about whether an intended change to an authorized process may be included in an annual report. Annual reports should be signed by a senior executive officer and sent to the Blood Establishment Regulation Unit at the BGTD. See subsection 6(1) of this guidance for contact information.

The following are examples of the types of changes that an establishment may describe in an annual report:

### 1. *Changes to the List of Unacceptable Medications*

Changes to the List of Unacceptable Medications used to assess donors of blood for transfusion.

### 2. *Maintenance changes for blood management information technology systems*

Changes to blood management information technology systems due to maintenance activities to enhance functionality with no operational changes (e.g. enhancing memory) or to restore functionality (e.g. bug fixes).

When preparing an annual report, an establishment should ensure that all maintenance changes for the blood management information technology system have been described in

the annual report, and that no new unauthorized processes have been inadvertently introduced.

## **Reporting requirements for annual reports**

The establishment must provide the following information in an annual report:

1. description of the change;
2. rationale for the change;
3. authorized processes involved, if applicable;
4. information technology systems implicated in the change, if applicable;
5. related errors or accidents, if applicable;
6. licence number of a current and valid medical device licence, if applicable;
7. implementation date; and
8. other information necessary to describe the change or the impact of the change.

Before filing an annual report, the establishment should confirm that complete supporting information or data for the changes is available upon request.

## **Changes that do not require annual reporting or an application to amend an Authorization**

The following types of changes are considered to have minimal potential to have an adverse effect on human safety or the safety of blood.

### *Donors*

1. Changes to donor consent procedures;
2. Changes to existing donor screening areas;
3. Changes to the format, colour or layout of the establishment's donor screening manual and questionnaire, and circular of information, where there is no change to authorized processes;

4. Changes to the malaria endemic areas in the establishment's manual for screening donors as long as they are the same as those areas identified by the Public Health Agency of Canada (PHAC) or the United States Centers for Disease Control and Prevention (CDC);
5. Changes to infectious disease testing used solely for counselling purposes;

*Equipment*

6. Changes to non-critical equipment or supplies. See section 1 of this guidance for the definition of *critical* and a list of non-critical equipment;
7. Label changes that do not impact the content and that pertain to the orientation or placement of information;
8. Provided that the establishment uses the same validation approach that was reviewed by the BGTD and used in the validation of the already approved device:
  - (i) replacement of a device with one of the same make and model;
  - (ii) replacement of a part of such a device; or
  - (iii) addition or removal of a unit of such a device.
9. Changes to the general validation approach unrelated to validation protocols used in the validation of blood processing;
10. Changes to versions of software in devices used for quality control testing provided there is no impact on blood component specifications or processes used in blood component preparation;
11. Changes to existing computer operating systems;
12. Changes to existing computer hardware;
13. Changes required to update virus scanning software or to install daylight savings time operating system patches;
14. Changes to "off-the-shelf" (non-configurable) software packages, e.g. Microsoft Office, provided there is no impact on authorized processes;

*Buildings*

15. Changes to existing building or room ventilation or air conditioning systems as long as the environmental parameters remain within the authorized range and do not affect blood component specific requirements;
16. Changes to the environmental data monitoring system. This is a system which accumulates environmental data and demonstrates that environmental parameters of areas housing critical processes are met; the system triggers an alarm when conditions are no longer within specifications;
17. Changes to existing building security;

*Quality management system*

*Blood inventory management*

18. Changes to blood inventory management;

*Transportation, shipping, and shipping packaging*

19. Changes to transportation of blood or blood components;
20. Changes to shipping and packaging for shipping of blood components;

*Transformation activities*

21. Changes to transformation activities performed on blood components, i.e. washing, pooling, gamma irradiating, see sections 77–80 of this guidance;

*Processes related to investigation and reporting management*

22. Changes to processes related to investigation and reporting management of the following, where there is no change to authorized processes:
  - errors and accidents;
  - adverse donor reactions;
  - adverse transfusion reactions;



- lookback/traceback investigations; and
- post-donation information.

## Section 13 New or amended terms and conditions

### New or amended terms and conditions

**13.** (1) The Minister may add terms and conditions to an establishment's authorization or amend its terms and conditions in either of the following circumstances:

- (a) the Minister has reasonable grounds to believe that it is necessary to do so to prevent a compromise to human safety or the safety of blood; or
- (b) the establishment fails to provide the Minister, on written request, with sufficient evidence to demonstrate that its processes will not compromise human safety and will result in blood that can be determined safe for distribution, by the date specified in the request.

### Notice

(2) Before adding terms or conditions to an authorization or amending its terms or conditions, the Minister must send the establishment a notice at least 15 days before the proposed terms and conditions are to take effect that sets out the Minister's reasons and that gives the establishment a reasonable opportunity to be heard concerning them.

### Urgent circumstances

(3) Despite subsection (2), the Minister may immediately add terms and conditions to an authorization or amend its terms and conditions if she or 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.

### Urgent circumstances — notice

(4) When the Minister adds or amends terms or conditions under subsection (3), the Minister must send the establishment a notice that sets out the reasons for the new or amended terms and conditions and that gives the establishment a reasonable opportunity to be heard concerning them.

### Removal of terms and conditions

(5) The Minister may, by notice in writing, remove a term or condition from an authorization if she or he determines that the term or condition is no longer necessary to prevent a compromise to human safety or the safety of blood.

## New or Amended Terms and Conditions placed on an Authorization

**13(1)** The BGTD may place or amend terms or conditions on an Authorization in order to address an identified safety risk, either within the context of an application for an Authorization or an Application to Amend an Authorization, or outside of the context of an application.

A Notice of Authorization (or Authorization Amendment) with Terms and Conditions permits an establishment to implement the processes proposed in its application but with certain restrictions. Terms and Conditions may be placed on a Notice of Authorization or Authorization Amendment in the following example situations:

1. to allow a pilot project or production trial to proceed during which data is collected for later review by the BGTD in support of the proposed changes;
2. to place conditions on an amendment, such as the requirement to provide post implementation data — see examples of terms and conditions below;
3. to require the establishment to provide additional data for an implementation with multiple stages;
4. to require subsequent studies to be performed;
5. when actions are needed to address an emergent pathogen; and
6. when a safety concern at the establishment has been identified.

Terms and Conditions may include any of the following:

- a. addition of a new donor screening test;
- b. addition of a new donor screening question;
- c. processing of a minimum number of donations as described in the application for an Authorization or the application for an Amendment to an Authorization;
- d. limitations on the type of donations collected;
- e. limitations on the type of activities that can be conducted;
- f. limitations on the distribution of all or specific blood components;
- g. provision of donor safety monitoring data;
- h. provision of quality control data on components processed;
- i. provision of additional stability studies;
- j. provision of additional information, as necessary;
- k. implementation of a corrective action due to an identified error or accident, following communications or interactions with Health Canada's Health Products and Food Branch Inspectorate; or

1. implementation of an improvement to component processing.

**13(2)** When Health Canada places terms or conditions on an Authorization, the Minister issues a Notice of Authorization Amendment with Terms and Conditions. The Minister must give the establishment 15 days to respond to the notice. After 15 days, the Terms and Conditions in the notice take effect if there is no response from the establishment or the response does not adequately address the risk. Discussion with the establishment can occur prior to the application of terms and conditions.

**13(3)** When urgent situations arise that put human safety or the safety of blood at risk, Health Canada may immediately add or amend terms and conditions to an Authorization. An example of an urgent situation is the emergence of a new pathogen that has the potential to be transmitted by blood.

Health Canada may also place urgent terms or conditions on an Authorization if an establishment has not taken corrective actions to address an issue that has the potential to cause a serious error or accident.

**13(5)** When the establishment addresses the identified safety risk to Health Canada's satisfaction, through the implementation of changes at the establishment or providing sufficient evidence to the Minister, Health Canada will remove the terms or conditions by communicating in writing. Where the Terms and Conditions were applied in the context of an application for Authorization or Authorization Amendment, an Application Closed Letter will be issued when the safety risk has been adequately addressed.

## Section 14 Suspension

### Suspension

**14. (1)** The Minister may suspend all or part of an authorization in either of the following circumstances:

- (a) information provided by the establishment under section 6 or 9 proves to be inaccurate or incomplete; or
- (b) the establishment fails to provide the Minister, on written request, with sufficient evidence to demonstrate that its processes will not compromise human safety and will result in blood that can be determined safe for distribution, by the date specified in the request.

### Notice

**(2)** Before suspending an authorization, the Minister must send the establishment a notice that

- (a) sets out the reasons for the proposed suspension and the effective date;
- (b) if applicable, indicates that the establishment must take corrective action and specifies the date by which it must be taken; and
- (c) gives the establishment a reasonable opportunity to be heard concerning the suspension.

Urgent circumstances

(3) Despite subsection (2), the Minister may immediately suspend all or part of an authorization if she or 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.

Urgent circumstances — notice

(4) When the Minister suspends an authorization under subsection (3), the Minister must send the establishment a notice that

(a) sets out the reasons for the suspension; and

(b) gives the establishment a reasonable opportunity to be heard concerning the suspension.

**14(1)** The circumstances for suspension, described in paragraphs 14(1)(a) and (b), also apply to establishments who received notices of approval under the *Food and Drug Regulations* prior to the coming into force of the *Blood Regulations*, since the sum of these notices are considered to be the establishment's Authorization under the new *Blood Regulations*.

## Section 15 Reinstatement

Reinstatement

**15. (1)** Subject to subsection (2), the Minister must reinstate an authorization if the establishment provides the Minister with sufficient evidence to demonstrate that its processes will not compromise human safety and will result in blood that can be determined safe for distribution.

Partial reinstatement

(2) If the Minister does not reinstate any part of an authorization that was suspended, the Minister must amend the authorization to remove that part.

## Section 16 Cancellation

Cancellation

**16. (1)** The Minister must cancel an authorization in either of the following circumstances:  
(a) the establishment fails to provide the Minister with the evidence described in paragraph 14(1)(b) within a reasonable period after the authorization was suspended; or  
(b) the establishment's licence is cancelled under section 29.

Notice

(2) When the Minister cancels an authorization, she or he must send the establishment a notice that sets out the reasons for the cancellation and the effective date.

## Sections 17–29 Establishment Licences

### Section 17 Establishment licence required

Establishment licence required

**17. (1)** An establishment that processes allogeneic blood — except, subject to subsection (2), blood from a pre-assessed donor — or that imports blood must have an establishment licence to do so.

Test labs

(2) An establishment that tests blood from a pre-assessed donor for transmissible diseases or disease agents must have an establishment licence to do so.

## **Processing allogeneic blood and importation**

An establishment must obtain an Establishment Licence (EL) if they process allogeneic blood or if they import blood. Processing activities include donor suitability assessment, collection, testing, and blood component preparation. An establishment must obtain an Establishment Licence if it intends to conduct any processing activity on behalf of another establishment.

## **Processing allogeneic blood by Pre-Assessed Donor Programs**

Pre-Assessed Donor Programs that process allogeneic blood do not require an Establishment Licence, but are required to be registered with Health Canada pursuant to section 30 of the *Blood Regulations*.

## **Testing**

Every establishment in Canada that performs testing of allogeneic blood, including the blood collected by a Pre-Assessed Donor Program, requires an Establishment Licence.

## **Testing by foreign establishments**

If testing is conducted by a foreign establishment on behalf of an establishment in Canada, the testing establishment must be listed on the Establishment Licence of the establishment in Canada. Guidance on section 18 of the *Blood Regulations* provides further details on the requirements for foreign establishments conducting activities on behalf of establishments in Canada.

## **Authorization before Establishment Licence**

An Authorization issued by the BGTD must be granted prior to the issuance of an Establishment Licence, with the exception of testing conducted for a Pre-Assessed Donor Program. See sections 5–16 for further guidance regarding an Authorization. (See section 20.)

An establishment may apply for both an Authorization and an Establishment Licence simultaneously (i.e., an establishment does not have to wait to hold an Authorization before it applies for an Establishment Licence). However, in such a case, the Establishment Licence will not be issued until the Authorization is approved.

An Authorization is not required prior to obtaining a Registration.

## **Summary of Requirements**

**Table 2. Comparison of Establishment Licensing and Registration Requirements**

Establishment Type/Activities	Establishment Licence	Registration
Processing allogeneic blood	Required	Not Required
Importing Blood	Required	Not Required
Pre-Assessed Donor Program	Not Required	Required
Testing laboratory for Pre-Assessed Donor Program	Required	Not Required
Autologous Program	Not Required	Required
Transformation of Blood	Not Required	Required

## Section 18 Application for establishment licence

Application for establishment licence

**18. (1)** An establishment must file with the Minister an application for an establishment licence in the form established by the Minister. The application must be dated and signed by a senior executive officer and contain all of the following information:

- (a) the applicant's name and civic address, and its postal address if different;
- (b) the civic address of each building in which records will be stored;
- (c) in the case of an establishment that previously conducted its activities under another name, that other name;
- (d) 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;
- (e) the name and telephone number of a person to contact in an emergency, if different from the person mentioned in paragraph (d);
- (f) a list of the establishment's activities;
- (g) a list of the whole blood and blood components in respect of which the activities are proposed to be conducted;
- (h) 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;
- (i) the name, civic address and licence number, if any, of any other establishment that it proposes to have conduct any of its activities;
- (j) sufficient evidence to demonstrate that the establishment can conduct its activities in accordance with its quality management system and the requirements of these Regulations and that its activities will not compromise human safety or the safety of blood;
- (k) in the case of an importer or an establishment that proposes to have any of its testing

conducted by a foreign establishment, the information described in paragraphs (a) and (f) to (j) with respect to every foreign establishment that processes or distributes the blood that they propose to process or import; and  
(l) in the case of an establishment that proposes to import blood in urgent circumstances, all of the information required by subsection 92(1).

Information on request

(2) An establishment must provide the Minister, on written request, with any information that the Minister determines is necessary to complete the Minister's review of the application, by the date specified in the request.

Section 18 of the *Blood Regulations* specifies the information must be provided in a Blood Establishment Licence Application Form. In the context of the Establishment Licences section of the *Blood Regulations*, the Minister's Blood Establishment Licensing powers are exercised by the Health Products and Food Branch Inspectorate.

### Where to find the application form

The Blood Establishment Licence Application Form, along with instructions, can be obtained by sending a request to: [blood\\_sang\\_questions@hc-sc.gc.ca](mailto:blood_sang_questions@hc-sc.gc.ca). Establishments will be informed by Health Canada of the location of the form when it is available.

It is the responsibility of the applicant to ensure that its Blood Establishment Licence Application is accurate and complete in accordance with the requirements of section 18 of the *Blood Regulations* before filing it with the Establishment Licensing, Billing and Invoicing Unit of the Inspectorate. This will help prevent confusion, errors, and delays in processing.

### Where to file the application form

By email: [elapplicationle@hc-sc.gc.ca](mailto:elapplicationle@hc-sc.gc.ca)

### Buildings in Canada

Paragraph 18(1)(h) requires the applicant to provide the civic address of each building in Canada in which the applicant proposes to conduct any activities with respect to blood.

Establishments that solely store blood do not require an Establishment Licence. All establishments who store blood must do so in accordance with the *Blood Regulations*.

### Establishments conducting activities on behalf of the applicant

Paragraph 18(1)(i) requires the applicant to provide the name, civic address and licence number (if applicable) of any other establishment, including foreign establishments\*, that (will) conduct activities on their behalf.

\*Note: Foreign establishments, conducting activities on behalf of an establishment in Canada, do not require an Establishment Licence under Canada's *Blood Regulations*; however, the foreign establishment must be listed on the Establishment Licence of the establishment in Canada for whom they are performing activities.

It is the responsibility of the applicant to ensure that appropriate written agreements are in place for all activities contracted out to other establishments.

### **Evidence to demonstrate compliance with the *Blood Regulations***

Applicants are required to have sufficient evidence to demonstrate their compliance with the *Blood Regulations*. Furthermore, in this respect, Health Canada may inspect the establishment during the review of an application. (See paragraph 18(1)(j) and section 19 of the *Blood Regulations*.)

Note: An establishment holding an Establishment Licence under the *Food and Drug Regulations* should refer to section 127 (Transitional Provisions) for additional information.

### **Evidence required for foreign establishments**

In accordance with paragraph 18(1)(k), the applicant must provide sufficient evidence to demonstrate that the foreign establishments meet the requirements of the *Blood Regulations*. If approved, these foreign establishment(s) will then be listed on the Establishment Licence of the establishment in Canada.

Sufficient evidence includes, but is not limited to, the following information:

- a list specifying the activities conducted at each building of that foreign establishment;
- a certificate from a Health Canada Inspector; or
- in the absence of a certificate from a Health Canada Inspector, the following documentation demonstrating that the foreign establishment meets the requirements of the *Blood Regulations* must be filed:
  - a. The most recent (within the last 3 years) signed inspection report issued by
    - i. a regulatory authority with which Canada has a Mutual Recognition Agreement e.g. Therapeutic Goods Administration (Australia), or
    - ii. an authority which is a member of the Pharmaceutical Inspection Cooperation/Scheme [PIC/S]), e.g. United States Food and Drug Administration;



- b. The corrective actions taken, if any, signed by a responsible official of the foreign establishment;
- c. A copy of the foreign establishment's procedures for handling deviations and out of specification test results;
- d. A copy of the quality agreement between the foreign establishment and the establishment in Canada including a list of the specific blood and blood components for supply in Canada;
- e. The Site Master File or equivalent document.

It is recognized that in some cases certain documentation may not exist. In such cases, a written justification explaining why the required documents cannot be filed should be provided to the Inspectorate, along with other documentation that encompasses the required information.

### **Foreign establishment compliance evidence expiry dates**

If a foreign building has a questionable compliance history, repeat observations are noted, and/or the Inspectorate requires additional information in order to fully assess compliance with the *Blood Regulations*, a shortened validity period may be issued until that additional information is received and assessed.

- The validity assigned to foreign buildings will be aligned with the start date of the filed inspection evidence.
- In most cases, the foreign building evidence will be considered valid for 3 years from the start date of the inspection evidence.

The act of filing alone does not guarantee that the foreign establishment would be acceptable and additional information may be requested.

### **Importation in urgent circumstances**

In accordance with paragraph 18(1)(l), an establishment in Canada that wishes to import blood in urgent circumstances must apply, in advance of the import in response to the urgent circumstance, to include that activity on their Establishment Licence. The applicant must satisfy all requirements under section 18 of the *Blood Regulations*, in addition to the information under section 92 of the *Blood Regulations*. See guidance under section 92 of the *Blood Regulations* for further details on the filing of the required information. The importer in Canada of the blood may

also be subject to an inspection to assess their compliance with the *Blood Regulations* as it relates to the activity of importing.

### Information on request

In accordance with subsection 18(2), the Inspectorate may send a written request to the applicant for any relevant information when necessary to complete the review of the establishment's licence application. The applicant must provide the additional information in writing and by the date specified in the request.

## Section 19 Inspection

### Inspection

**19.** (1) During the review of an application for an establishment licence, the Minister may inspect the establishment's facilities and equipment to assess whether the applicant's activities are conducted in accordance with its proposed authorization and with these Regulations.

### Information on request

(2) An establishment must provide the Minister, on written request, with any information that she or he determines is necessary to complete the inspection, by the date specified in the request.

Establishments may be inspected prior to the issuance of the Establishment Licence and, therefore, must be prepared for the possibility of an inspection when filing the application for an Establishment Licence. Upon review of the completed application form, the Establishment Licensing, Billing and Invoicing Unit will advise the appropriate Inspectorate Regional Program office. An inspection will be scheduled as required and the inspection results will be communicated to the establishment.

During an inspection, an establishment is inspected for their compliance with the requirements of the *Blood Regulations* and their Authorization. The outcome of the inspection will be communicated to the Establishment Licensing, Billing and Invoicing Unit by the Regional Program office. If a *Compliant* Rating is issued, the Establishment Licence will be issued to the establishment.

## Section 20 Issuance

### Issuance

**20.** On completion of the review of an application, the Minister must issue an establishment licence, with or without terms or conditions, if both of the following requirements are met:

- (a) an authorization has been issued with respect to the blood — except blood from a pre-assessed donor — that is proposed to be processed or imported under the licence; and
- (b) the Minister determines that the application provides sufficient evidence to demonstrate that issuance of the licence will not compromise human safety or the safety of blood.

Once the Inspectorate processes the establishment's application, an Establishment Licence can be issued if the following requirements are met:

- an Authorization has already been issued in respect of the blood; and
- the Minister is satisfied that issuance of the Establishment Licence will not compromise human safety or the safety of blood.

### Information related to licensed establishments

The information related to licensed establishments in Canada, including terms and conditions of buildings in Canada, can be publicly available. For example, the listing of licensed establishments may be accessible via the Health Canada website and public information may be shared in response to specific inquiries made to the department.

### Establishment Licence expiry

An Establishment Licence issued under the *Blood Regulations* will not expire. However, licensed establishments will be subject to regular inspections to assess their continued compliance with the *Blood Regulations*.

### Section 21 Refusal

#### Refusal

**21.** The Minister may refuse to issue a licence if she or he determines that any of the information provided by the establishment in its application is inaccurate or incomplete.

It is the applicant's responsibility to ensure that a complete and accurate application is filed with the Minister as represented by the Inspectorate of Health Canada. Failure to file a complete application may result in the refusal of the application. If the application is refused, the establishment will be informed in writing.

### Section 22 Changes requiring application to amend licence

#### Changes requiring application to amend licence

**22.** (1) Before making any change that affects the information provided under any of paragraphs 18(1)(f) to (i), (k) and (l), the establishment must, subject to paragraph 23(b), file with the Minister an application to amend the licence.

#### Applications

(2) Sections 18 to 21 apply to an application to amend a licence, with any necessary modifications.

Amendments (including additions, removals, modifications, and corrections) to information provided under any of paragraphs 18(1)(f) to (i), (k) and (l) can be filed with the Establishment Licensing, Billing and Invoicing Unit using a Blood Establishment Licensing Application Form with an accompanying cover letter summarizing the changes to be made. Please see the form for further instructions.

If the application to amend the licence meets the requirements of the *Blood Regulations*, an updated Establishment Licence will be issued to reflect the amendment(s).

Note: Temporary cessation of activities does not require an amendment or notification.

## Section 23 Administrative changes — notice

Administrative changes — notice

**23.** An establishment must notify the Minister in writing of the following changes:  
(a) as soon as possible after any change is made to the information provided under any of paragraphs 18(1)(a) to (e); and  
(b) within 30 days after the cessation of any licensed activity.

Establishments may use a cover letter and, if convenient, a Blood Establishment Licence Application Form, when notifying the Establishment Licensing, Billing and Invoicing Unit of administrative changes. Please see section 18 of this guidance for methods of filing.

## Section 24 Changes requiring amendment of licence by Minister

Changes requiring amendment of licence by Minister

**24.** The Minister must amend an establishment licence in any of the following circumstances:  
(a) an authorization is amended in a way that affects the information provided by the establishment under any of paragraphs 18(1)(f) to (k);  
(b) the Minister receives a notice from the establishment under paragraph 23(a) concerning a change to the information provided under paragraph 18(1)(a);  
(c) the Minister receives a notice from the establishment under paragraph 23(b) that it has ceased one or more but not all of its licensed activities; or  
(d) an authorization is cancelled, and the cancellation affects the information provided by the establishment under any of paragraphs 18(1)(f) to (k).

## Change to Authorization before Establishment Licence

If a licensed establishment intends to add an activity to their Establishment Licence, they must first add the processing or importation activities to their Authorization.

## Section 25 New or amended terms and conditions

New or amended terms and conditions

**25.** (1) The Minister may add terms and conditions to an establishment licence or amend its terms and conditions in either of the following circumstances:  
(a) the Minister has reasonable grounds to believe that it is necessary to do so to prevent a compromise to human safety or the safety of blood; or  
(b) the establishment fails to provide the Minister, on written request, with sufficient evidence to demonstrate that the activities it conducts are in compliance with these Regulations, by the date specified in the request.

Notice

(2) Before adding terms or conditions to a licence or amending its terms or conditions, the Minister must send the establishment a notice at least 15 days before the day on which the proposed terms and conditions are to take effect that sets out the Minister's reasons and that gives the establishment a reasonable opportunity to be heard concerning them.

Urgent circumstances

(3) Despite subsection (2), the Minister may immediately add terms and conditions to a licence or amend its terms and conditions if she or 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.

Urgent circumstances — notice

(4) When the Minister adds or amends terms or conditions under subsection (3), the Minister must send the establishment a notice that sets out the reasons for the new or amended terms and conditions and that gives the establishment a reasonable opportunity to be heard concerning them.

Removal of terms and conditions

(5) The Minister may, by notice in writing, remove a term or condition from a licence if she or he determines that the term or condition is no longer necessary to prevent a compromise to human safety or the safety of blood.

## Outlining terms and conditions

If assigned, an establishment must comply with all terms and conditions set out by the Minister. These terms and conditions are outlined in the terms and conditions annex to the Establishment Licence.

## Removing terms and conditions

The Minister may remove a term or condition from the Establishment Licence if she or he determines that it is no longer necessary. In such a case, an amended Establishment Licence will subsequently be issued to the establishment.

## Section 26 Additional information

Additional information

**26.** An establishment must provide the Minister, on written request, with any additional relevant information to demonstrate that the activities it conducts are in compliance with these Regulations, by the date specified in the request.

## Section 27 Suspension

Suspension

**27.** (1) The Minister may suspend all or part of an establishment licence in any of the following circumstances:

- (a) information provided by the establishment under section 18 or 22 proves to be inaccurate or incomplete;
- (b) the establishment fails to provide the Minister, on written request, with sufficient evidence to demonstrate that the activities it conducts are in compliance with these Regulations, by the date specified in the request; or
- (c) the establishment is not in compliance with these Regulations.

Notice

(2) Before suspending a licence, the Minister must send the establishment a notice that

- (a) sets out the reasons for the proposed suspension and the effective date;
- (b) if applicable, indicates that the establishment must take corrective action and specifies the date by which it must be taken; and
- (c) gives the establishment a reasonable opportunity to be heard concerning the suspension.

**Urgent circumstances**

(3) Despite subsection (2), the Minister may immediately suspend all or part of a licence if she or 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.

**Urgent circumstances — notice**

(4) When the Minister suspends a licence under subsection (3), the Minister must send the establishment a notice that

- (a) sets out the reasons for the suspension; and
- (b) gives the establishment a reasonable opportunity to be heard concerning the suspension.

An establishment may not conduct any activities that the Minister has suspended on their Establishment Licence.

## Section 28 Reinstatement

**Reinstatement**

**28.** (1) Subject to subsections (2) and (3), the Minister must reinstate an establishment licence if the establishment provides the Minister with sufficient evidence to demonstrate that it is in compliance with these Regulations.

**Exception — compliance history**

(2) The Minister may refuse to reinstate an establishment's licence if its compliance history demonstrates an inability to consistently conduct its activities in accordance with these Regulations.

**Partial reinstatement**

(3) If the Minister does not reinstate any part of a licence that was suspended, the Minister must amend the licence to remove that part.

The Minister may refuse to reinstate all or part of an establishment's licence if the establishment does not consistently comply with the *Blood Regulations* or the *Food and Drugs Act*. Although the Inspectorate will work with establishments to bring them into compliance with the *Blood Regulations*, if an establishment does not demonstrate willingness or consistently refuses to implement corrective actions for non-compliance or the corrective actions fall short of rectifying the non-compliance, the Minister will not reinstate the establishment's licence.

## Section 29 Cancellation

**Cancellation**

**29.** (1) The Minister must cancel an establishment licence in any of the following circumstances:  
(a) the establishment notifies the Minister under paragraph 23(b) that it has ceased all activities under the licence;  
(b) the establishment fails to provide the Minister with the evidence described in paragraph

27(1)(b) within a reasonable period after the licence was suspended;  
(c) the establishment's compliance history demonstrates an inability to consistently conduct its activities in accordance with these Regulations; or  
(d) no authorization under which the establishment processes blood remains in effect.

Notice

(2) On the cancellation of a licence, the Minister must send the establishment a notice that sets out the reasons for the cancellation and the effective date.

An establishment is not allowed to conduct any activities requiring a licence at a building for which it does not hold an Establishment Licence, including those where the licence has been cancelled. If an establishment intends to commence activities requiring a licence at a site for which its Establishment Licence was cancelled, it must file a new Blood Establishment Licence Application Form.

## Sections 30–37      Registration

### Section 30 Requirement to register

Requirement to register

**30.** (1) An establishment that processes autologous blood, that transforms blood or that has a pre-assessed donor program must be registered under these Regulations to do so.

Exceptions

(2) Subsection (1) does not apply to an establishment that only tests autologous blood or to an establishment whose only transformation activity is to pool cryoprecipitate.

### Who is required to register?

The *Blood Regulations* require each of the following establishments to be registered:

- A. Establishments that collect autologous blood, except for those that only test autologous blood samples

Establishments that conduct collection or component preparation of autologous blood are required to register with Health Canada. If another establishment conducts the testing on behalf of the establishment who collects autologous blood, the applicant must list them on their application. The establishment who collects autologous blood is responsible for the testing activity whether it is conducted by them or by another establishment on their behalf.

Establishments that only test autologous blood samples on behalf of an establishment that holds a Registration to process autologous blood are not required to register.



Contract establishments are listed as Other Establishments on the Registration application and registration certificate of the registrant.

B. Establishments that have a Pre-Assessed Donor Program

C. Establishments that transform blood

Based on the definition of *transformation*, if an establishment pools, irradiates or washes blood, then they are required to register with Health Canada for those activities.

Establishments whose only transformation activity is to pool cryoprecipitate are not required to register.

In addition to the washing of red blood cells to remove any trace of plasma proteins and anticoagulant, the washing of thawed red blood cells to remove the cryoprotectant is also included in transformation activities.

See APPENDIX B for a Pre-Registration Self-Assessment Tool for Establishments applying for a Blood Establishment Registration.

### Section 31 Application for registration

Application for registration

**31. (1)** An establishment must file with the Minister an application for registration in the form established by the Minister that contains all of the following information:

- (a) the applicant's name and civic address, and its postal address if different;
- (b) in the case of an establishment that previously conducted its activities under these Regulations under another name, that other name;
- (c) 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;
- (d) the name and telephone number of a person to contact in an emergency, if different from the person mentioned in paragraph (c);
- (e) a list of the processing activities that the establishment proposes to conduct in respect of autologous blood and a list of the whole blood and blood components that it proposes to process;
- (f) a list of the transformation activities that the establishment proposes to conduct and a list of all the whole blood and blood components that it proposes to transform;
- (g) a statement of whether the establishment has a pre-assessed donor program;
- (h) 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;
- (i) the name and civic address of any other establishment that it proposes to have conduct any of its activities; and
- (j) a statement, dated and signed by a senior executive officer, that certifies both of the following:
  - (i) that the establishment has sufficient evidence to demonstrate that it is in compliance with



these Regulations, and  
(ii) that all of the information in the application is accurate and complete.

Information on request

(2) An establishment must provide the Minister, on written request, with any information that the Minister determines is necessary to complete the Minister's review of the application, by the date specified in the request.

Section 31 of the *Blood Regulations* specifies the information that must be provided in the Blood Establishment Registration Application Form.

### Where to find the application form

The Blood Establishment Registration Application Form, along with instructions, will be available on the Health Canada website. Establishments will be informed by Health Canada of the location of the form when it is available.

It is the responsibility of the applicant to ensure that the Blood Establishment Registration Application Form is accurate and complete in accordance with the requirements of section 31 of the *Blood Regulations* before filing it with the Establishment Licensing, Billing and Invoicing Unit of the Inspectorate. This will help prevent delays in processing.

### Where to file the application form

By email: [elapplicationle@hc-sc.gc.ca](mailto:elapplicationle@hc-sc.gc.ca)

### Section 32 Registration

Registration

**32.** (1) On completion of the review of an 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.

Refusal

(2) The Minister may refuse to register an establishment if she or he determines that the information provided by the establishment in its application is incomplete or if she or he has reasonable grounds to believe that issuance of the registration could compromise human safety or the safety of blood.

### Inspection

Health Canada may inspect establishments prior to and/or after the issuance of a registration number.

### Information related to registered establishments

The information related to registered establishments in Canada, including terms and conditions of buildings in Canada, can be publicly available. For example, the listing of registered

establishments may be accessible via the Health Canada website and public information may be shared in response to specific inquiries made to the department.

### Registration expiry

Subject to section 37, there is no expiry for a Registration and hence no renewal process. However, an updated registration certificate will be issued if any amendments are made to its corresponding Registration.

See also section 35 for Annual Statement of Compliance.

### Section 33 Changes — notice

Changes — notice

**33.** An establishment must notify the Minister in writing of any change to the information provided under section 31, within 30 days after the day on which the change is made, and in the case of a change to the information provided under any of paragraphs 31(1)(e) to (i), include in the notice another statement described in paragraph 31(1)(j).

Notifications and amendments can be filed with the Establishment Licensing, Billing and Invoicing Unit using a Blood Establishment Registration Application Form with an accompanying cover letter summarizing the changes made. Please see the form for further instructions.

It is recommended that establishments notify the Establishment Licensing, Billing and Invoicing Unit of any changes as early as possible, as this will allow these changes to be processed and reflected on their registration certificates in a timely manner.

### Section 34 Amendment by Minister

Amendment by Minister

**34.** The Minister may amend an establishment's registration to remove from it any activity or building if she or 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.

### Removed activities

An establishment is not permitted to conduct any activities requiring a Registration that have been removed from or do not appear on their Registration. The establishment will be informed in writing upon removal of activities from its Registration, and will correspondingly receive a revised registration certificate.

### Removed buildings

An establishment is not permitted to conduct any activities requiring a Registration in a building that has been removed from or does not appear on their Registration.

## Re-addition of removed activities/buildings

If a registered establishment would like to add removed activities/buildings to their Registration, it must file an application to Health Canada (as per section 31 of the *Blood Regulations*). The establishment may be subject to an inspection and/or the provision of supporting documents to verify the compliance of the requested activities/buildings.

## Section 35 Annual statement of compliance

### Annual statement of compliance

**35.** An establishment must, by April 1 of each year, provide the Minister with a statement dated and signed by a senior executive officer that certifies that the establishment has sufficient evidence to demonstrate that it is in compliance with these Regulations.

Although an establishment's registration number does not expire, the establishment must renew their statement of compliance every year before April 1<sup>st</sup> in order for their Registration number to remain valid.

A registered establishment may renew their annual statement of compliance by using the Blood Establishment Registration Application Form. Additional instructions are provided with the form.

If an establishment does not renew their annual statement of compliance, the Minister may have reason to believe the establishment is not in compliance with the *Blood Regulations* and may cancel the Registration as stated in section 37.

## Section 36 Additional information

### Additional information

**36.** An establishment must provide the Minister, on written request, with any additional relevant information to demonstrate that the activities it conducts are in compliance with these Regulations, by the date specified in the request.

## Section 37 Cancellation

### Cancellation

**37.** (1) The Minister may cancel a registration in any of the following circumstances:

- (a) the Minister receives a notice under section 33 that the establishment has ceased all of its activities that are the subject of the registration;
- (b) information provided by the establishment under section 31 proves to be false or misleading;
- (c) the establishment has not complied with a request for additional information made under section 36;
- (d) the establishment fails to take any corrective action within the required period; or
- (e) the Minister has reasonable grounds to believe that the establishment is not in compliance with these Regulations or that human safety or the safety of blood could be compromised.

### Notice

(2) Before cancelling a registration, the Minister must send the establishment a notice that

- (a) sets out the reasons for the proposed cancellation and the effective date;
- (b) if applicable, indicates that the establishment must take corrective action and specifies the date by which it must be taken; and
- (c) gives the establishment a reasonable opportunity to be heard concerning the cancellation.

*Urgent circumstances*

(3) Despite subsection (2), the Minister may immediately cancel a registration if she or 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.

*Urgent circumstances — notice*

(4) When the Minister cancels a registration under subsection (3), the Minister must send the establishment a notice that

- (a) sets out the reasons for the cancellation;
- (b) if applicable, indicates that the establishment must take corrective action and specifies the date by which it must be taken; and
- (c) gives the establishment a reasonable opportunity to be heard concerning the cancellation.

*Action by establishment on cancellation*

(5) On the cancellation of its registration for any reason set out in paragraphs (1)(b) to (e), the establishment must immediately notify any establishment to which it distributed blood that it processed or transformed during the period set out in the notice that its registration has been cancelled and the effective date of the cancellation.

An establishment is not permitted to conduct any activities requiring a Registration at a building that is not registered or for which its Registration is cancelled. If an establishment intends to conduct activities requiring a Registration, it must file a new Blood Establishment Registration Application Form.

## Sections 38–58 Processing

### Sections 38–44 Donor Suitability Assessment

#### Section 38 Non-application — autologous donations

*Non-application — autologous donations*

**38.** Sections 39 to 44 do not apply to an autologous donation.

The donor suitability assessment of an autologous blood donor is not within the scope of the *Blood Regulations*.

#### Section 39 Licensed establishments

*Licensed establishments*

**39.** A licensed establishment that collects allogeneic blood must, before the collection, assess the donor's suitability to donate against the establishment's authorized criteria.

### **Authorized criteria for donor suitability assessment**

Section 39 only applies to licensed establishments that collect allogeneic blood for transfusion or for further manufacture.

A registered establishment that collects blood from a pre-assessed donor is not required to have authorized criteria, therefore, section 39 does not apply. See subsection 5(2) for the Pre-Assessed Donor Program exception.

A physician or physician substitute must assess a plasmapheresis donor's suitability to donate. See 1.5 Definitions, *physician* and *physician substitute*.

### **Criteria included in a donor suitability assessment**

A donor suitability assessment includes donor screening and donor deferral criteria. A deferral occurs when a donor is temporarily or indefinitely unsuitable to donate blood. See section 1, the Interpretation section, for guidance concerning the definition of *donor suitability assessment*.

### **Requirement for operating procedures**

Donor suitability assessment criteria approved by Health Canada protects human safety and the safety of blood. The establishment must develop and maintain operating procedures describing in detail the criteria and the methods for assessing donor suitability. The establishment's operating procedures must also specify frequency of donation and donor deferral time frames. See section 95 for further guidance concerning the requirement for operating procedures.

### **Requirement to file significant changes to donor suitability assessment criteria**

An establishment must apply to the BGTD to amend their Authorization prior to implementing significant changes to its donor suitability assessment criteria. See section 9 for guidance on significant changes to authorized processes.

### **Requirement to provide foreign establishment's donor suitability assessment criteria if importing blood**

If a licensed establishment proposes to import blood, they must provide the foreign establishment's donor suitability assessment criteria with their application for an Authorization or an amendment to their Authorization. This must occur prior to the establishment importing the foreign blood.

## Section 40 Past unsuitability

Past unsuitability

**40.** In conducting a donor suitability assessment, an establishment must verify whether the donor has been previously determined unsuitable, and the reason why and the duration, if applicable.

This section applies to licensed establishments that collect allogeneic blood as well as to registered establishments that have a Pre-Assessed Donor Program.

### Accessibility of donor deferral records

A licensed or registered establishment must have a system for retaining and accessing donor deferral records. An establishment should have a system to check the donor deferral records of other licensed establishments in Canada.

### Considering the suitability of a donor by checking donor deferral records

When considering the suitability of a donor, a licensed or registered establishment must

- confirm the donor's identity;
- use the donor's name to check its donor deferral system; and
- record the reason for the deferral and the duration, if applicable.

As stated in subsection 88(1), a regular donor suitability assessment, including past unsuitability, must occur every 3 months for pre-assessed donors.

### Requirement to keep records of determinations of donor unsuitability

See items 5 and 6 in the Table to section 119, Records and retention periods, for the requirement to keep records of determinations of donor unsuitability.

## Section 41 Donor screening

**41.** In conducting a donor suitability assessment, an establishment must take both of the following steps:  
(a) obtain information from the donor by use of a questionnaire or other similar means about their identity and medical history, and their social history to the extent that it is relevant in determining the presence of risk factors for diseases transmissible by blood; and  
(b) provide the donor with information about the risks associated with donating blood and the risks to the recipient of contracting a transmissible disease.

**41(a) and (b)** Subsections 41(a) and (b) apply to licensed establishments that collect allogeneic blood as well as to registered establishments that have a Pre-Assessed Donor Program.

## General donor screening requirements for allogeneic blood donors

**41(a)** On the day of donation, a licensed or registered establishment must assess the donor in accordance with all of the requirements in section 41. The establishment must conduct donor screening in an area that provides privacy. The establishment must provide the donor with opportunities to ask questions and to exclude themselves from donating.

A licensed establishment must base donor suitability on the following Health Canada approved criteria:

- frequency of donation;
- donor deferral criteria, see section 39;
- laboratory test results, see section 56;
- donor medical history and/or physical examination; and
- donor social history.

## Screening a pre-assessed donor

Registered establishments that have a Pre-Assessed Donor Program should have a donor screening process that reflects the Health Canada approved criteria listed on a licensed establishment's donor screening questionnaire. A pre-assessed donor should meet the same donor suitability requirements as an allogeneic blood donor whose blood is destined for the general blood supply. See section 42 of this guidance document for details concerning exclusion criteria.

## Donor medical history and social history

A donor's medical history refers to (1) conditions that could pose a risk to the donor, and (2) vaccinations, medications and transmissible diseases that could pose a risk to the recipient.

A donor's social history refers to the prior activities of a donor that could put the donor and recipient(s) at risk for infection with transmissible disease(s).

See section 1, the Interpretation section, for general guidance about medical history and social history in the context of a *donor suitability assessment*.

## Requirement to provide information about risks

**41(b)** A licensed or registered establishment must inform the donor of the following:

- any potential risks to the donor's health arising from donating blood;
- any potential risks to the recipient of contracting a transmissible disease; and
- any other information that is necessary for the donor to make an informed decision to donate blood.

Establishments must have documentation, including paper or electronic documents, that communicates all of the risks in plain language that a donor can easily understand. A donor must have the opportunity to change their decision to donate at any time.

## Requirement to keep records of donor suitability assessment

See item 4 in the Table to section 119, Records and retention periods, for the requirement to keep records of donor suitability assessment.

## Section 42 Exclusion criteria

Exclusion criteria

**42.** An establishment must determine that a donor is unsuitable to donate if any of the information obtained under sections 39 to 41 indicates that human safety or the safety of blood could be compromised.

Section 42 applies to licensed establishments that collect allogeneic blood as well as to registered establishments that have a Pre-Assessed Donor Program.

A licensed or registered establishment's donor suitability assessment process must identify and manage conditions and factors that could affect human safety or the safety of blood.

## Requirement to defer a donor — licensed establishment

A licensed establishment must defer a donor if the donor does not meet the establishment's authorized donor suitability assessment criteria. A donor deferral must also occur for any other medical reason that could affect human safety or the safety of blood. The donor's temporary or indefinite deferral depends on the criteria that they did not meet.



## **Requirement to defer a donor — registered establishment with a pre-assessed donor program**

A registered establishment with a Pre-Assessed Donor Program must determine the donor's suitability to donate based on the most current criteria for allogeneic blood donors. It is recommended that the Pre-Assessed Donor Program contact the licensed establishment in their jurisdiction, to obtain the applicable criteria and the donor screening questionnaire.

### **Section 43 When donor determined unsuitable**

When donor determined unsuitable

**43.** If a donor is determined unsuitable to donate, the establishment must not collect blood from that donor and must inform the donor of the reasons why they are not suitable to donate and indicate the date, if any, when the donor will again be suitable to donate.

Section 43 applies to licensed establishments that collect allogeneic blood as well as to registered establishments that have a Pre-Assessed Donor Program.

## **Requirement to inform the donor of their deferral information**

The licensed or registered establishment must inform the donor of the reason(s) why they must not donate blood during the deferral period. When communicating deferral information to the donor, a licensed or registered establishment must make sure that the donor clearly understands the date, if any, when the donor is eligible to donate blood. An establishment may inform the donor of the deferral either in person or in writing.

## **Requirement to defer an unsuitable donor in a pre-assessed donor program**

As stated in section 88, a regular donor suitability assessment must occur every 3 months for pre-assessed donors. A registered establishment may determine a pre-assessed donor as unsuitable to donate either during the regular assessment or immediately prior to collection. A registered establishment must defer an unsuitable pre-assessed donor either indefinitely or temporarily. During the deferral period, the registered establishment must not collect blood from the donor. See section 42 for guidance concerning *Requirement to defer a donor — registered establishment with a pre-assessed donor program*.

## **Requirement to keep records of determinations of donor unsuitability**

See items 5 and 6 in the Table to section 119, Records and retention periods, for the requirement to keep records of determinations of donor unsuitability, also known as donor deferral records.

## Section 44 When donor determined suitable

When donor determined suitable

**44.** (1) If a donor is determined suitable to donate, the establishment must take both of the following steps:

- (a) assign a donor identification code to the donor, if the donor does not already have one; and
- (b) instruct the donor to inform the establishment in either of the following situations:
  - (i) the donor develops, within the periods set out in the establishment's operating procedures, an illness or condition that may potentially compromise the safety of donated blood, or
  - (ii) after the donation the donor has any reason to believe that their blood should not be used.

Reassessment

(2) On receipt of any post-donation information under paragraph (1)(b), the establishment must evaluate the information to reassess the safety of the current and any other donation made by that donor and the donor's suitability for future donations.

Notice

(3) If the reassessment shows that the safety of the blood may have been compromised and the establishment has already distributed the blood, it must notify every person to which it distributed the blood to that effect, and if the person is an establishment, specify in the notice that the blood must not be distributed or transfused.

**44** Subsections 44(1) and (2) apply to licensed establishments that collect allogeneic blood as well as to registered establishments that have a Pre-Assessed Donor Program.

### Requirement for an establishment to assign a donor identification code

**44(1)(a)** An establishment must assign a donor identification code to a donor, if the donor is determined suitable to donate and if the donor does not already have one. Registered establishments should refer to subsection 89(b) for guidance concerning donor identification codes for pre-assessed donors.

### Post-donation information — licensed establishment

**44(1)(b)** A licensed establishment must inform the donor about when to provide the establishment with post-donation information. This includes any information provided by the donor that may affect the safety of the blood they donated, such as the following:

- the donor discovers or develops an illness, disease or condition;
- the donor recalls any information or history they believe was omitted during the screening process; or
- the donor has any other reason for why the establishment must not use their blood.

**44(2)** When a licensed establishment receives post-donation information, this information must be taken into account when determining the safety of a donor's blood for transfusion or blood for further manufacture into a drug for human use. A licensed establishment must consider the safety of both current and previous donations when it receives a report of post-donation information.

Furthermore, upon receipt of post-donation information, a licensed establishment must reassess the donor's suitability to donate blood in the future for transfusion or for further manufacture.

### **Post-donation information — registered establishment with a pre-assessed donor program**

**44(1)(b)(i)** A registered establishment should follow clause 5.1.7 of the CSA Blood Standard when instructing a pre-assessed donor about the reporting of post-donation information related to the development of an illness or condition that could affect the safety of the blood they donated.

**44(1)(b)(ii)** Blood collected from a pre-assessed donor is used immediately in an emergency situation. However, a registered establishment must still instruct pre-assessed donors to inform the establishment if, after their blood has been collected, they have any reason to believe that their blood should not have been transfused.

**44(2)** With respect to post-donation information, a registered establishment with a Pre-Assessed Donor Program should follow clauses 19.1.2 through 19.1.6 of the CSA Blood Standard.

### **Lookback Procedure for a licensed or registered establishment**

A licensed or registered establishment must perform a lookback procedure on previous donations from an allogeneic blood donor whose blood or blood components have evidence of confirmed infection for at least any of the following:

- a. HIV 1 and 2
- b. HCV
- c. HBV
- d. HTLV I/II
- e. WNV

Licensed establishments should refer to section 52 and subsection 56(1) of this guidance for clarification of testing requirements.

A report of post-donation information affects the suitability of the current donation and must also be considered for previous donations, depending on the type of information reported. Post-donation information triggers a lookback procedure when there is a nucleic acid positive test

result or serology tests are reactive and confirmed positive for the transmissible diseases or disease agents listed above.

The medical director should be consulted, as needed, during a lookback procedure.

See 1.5 Definitions, *lookback*. See also subsection 56(1) for guidance on lookback procedures.

### **Requirement if a reassessment shows the safety of the blood may have been compromised**

**44(3)** When a licensed establishment determines through its reassessment of the post-donation information that the safety of the blood might have been compromised, it must notify every establishment and person (e.g., blood product fabricator) to whom it distributed the blood.

When a licensed establishment notifies any establishment(s) to whom it distributed blood for transfusion the notice must say that the blood must not be further distributed or transfused.

## **Sections 45–51 Collection**

### **Section 45 Licensed establishments**

Licensed establishments

**45.** A licensed establishment that collects allogeneic blood must do so in accordance with its authorization.

### **Requirement to collect allogeneic blood in accordance with an Authorization**

A licensed establishment must collect allogeneic blood in accordance with its Authorization.

### **Requirement to file significant changes to collection processes**

An establishment must file for review and approval by Health Canada any significant changes to its collection processes. See section 9 for guidance on significant changes to an authorized process.

### **Section 46 Donor identification code**

Donor identification code

**46.** An establishment that collects autologous blood must assign a donor identification code to the donor.

### **Section 47 Donation code**

Donation code

**47.** An establishment that collects blood must assign a donation code to every unit of blood that

it collects and link the code in its records to the donor identification code.

Section 47 applies to licensed establishments that collect allogeneic blood and registered establishments that collect autologous blood.

## Requirement to have a donation code assigned at the time of the blood donation

Each unit of blood must have a donation code assigned at the time of the blood donation. Record-keeping procedures must allow for a link between the donation code and the donor identification code. For traceability purposes, an establishment must be able to identify the donor of a specific donation and all other donations from the same donor. The donation code must link the donor, applicable samples collected, unit of blood, time or date of collection, and donor suitability assessment records. *Donation code* and *donor identification code* are defined in section 1, the Interpretation section, of the *Blood Regulations*.

## Registered establishment — Pre-Assessed Donor Program

A registered establishment with a Pre-Assessed Donor Program should refer to subsection 89(b).

## Section 48 Labelling of containers

Labelling of containers

**48.** Subject to section 59, an establishment that collects blood must ensure that every container is labelled in accordance with section 63 at the time of the collection.

## Labelling of containers in accordance with section 63

Establishments that collect blood, with the exception of blood collected from a pre-assessed donor, must label every container at the time of collection in accordance with section 63. A registered establishment with a Pre-Assessed Donor Program should refer to section 90 for specific labelling requirements.

## Section 49 Collection procedures

Collection procedures

**49.** (1) An establishment that collects blood must conduct the collection in the following way:

- (a) use aseptic methods;
- (b) use collection equipment that is licensed under the *Medical Devices Regulations*;
- (c) use containers that are licensed under the *Medical Devices Regulations* and free from defects or damage; and
- (d) record the container lot number in the records and link it to the donation code.

Reuse of containers prohibited

(2) An establishment must ensure that the containers that it uses are used only once.

## Blood donation collection procedures

**49** All of the requirements in section 49 must be met by licensed establishments that collect allogeneic blood and by registered establishments that collect autologous blood or blood from a pre-assessed donor. A registered establishment with a Pre-Assessed Donor Program must also meet the Pre-Assessed Donor Program collection requirements in section 89.

**49(1)(b)** A licensed or registered establishment must use collection equipment licensed under the *Medical Devices Regulations*.

## Use of an automated apheresis device to collect autologous blood

In addition to the requirement for collection equipment to be licensed under the *Medical Devices Regulations*, a *registered establishment* should meet the following requirements if it uses an automated apheresis device to collect autologous blood:

1. In order to ensure human safety and the safety of the blood, a registered establishment should follow collection protocols and procedures specific to the apheresis device. The registered establishment's operating procedures should specify, for each type of blood component or combination, all requirements and criteria to achieve these goals.
2. The requirements and criteria to achieve the goals stated above should be based on clinical and scientific evidence and the most up-to-date scientific knowledge supporting the chosen criteria.

## Container lot number

**49(1)(d)** After recording the container lot number, a licensed or registered establishment may over-label the lot number barcode with the blood component label. In cases where a licensed or registered establishment over labels the lot number bar code, the establishment should leave the lot number text as eye-readable on the container label. The establishment must have a system to trace the specific container lot number associated with each donation.

## Reuse of containers prohibited

**49(2)** A licensed or registered establishment must only use a container once to collect blood. The sterility of the container must not be breached.

## Section 50 Samples

Samples

**50.** An establishment that collects blood must obtain samples of blood for testing at the same time as the collection in a way that avoids contamination of the donated blood and the samples.

## **Blood sample collection requirement for establishments that collect blood**

Section 50 applies to licensed establishments that collect allogeneic blood and registered establishments that collect autologous blood or blood from a pre-assessed donor.

### **Additional requirement for a registered establishment with a pre-assessed donor program**

In addition to meeting the requirement in section 50, when collecting a sample of blood, a registered establishment must also comply with the requirement in subsection 89(c) after collecting a sample of blood from a pre-assessed donor.

## **Section 51 Autologous donations**

### **Autologous donations**

**51.** An establishment that collects autologous blood must  
(a) comply with the criteria set out in section 12.2.1 of the standard; and  
(b) when appropriate, adjust the volume of the blood collected and the volume of anticoagulant based on the donor's weight.

### **Autologous donations — volume of blood and volume of anticoagulant**

**51(b)** When considering the volume of blood to collect from an autologous blood donor and the volume of anticoagulant needed, a registered establishment should refer to clauses 6.2.4 and 12.1.4 of the CSA Blood Standard.

## **Sections 52–56 Testing**

### **Section 52 Authorization**

#### **Authorization**

**52.** A licensed establishment that tests allogeneic blood — except blood from a pre-assessed donor — must do so in accordance with an authorization.

### **Requirement to test allogeneic blood in accordance with an Authorization**

The establishment that holds the Authorization assumes the responsibility for the testing activity and is required to apply to Health Canada for an Authorization or for Authorization amendments for that activity.

### **Exception — Testing of allogeneic blood from a pre-assessed donor**

The testing of blood from a pre-assessed donor must be conducted by a licensed establishment as stated in subsection 17(2). A licensed establishment that tests blood from a pre-assessed donor must conduct the testing in accordance with sections 55 b), 88 and 89.

## **Contracting testing activities to another establishment**

An establishment that holds an Authorization may contract out processing activities to an establishment in Canada or a foreign establishment; for example, testing of blood samples for viral markers. Health Canada does not require the contract establishment that tests the blood samples to apply for an Authorization as long as they do no other allogeneic blood processing activities. Health Canada does require a contract establishment in Canada to file an application with Health Canada for an Establishment Licence (see section 17). Health Canada does not require the foreign testing establishment to hold an Establishment Licence in Canada. See sections 17 and 18 of this guidance for more information for testing contracted to foreign establishments.

If an establishment contracts the testing to another establishment, the testing must be conducted in accordance with the contracting establishment's Authorization. See subsection 5(1), paragraphs 6(1)(h), 6(1)(j) and 6(1)(k).

## **Tests that Health Canada considers appropriate and effective for testing allogeneic blood**

All allogeneic blood donors must be tested and found negative or non-reactive for transmissible diseases and disease agents using appropriate and effective tests performed on a sample obtained from each donation. See sections 88 and 89 for further details concerning testing blood samples from pre-assessed donors.

A test kit used by a laboratory in Canada is considered appropriate and effective if the following requirements are met:

1. It is licensed for the detection of the transmissible disease agent or marker in accordance with the licensing requirements indicated under the *Food and Drugs Act* and the *Medical Devices Regulations*; and
2. The establishment uses a test kit:
  - a. in accordance with the test kit manufacturer's instructions;
  - b. in accordance with their Authorization for the detection of a transmissible disease agent or marker; and
  - c. that is equivalent or exceeds the specificity and sensitivity that is required.



An establishment's Authorization lists the disease agents and markers for which an establishment must carry out transmissible disease testing on allogeneic blood for transfusion or for further manufacture.

### **Testing of samples from each allogeneic blood donation for further manufacture**

Health Canada requires that an establishment test samples from each allogeneic blood donation for further manufacture for transmissible disease agents or markers, including:

- a. antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);
- b. hepatitis B surface antigen (HBsAg);
- c. antibodies to hepatitis C virus (anti-HCV); and
- d. nucleic acid testing (NAT) for HIV-1, HCV, and HBV.

A licensed establishment must test a sample for syphilis using a non-treponemal or treponemal-specific assay as per the frequency specified in the establishment's Authorization.

### **When licensed *in vitro* diagnostic devices are unavailable**

If no *in vitro* diagnostic device (which may include both the testing platform and the test kit) — licensed in Canada — is available to test for a particular disease agent or marker, a licensed establishment may

- use an *in vitro* diagnostic device that has received Special Access or Investigational Testing authorization by the Medical Devices Bureau, Therapeutic Products Directorate, Health Canada; or,
- apply for an amendment to their Authorization to use an in-house test kit.

For an *in vitro* diagnostic device that has received Special Access or Investigational Testing authorization by the Medical Devices Bureau, the licensed establishment must follow the *in vitro* diagnostic device manufacturer's instructions, including the following:

- a. the collection, handling, and storage of blood specimens;
- b. the time frame within which samples must be tested, if applicable;
- c. the procedure for testing; and

- d. the interpretation of the test results, including the interpretation of repeat reactive or positive results.

The licensed establishment applying for an amendment to their Authorization to use the in-house diagnostic device must include the instructions required and itemized in the list a–d above, in addition to the full set of validation data supporting the use of the in-house diagnostic device in their processing activities.

### **When testing is performed by a laboratory outside of Canada**

If testing is performed outside Canada, the following information must be provided to Health Canada as part of the Authorization:

- a. details of transmissible disease agents or markers and serology testing to be employed in blood screening testing;
- b. algorithms to be used for each marker, in case of initial reactive tests;
- c. a list of all test kits currently in use at the facility;
- d. certification that the kit is approved by the United States Food and Drug Administration, or Health Canada's Medical Devices Bureau, or alternatively, approval to use the kit must be obtained from Health Canada's Biologics and Genetic Therapies Directorate;
- e. evidence of the regulatory compliance of the testing facility;
- f. confirmation of the date of the last audit by the establishment of the contract facility and the proposed time frame for subsequent audits;
- g. a copy of the most recent United States FDA 483, where applicable, and a copy of the response provided; and
- h. proof of an internal or external auditing system for the contract testing facilities.

### **Bacteriological testing of platelets**

A licensed establishment that collects or prepares platelets must have a method, authorized by Health Canada under the *Blood Regulations*, to detect bacterial contamination of platelets. Completion of bacteriological testing is not necessary prior to release of blood components for transfusion.

A licensed establishment's quality management system must have protocols in place for the management of platelet units and associated components for which there is a reactive result. See section 94 for quality management system requirements.

## Quality control testing

See paragraph 94(1)(b) of this guidance for quality control testing.

## Section 53 Autologous donations — transmissible disease testing

Autologous donations — transmissible disease testing

**53.** An establishment that collects autologous blood must test a sample of the blood using appropriate and effective tests for transmissible diseases and disease agents in accordance with section 12.3.1.2 of the standard.

## Frequency of transmissible disease testing — autologous donations

When a registered establishment collects more than one donation from an autologous blood donor over a 42-day period, testing is only required on the first donation for transmissible disease agents listed in clause 12.3.1.2 of the CSA Blood Standard. Once a new 42-day period begins, the establishment must test the donor's first autologous donation for that period.

## Appropriate and effective tests for transmissible diseases and disease agents

Health Canada considers tests for the following infectious disease markers to be appropriate and effective in order to comply with clause 12.3.1.2 of the Standard:

- a. antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);
- b. hepatitis B surface antigen (HBsAg);
- c. antibodies to hepatitis C virus (anti-HCV); and
- d. antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II).

Nucleic acid testing and syphilis testing of autologous donors is not required.

## Section 54 Autologous donations — ABO and Rh

Autologous donations — ABO and Rh

**54.** (1) An establishment that collects autologous blood must test a sample of the blood at the time of each donation to identify both of the following:

- (a) the ABO group; and
- (b) the Rh factor, including weak D testing when appropriate.

Comparison of results

- (3) The establishment must compare the results of the tests conducted under paragraphs (1)(a) and (b) with the last available results, if any, for that donor.

Discrepancies

(3) If the comparison indicates a discrepancy, the establishment must repeat the tests and must not transfuse the blood until the discrepancy is resolved.

## Section 55 Medical devices

Medical devices

**55.** When testing autologous blood or blood that is collected from a pre-assessed donor, an establishment must use medical devices that are licensed under the *Medical Devices Regulations* for the following purposes:

- (a) either for diagnosis or for screening donors, in the case of autologous blood; and
- (b) for screening donors, in the case of blood that is collected from a pre-assessed donor.

### Test kit requirements for testing autologous blood

**55(a)** Subsection 55(a) applies to registered establishments that test autologous blood.

Test kits licensed as diagnostic assays or as screening assays must be used when testing autologous donations. The use of unlicensed test kits — including in-house tests — is prohibited.

The registered establishment must follow the test kit manufacturer's instructions including the following:

- a. the collection, handling, and storage of blood specimens;
- b. the time frame within which samples must be tested, if applicable;
- c. the procedure for testing; and
- d. the interpretation of the test results.

Registered establishments must have operating procedures for transmissible disease testing that conform with the manufacturer's instructions. When a contract laboratory or another establishment tests the samples, the establishment must ensure that the operating procedures of the testing laboratory conform with the test kit manufacturer's instructions. See section 95 for guidance concerning operating procedures.

### Test kit requirements for testing allogeneic blood from a pre-assessed donor

**55(b)** A licensed establishment must test allogeneic blood from a pre-assessed donor for transmissible disease agents and markers using test kits *licensed for donor screening* by Health Canada. An establishment must not use test kits licensed for diagnostic use to test allogeneic blood for transmissible diseases or disease agents.

Donor screening test kits are licensed based on testing that has been conducted in a population with a low disease prevalence (e.g. healthy blood donors), with an emphasis on test sensitivity. In contrast, diagnostic test kits are licensed based on testing conducted in a symptomatic population, with an emphasis on test specificity. Thus, Health Canada considers test kits licensed for donor screening as more appropriate for screening allogeneic blood donors.

## Section 56 Test results

Test results — allogeneic blood

**56. (1)** An establishment that collects allogeneic blood must immediately take all of the following actions if a donor's blood is positive or repeat reactive for a transmissible disease agent or marker listed in its authorization as a contraindication to use:

- (a) quarantine any blood that was collected from that donor at that donation;
- (b) identify and quarantine any other implicated blood from the same donor in the establishment's possession; and
- (c) notify every person to which it distributed any of the implicated blood from the same donor of the test results and, if the person is an establishment, specify in the notice that the blood must not be distributed or transfused.

Test results — autologous blood

**(2)** An establishment that collects autologous blood must inform the donor's physician of any of the test results described in section 12.3.1.6 of the standard.

### Test results that are a contraindication to use allogeneic blood

**56(1)** A licensed establishment must not distribute allogeneic blood or plasma for transfusion or for further manufacture if any test results for transmissible disease agents or markers, as required by their Authorization, are positive or repeat reactive. Any test results for transmissible disease agents or markers — that are a contraindication to use the blood — must be negative.

In the case of a repeat reactive or positive test for a transmissible disease agent or marker listed in the establishment's Authorization as a contraindication to use, the establishment must notify as soon as possible every establishment and person (e.g., blood product fabricator) to which it distributed any implicated blood from the same donor.

### *Exception — Cytomegalovirus testing*

A licensed establishment that collects allogeneic blood for transfusion may choose to test certain donors for cytomegalovirus (CMV). Health Canada recommends that a donor who previously tested negative for cytomegalovirus be retested at each donation, if the establishment intends to label and distribute the unit of blood as CMV negative. See clause 8.6.5.3 of the CSA Blood Standard. If a unit of blood is CMV positive, it does not require any special treatment or labelling. An establishment may distribute CMV positive blood.

## Interpretation of Transmissible Disease Test Results — Allogeneic donation

- *All test results must be negative in order for a donor to be suitable.*
- If test results are initially reactive, the establishment must repeat the testing of the sample as per the package insert instructions.
- If the donor's specimen is repeatedly reactive or positive for a transmissible disease agent or marker listed in the establishment's Authorization, the establishment must not release the blood for transfusion or for further manufacture.
- If a donor's specimen tests positive for a transmissible disease agent or marker the donor must be deferred in accordance with the criteria listed in the establishment's Authorization. In the case of a positive donor specimen from a pre-assessed donor, see section 42 for guidance concerning *Requirement to defer a donor — registered establishment with a pre-assessed donor program*.
- When an allogeneic unit of blood is repeat reactive or positive for a transmissible disease agent or marker, an establishment must inform other establishments to whom it distributed any blood from the same donor.
- A licensed establishment must include the interpretation of the transmissible disease test results, according to the test kit manufacturer's instructions, when determining if blood is safe for distribution.

## Donor Re-entry Criteria

A donor re-entry algorithm specifies the processes, including donor testing and waiting period, that a licensed establishment must follow in order for a previously deferred donor to be considered for re-entry as a suitable donor. Donor re-entry algorithms must be approved by Health Canada as part of an establishment's Authorization.

If a licensed establishment intends to use donor re-entry algorithms for the transmissible disease agents or markers listed in their Authorization, they must file an application for an Authorization amendment providing algorithms to be used for each marker, including confirmatory testing, with supporting scientific evidence and rationale.

## Lookback Procedure

A licensed establishment must carry out the lookback procedure as required by their Authorization and may choose to conduct a lookback procedure for other disease agents that are not listed in their Authorization. A licensed establishment that collects blood must initiate a lookback procedure when it receives any of the following results from donor testing, as applicable:

- Positive Nucleic Acid Test result for HIV-1, HIV-2, HCV, HBV, or WNV;
- Confirmatory positive HIV-1, HIV-2, HCV, HBsAg or HTLV test result following a repeat reactive serology test;
- Notification of confirmatory positive test results of a donor from any of the following:
  - Physician
  - Establishment, such as a hospital, a licensed or a registered establishment
  - Public Health Authority
  - Information from a Traceback investigation, or
  - Donor
- Lookback Investigation (Recipient tracing).

Note: The establishment conducting the lookback procedure should receive a report containing all of the test results if it receives information from an external source.

See 1.5 Definitions, *lookback*.

## Test results — autologous blood

**56(2)** A registered establishment must inform the autologous blood donor's physician of any abnormal test results for the diseases and disease agents specified in clause 12.3.1.2 of the CSA Blood Standard. See also section 53.

## Sections 57–58 Blood Component Preparation

### Section 57 Licensed establishments

Licensed establishments

**57.** A licensed establishment must prepare allogeneic blood components in accordance with its authorization.

### Section 58 Registered establishments

Registered establishments

**58.** A registered establishment must prepare autologous blood components in accordance with sections 7.1.3, 7.2, 7.3.1, 7.3.2, 7.5.1.1 (without regard to the reference to Table 3), 7.5.1.2 and 7.5.1.5, paragraphs 7.5.2.1(a) to (c) and section 7.5.2.2 of the standard.

## Sections 59–68 Labelling

### Section 59 Non-application — pre-assessed donors

Non-application — pre-assessed donors

**59.** Sections 60 to 68 do not apply to the labelling of blood collected from a pre-assessed donor.

See section 90 for labelling requirements that apply to blood collected from a pre-assessed donor.

### Section 60 Language requirement

Language requirement

**60.** All of the information that is required by these Regulations to appear on a label or circular of information must be in English or French.

### Section 61 General requirements

General requirements

**61.** A label must meet all of the following requirements:

- (a) all information on the label must be accurate and must be presented clearly and legibly;
- (b) it must be made using only adhesives and inks that will not permeate the container;
- (c) it must be permanently affixed to the container; and
- (d) in the case of a tag, it must be firmly attached to the container.

**61** The label on a unit of blood must provide accurate information about the contents of the container. See clause 8.6.3.2 of the CSA Blood Standard for instances when a label may be obscured, altered or removed.

**61(d)** When an establishment attaches a supplementary tag to a container, this is also considered a label. Likewise, a tag must have accurate, clear and legible text.

### Section 62 Circular of information

Circular of information

**62.** (1) An establishment that collects allogeneic blood for transfusion must prepare a circular of information in accordance with the authorization and must ensure that it makes the circular available to every establishment to which the blood is distributed and to any other person who requests a copy of it.

Exception

(2) Subsection (1) does not apply if the blood is transfused in the same establishment where it is collected.

**62(1)** See paragraphs 6(1)(h), 6(1)(i) and 6(1)(k) for Authorization requirements that pertain to labelling, including the circular of information.

A licensed establishment that collects allogeneic blood for transfusion must prepare a circular of information in accordance with the Authorization and must ensure that it makes the circular



available to every establishment to which the blood is distributed and to anyone who requests a copy of it.

**62(2)** An example of when it is not necessary to prepare a circular of information is an establishment that collects iRBCs for the immunization of plasma donors at the same establishment.

A registered establishment that collects autologous blood is not required to prepare a circular of information. *Circular of information* is defined in section 1, the Interpretation section, of the *Blood Regulations*.

### Section 63 Donation code

#### Donation code

**63.** An establishment that collects blood must ensure that every container into which blood is collected has a label on it on which the donation code is permanently marked at the time of the collection.

The container must have a label with the donation code at the time of collection. If the donation code is missing or illegible the establishment must not distribute the blood for transfusion or for further manufacture. See paragraph 74(2)(a).

### Section 64 Contents of label

#### Contents of label — blood

**64. (1)** An establishment that collects blood for transfusion must ensure that all of the following information appears on the label of the blood:

- (a) the establishment's name and civic address;
- (b) the establishment's licence number, if it has one, or its registration number;
- (c) the donation code;
- (d) a statement of whether the donation is whole blood or a blood component, and if it is a component, its name;
- (e) when appropriate, the ABO group and Rh factor of the blood;
- (f) except in the case of apheresis, the approximate volume of the whole blood collected;
- (g) the approximate volume of the contents of the container;
- (h) the name of any anticoagulant or additive in the container; for transfusion
- (i) the recommended storage temperature;
- (j) the expiry date and, if applicable, the time;
- (k) in the case of blood for transfusion, a warning that the blood could transmit infectious agents; and
- (l) in the case of allogeneic blood for transfusion, a direction to refer to any applicable circular of information for indications, contraindications, warnings and a list of possible adverse reactions.

#### Autologous blood

**(2)** In addition to the information required by subsection (1), the establishment must ensure that all of the following information appears on the label of autologous blood:

- (a) the statement "For Autologous Use Only";
- (b) if the test results indicate that the blood is positive for a transmissible disease or disease agent

listed in section 12.3.1.2 of the standard, a symbol or words to indicate that the blood is a biohazard; and  
(c) if the blood has not been tested for the transmissible diseases and disease agents listed in section 12.3.1.2 of the standard, an indication to that effect.

Contents of label — blood for use in manufacture of drug for human use

(3) An establishment must ensure that all of the following information appears on the label of blood that is for use in the manufacture of a drug for human use:

- (a) the name, civic address and licence number of the establishment that collected the blood;
- (b) the donation code; and
- (c) the statement “Caution: For Manufacturing Use Only”.

**64** When labelling allogeneic blood for transfusion, an establishment must meet the requirements in 64(1)(a)–(f). The establishment may also indicate on the label if the blood tested negative for cytomegalovirus.

A licensed establishment attaches the final label to the container at the end of processing and prior to transformation or distribution.

**64(1)(a)** The civic address on the label may be the address of the head office of an organization.

**64(1)(b)** Allogeneic blood for transfusion, processed in accordance with an Authorization, must have the processing establishment’s licence number on its label. In the case of an establishment with a number of collection or production sites, the Establishment Licence number can be a single number assigned by Health Canada to the establishment and its sites.

Some establishments may have an Establishment Licence number and a Registration number. These establishments have the option of using their Establishment Licence number on the label of autologous blood.

If an establishment collects blood for transfusion and does not have an Establishment Licence number, they must ensure that their Registration number appears on the label of any autologous units of blood that they collect.

**64(1)(d)** The label must have the name of the blood or blood component in eye-readable text. The name of the component includes the blood component preparation method, when appropriate, e.g. ACD Fresh Frozen Plasma Apheresis. The naming convention in the ISBT 128 Standard is recommended.

A registered establishment must also indicate on the label if a blood component has been transformed. Transformation refers to the washing, pooling (including the pooling of cryoprecipitate), and irradiation of blood components after they have been determined safe for transfusion. It does not include blood component preparation or pathogen reduction technologies

that are considered part of blood component preparation. See subsections 78(2), 79(2) and section 80 for requirements specific to labelling transformed blood.

**64(1)(g)** Unless otherwise indicated on the label or in Circular supplements, the contents or volume are as described in different parts of the Circular of Information or blood and blood component information. Examples of blood component information are information bulletins or other forms of interim documentation.

**64(1)(h)** The label must include the name of any additive or anticoagulant in the container. This requirement includes any anticoagulant or other additive used in the preparation of the blood or blood components. The label must also include any sedimenting agent used during cytapheresis, if applicable.

**64(1)(i)** The label must include the recommended storage temperature. This requirement includes the temperature range for storing the blood or blood component.

**64(1)(j)** The label must include the expiry date. If an expiration time is not indicated, the unit of blood expires at 23:59 on the expiry date. Expiry labels for products with a shelf-life of 72 hours or less must include the time of expiry.

For most blood components, the licensed or registered establishment may choose to include the collection date on the label.

**64(2)** When labelling autologous blood for transfusion, an establishment must meet the requirements in 64(1)(a)–(k).

**64(2)(b)** If an autologous blood donor tests positive for a transmissible disease or disease agent, the label on the autologous unit of blood must have a biohazard symbol or words to indicate that the blood is biohazardous.

**64(3)** Blood for use in the manufacture of a drug for human use should clearly state the name of the component on the label.

## Section 65 Aliquots

### Aliquots

**65.** Except for purposes of immunization, an establishment that divides blood into aliquots for transfusion must ensure that all of the following information appears on the label on each aliquot container:

- (a) the donation code;
- (b) the name of the blood component;
- (c) a code that identifies the aliquot;
- (d) when appropriate, the ABO group and Rh factor of the blood; and
- (e) the expiry date.

**65** Aliquoting is not a processing activity. Blood component preparation does not include transformation or dividing blood into aliquots. Transformation does not include dividing blood into aliquots after the end label has been applied.

For transfusion purposes, the following containers are considered suitable for dividing blood into aliquots:

- a transfer pack or a series of transfer packs using closed system technology;
- sterile vials; or
- syringes.

**65(e)** If an establishment divides blood into aliquots using an open system, then the establishment needs to adjust the expiry date.

If an establishment divides blood into aliquots using a closed system, then the expiry date is the original expiry date.

The expiry date is also dependent upon storage temperatures and the type of blood component. See Table 2 of the CSA Blood Standard for storage temperatures and expiration criteria.

## Section 66 Designated donations

Designated donations

**66. (1)** In addition to the information required by subsection 64(1), an establishment that collects blood for designated use must ensure that the identity of the intended recipient appears on the label.

Change of use

**(2)** The establishment must remove from the label the mention of the identity of the intended recipient when the blood is no longer intended for designated use.

**66(2)** Designated donations may be moved into the general allogeneic blood inventory if the following requirements for general allogeneic blood are met:

1. the donor meets all donor suitability criteria; and
2. the label meets the labelling requirements.

## Section 67 Directed donations

Directed donations

**67.** In addition to the information required by subsection 64(1), an establishment that collects blood for directed use must ensure that the expression “Directed Use Only” and the identity of the intended recipient appear on the label.

A directed donation may only be used for the intended recipient. Directed donations must never be relabelled for any other use.

## Section 68 Label verification

Label verification

**68.** An establishment that labels blood must verify that all of the information that it adds to the label is accurate and complete.

This requirement applies to any establishment that adds information to the label.

Labelling, *after the blood is determined safe for distribution*, is an activity that applies to establishments that transform blood and/or transfuse blood. In addition to meeting this requirement, see subsections 78(2), 79(2) and section 80 for requirements specific to labelling transformed blood.

For registered establishments that label autologous units of blood, table 3 summarizes the required label information for verification. The asterisks indicate when additional machine readable code should be added, if possible. The autologous blood donor/patient name may also appear on the label of the autologous unit.

**Table 3. Autologous unit of blood label verification**

Item	Required Information	Machine Readable Code
1.	Collecting establishment's name	*
2.	Collecting establishment's civic address	
3.	Collecting establishment's Registration number or Establishment Licence number	
4.	Donation code	*
5.	Whole blood or the name of the blood component	*
6.	ABO and Rh group	*
7.	Volume of the whole blood collection, except in the case of apheresis	
8.	Approximate volume of the container contents	
9.	Recommended storage temperature	
10.	Expiry date	
11.	"This product may transmit infectious agents."  <i>Optional:</i> See circular of information for indications, contraindications, cautions and methods of infusion, if applicable.	
12.	Biohazard text or label, if the donor tests positive for a transmissible disease agent for which testing is required	
13.	"For autologous use only"	

Item	Required Information	Machine Readable Code
14.	If a subsequent unit of blood, within a 42-day period, the statement “Untested for HIV, HBV, HCV, HTLV I/II” as appropriate	
15.	Name of intended transfusing establishment, if known	

## Sections 69–72 Storage

### Section 69 Criteria

Criteria — collecting establishment

**69.** (1) An establishment that collects blood must store the blood in accordance with the following:

- (a) in the case of a licensed establishment, its authorization; and
- (b) in the case of a registered establishment, the storage and expiration criteria specified in Table 2 of the standard.

Criteria — receiving establishment

(2) An establishment that receives blood from another establishment must store it in accordance with the directions on its label and with any other directions that are specified in writing by the establishment that collected it.

#### 69(1)(a) Criteria — collecting establishment — licensed

A licensed establishment that stores allogeneic blood must file an application with the BGTD to amend its Authorization if it intends to make a change to the storage and expiration criteria required by its Authorization for the allogeneic blood it has collected. Please refer to section 9 for guidance regarding an application to amend an Authorization.

#### 69(1)(b) Criteria — collecting establishment — registered

A registered establishment that collects autologous blood or allogeneic blood from pre-assessed donors must follow the requirements for the storage temperatures and expiration criteria of that blood as specified in the respective columns of Table 2 of the CSA Blood Standard.

### Section 70 Storage location

Storage location

**70.** An establishment that stores blood must do so in a location that has appropriate environmental conditions that maintain the safety of the blood and that is secure against the entry of unauthorized persons.

All blood must be stored under defined and controlled environmental conditions. The appropriate environmental conditions for storing blood must be defined in an operating procedure.

Environmental parameters for storage, such as temperature must be controlled and monitored. Temperature monitoring probes or devices should be located at points that represent extreme temperature areas, as determined by a temperature mapping study, if applicable. Parameters such as lighting, humidity and ventilation should be appropriate and controlled to the extent necessary to safeguard blood. An establishment that stores blood must keep documentation as evidence that units of blood were maintained under the appropriate environmental conditions. This documentation must be available upon request.

If the storage area has an alarm system with audible signals, alarm activation points should be set at temperatures that allow time for appropriate corrective actions before the units of blood reach unacceptable temperatures. The alarm warning should signal in a location that is continually monitored or staffed so that corrective action can be taken immediately.

An establishment that stores blood must have written procedures describing the corrective actions to be taken in the event of a deviation from established storage criteria. Such an event must be appropriately investigated and documented.

Access to storage areas must be restricted to designated personnel. Where physical quarantine areas are used, they must be marked appropriately with access restricted to designated personnel. Where electronic quarantine is used, electronic access must be restricted to designated personnel.

## **Section 71 Segregation — autologous, designated and directed donations**

Segregation — autologous, designated and directed donations

**71.** An establishment that stores blood must ensure that blood that is intended for autologous, designated or directed use is segregated from blood that is intended for other allogeneic use.

Autologous, designated and directed units of blood must be clearly labeled and segregated from blood that is intended for other allogeneic use either by physical segregation and/or by using a validated electronic segregation system.

## **Section 72 Segregation — untested or positive or reactive test results**

Segregation — untested or positive or reactive test results

**72.** An establishment that stores blood must segregate all of the following blood from blood that has been determined safe for distribution or autologous transfusion under section 73:

- (a) blood that is untested;
- (b) blood for which the testing is incomplete or for which all of the test results are not yet available; and
- (c) blood for which the test results on blood samples are positive or repeat reactive for transmissible disease agents or markers.

Units of blood that are untested, for which testing is incomplete, or for which the results are not yet available, or blood for which the results are positive or repeat reactive, should be clearly labelled and must be controlled by a system that ensures the segregation of that blood from blood that has been tested and determined safe for distribution or autologous transfusion. This can be

achieved by either physical segregation and/or the use of a validated electronic segregation system.

## Sections 73–76      Distribution

### Section 73    Determination of safety

Determination of safety — allogeneic blood

**73.** (1) An establishment that collects allogeneic blood must, before distributing it for transfusion or for use in the manufacture of a drug for human use, determine that it is safe for distribution once the establishment is satisfied that the blood has been processed in accordance with these Regulations.

Determination of safety — autologous blood

(2) An establishment that collects autologous blood must, before distributing it for transfusion, determine that it is safe for autologous transfusion once the establishment is satisfied that the blood has been processed in accordance with these Regulations.

See section 1, the Interpretation section, of this guidance document for the interpretation of *distribute* in the *Blood Regulations*.

#### 73(1) Determination of safety — allogeneic blood

Allogeneic blood must meet the safety requirements of the *Blood Regulations* prior to distribution, including specific processing requirements within an establishment's Authorization. A licensed establishment that collects allogeneic blood is responsible for determining that the blood is safe for distribution.

### Section 74    Verification

Verification

**74.** (1) Before distributing blood for transfusion or for use in the manufacture of a drug for human use, an establishment must examine the container to verify all of the following:

- (a) the information on the label is legible;
- (b) the integrity of the container is intact;
- (c) there are no signs of deterioration or contamination of the blood; and
- (d) any frozen blood components show no signs of thawing.

Prohibition — distribution

(2) An establishment must not distribute blood for transfusion or for use in the manufacture of a drug for human use if the verification carried out under subsection (1) indicates any of the following:

- (a) the donation code is missing or illegible;
- (b) any information — other than the donation code — that is required by these Regulations to appear on the label of blood is missing or is illegible, unless the missing or illegible information can be retrieved from the establishment's records;
- (c) the container is defective or damaged to the extent that it does not protect the blood against external conditions; or
- (d) there are signs of deterioration or contamination of the blood.



Each collection bag must be visually examined for damage or evidence of contamination prior to release into available inventory; before the released blood or blood component is distributed; and, if applicable, prior to further distribution. When any defect, improper labelling or abnormal appearance is observed, the component must be immediately quarantined and properly discarded. An establishment should quarantine returned units of allogeneic blood until the blood is deemed suitable for transfusion. Returned units of blood should not be redistributed unless the blood meets all of the requirements in sections 70 and 74 of the *Blood Regulations*.

**74(1)** Steps 74(1)(a) to (d) should occur throughout the processing of blood. An establishment must meet the requirements in paragraphs 74(1)(a) to (d) prior to distributing blood for transfusion or for further manufacture.

**74(1)(c)** and **74(2)(d)** Examples of deterioration and/or contamination of the blood may include hemolysis, clots, fibrant strands, cellular aggregates, particulate matter or discoloration.

## Section 75 Shipping containers

Shipping containers

**75.** An establishment that ships blood must

(a) examine the blood containers before shipping to verify the integrity of the container and the legibility of the labels; and

(b) use shipping containers that are capable of resisting damage and maintaining the safety of the blood.

### 75(b) Shipping blood to another establishment or between different sites of the same establishment

During shipping to another establishment or between different sites of an establishment, if the blood is transported by someone other than an employee of the establishment, the shipping container must maintain the safety of the blood to ensure no tampering occurred that could affect the safety of the blood. A tamper-proof seal is one way of maintaining and verifying the integrity of the container.

## Section 76 Storage during transportation

**76.** An establishment that ships blood for transfusion must ensure that the blood is stored during transportation in accordance with the criteria specified in Table 2 of the standard.

Section 76 applies to all establishments that ship blood for transfusion.

## Sections 77–80 Transformation

### Section 77 Transformation methods

Transformation methods

**77.** An establishment that transforms blood must do so using safe and effective methods.

The guidance in this section is intended for registered establishments that transform blood components, as interpreted in the definition of *transformation* in the *Blood Regulations*. Transformation activities include washing, pooling and irradiating, once the blood is determined safe for transfusion.

*Note: Transformation activities are not included within the scope of blood component preparation. Pathogen inactivation technologies are not included within the scope of transformation.*

Registered establishments that transform blood components must have validated operating procedures for washing, pooling or irradiating blood components as required in sections 95, 96 and 97 of the *Blood Regulations*.

Records of washing, pooling and irradiating must be kept in accordance with sections 117, 118, and 121 of the *Blood Regulations*.

Prior to washing, pooling or irradiating, the components to be transformed must be inspected for evidence of leaking. Each component must be visually inspected to determine if the component is suitable for transfusion. If the component's appearance is abnormal, the registered establishment must follow procedures as defined by their quality management system.

## **Washing**

A registered establishment must meet the requirements in section 78, in addition to the following safe and effective methods.

### ***Platelets – Washed***

Registered establishments that wash platelets must develop and maintain operating procedures that describe the wash procedure. It is recommended that platelets be washed in sterile normal saline solution and used within 4 hours after washing.

### ***Red Blood Cells, Thawed and Washed***

Red blood cells that are frozen with a cryoprotectant agent must be washed before transfusion and suspended in a Health Canada approved additive solution. A registered establishment must validate and document the thawing and washing process. Registered establishments that wash red blood cells should follow the quality control specifications for “Red blood cells – frozen (deglycerolized)” in table 3 of the CSA Blood Standard.

## **Pooling**

An establishment must meet the requirements in section 79, in addition to following safe and effective methods. An establishment that pools blood components must do so in an environment

that is suitable for this purpose. Precautions must be taken by the establishment to prevent contamination of the unit of blood's ports. If a biological safety cabinet or laminar flow hood is used, when pooling in an open system, it must be used according to the manufacturer's instructions. See 1.5 Definitions *pooling*: pooling includes mixing.

### ***Cryoprecipitate, pooled***

Cryoprecipitate is prepared by licensed establishments that hold an Authorization. Pooling of cryoprecipitate is a transformation activity that does not require a Registration. Establishments that pool cryoprecipitate must use safe and effective methods.

## **Irradiation**

Irradiation requirements, within the scope of transformation activities, are specific to gamma irradiation. A registered establishment must meet the requirements in section 80, in addition to the following safe and effective methods. Health Canada recommends dedicated irradiation equipment be used when irradiating blood components. If a registered establishment intends to use radiotherapy machines to irradiate blood components, equivalent validated operating procedures are required for the use of this equipment for this purpose. The irradiation equipment must be maintained as required in section 100 of the *Blood Regulations*. Irradiation dosage measurements must be monitored and documented by the establishment.

### ***Platelets, irradiated***

A registered establishment may irradiate platelets at any time during their five-day storage period. Once the platelets are irradiated, they may continue to be stored up to their standard expiry date.

### ***Granulocytes, irradiated***

When granulocytes are to be irradiated, a registered establishment should irradiate them as soon as possible following component preparation. Irradiated granulocytes should be transfused as soon as possible.

## **Section 78 Washing**

### **Washing**

**78.** (1) An establishment that washes blood must do so in accordance with sections 7.5.2.3 and 7.5.3 of the standard.

### **Labels**

(2) An establishment that washes blood must amend the label to add to it a mention of the washing and any new expiry date and time.

**78(1)** Red blood cells — washed in an open system — must be stored in accordance with clause 7.5.3.4 of the CSA Blood Standard.

If a closed system is used, the red blood cells must be stored in accordance with a defined validated period. A closed system has little or no interaction with external environmental conditions that could lead to the contamination of the blood component. An establishment may use sterile connecting devices to avoid contamination of the blood component during the washing process.

An establishment that washes red blood cells must meet the storage requirements stated in Table 2 of the CSA Blood Standard.

**78(2)** If the washed red blood cells are transferred into a new blood container, the new label must contain the information from the original label, including the donation code, in addition to the name of the washed red blood cell component and the new expiry date.

## Section 79 Pooling

### Pooling

**79.** (1) An establishment that pools blood components must do so in accordance with sections 7.11.1 and 7.11.3 of the standard.

### Labels

(2) An establishment that pools blood components must ensure that all of the information specified in sections 10.8.2 and 10.8.3 of the standard appears on the label of the pooled components.

## Section 80 Irradiation

### Irradiation

**80.** An establishment that irradiates blood must do so in accordance with sections 7.12.2 to 7.12.6 of the standard.

In accordance with clause 7.12.3 of the CSA Blood Standard, a registered establishment must have a validated method in place to ensure that the blood component has received the required dosage of irradiation. An establishment can monitor the irradiation of blood components by using a radiation sensitive label or device and documenting the blood component dosimetry results in its records. An establishment should be able to demonstrate compliance of its component labelling and release procedures through an audit of the irradiation process.

## Sections 81–85 Exceptional Distribution

### Section 81 Conditions

#### Conditions

**81.** 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 following 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.

This section only permits blood otherwise processed in accordance with an Authorization to be exceptionally distributed for transfusion. The blood that is the subject of the exceptional distribution will therefore be allogeneic blood pursuant to an Authorization but that has not been fully tested in accordance with the Authorization.

Exceptional distribution occurs as an emergency treatment for a single patient on a case-by-case basis, and when the two conditions in 81(a) and (b) are met.

Allogeneic blood donors must meet the donor suitability requirements of the *Blood Regulations*. The exceptional distribution section of the *Blood Regulations* allows for the transfusion of allogeneic blood to a single patient when all test results are not yet available for the unit(s) of blood. An establishment may release blood components for transfusion prior to the completion of bacteriological testing. Please refer to section 52, *bacteriological testing of platelets*, of this guidance.

## Section 82 Notice of exceptional distribution

Notice of exceptional distribution

**82. (1)** An establishment that distributes blood under section 81 must complete a notice of exceptional distribution that contains all of the following information:

- (a) the name of the establishment and the signature of the medical director;
- (b) the donation code;
- (c) a statement of whether the blood was whole blood or a blood component, and if it was a component, its name;
- (d) a list of the test results that were not available at the time of the distribution;
- (e) the name and signature of the recipient's physician;
- (f) the justification for the distribution;
- (g) the name of the establishment to which it distributed the blood; and
- (h) the date and time of the distribution.

Notice in establishments' records

(2) The establishment must keep the notice in its records and send a copy of it to the establishment to which it distributed the blood.

Notice to be forwarded

(3) If the establishment to which the blood is distributed does not perform the transfusion, it must send a copy of the notice to the establishment where the transfusion is performed.

Notice in recipient's file

(4) The establishment where the transfusion is performed must keep the notice in the recipient's file.

**82(1)(d)** The notice must contain information about all test results that were not available at the time of exceptional distribution.

## **82(2) Notice of exceptional distribution in the establishment's records**

An establishment that holds an Authorization and makes an exceptional distribution of blood must keep a copy of the notice in its records. The notice of exceptional distribution must be accessible. Similarly, follow-up assessment and donor testing results must be available in the records of the establishment that made the exceptional distribution.

## **82(3) Notice of exceptional distribution to be forwarded**

If the intended recipient of the blood that is the subject of exceptional distribution is transferred to another establishment, the establishment must forward the notice of exceptional distribution to the establishment where the transfusion is performed.

## **82(4) Notice of exceptional distribution in the recipient's file**

The establishment, where the transfusion was performed, must keep a copy of the notice in the recipient's file. Similarly, follow-up assessment and testing results of the donor are to be added to the recipient's file.

The notice of exceptional distribution must be accessible upon request.

## **Section 83 Labelling**

### **Labelling**

**83.** An establishment that distributes blood under section 81 must label it to indicate that the testing required by these Regulations is incomplete or that all of the test results are not yet available, as the case may be.

## **Section 84 Follow-up**

### **Follow-up**

**84. (1)** An establishment that distributes blood under section 81 either before the testing is complete or before the test results are all available must, after the distribution, conduct any remaining testing and provide the establishment to which it distributed the blood with all of the relevant test results as soon as they become available.

### **Results to be forwarded**

**(2)** If the establishment to which the blood was distributed did not perform the transfusion, it must send a copy of the test results to the establishment where the transfusion was performed.

An establishment that holds an Authorization and distributes blood under the conditions of exceptional distribution must complete all testing and conduct any other appropriate follow-up testing. The establishment that distributed the blood under section 81 must notify the establishment where the blood was distributed of the test results as soon as they are available.

## Section 85 When blood not transfused

When blood not transfused

**85.** If blood that is the subject of an exceptional distribution is not transfused into the intended recipient in the emergency, the establishment that was to perform the transfusion must not store the blood or transfuse it into another recipient.

See item 7 of the Table to section 122, Records and retention periods, for record-keeping requirements regarding the disposition of unused allogeneic blood for transfusion.

## Sections 86–91 Pre-Assessed Donor Programs

### Section 86 Program characteristics

Program characteristics

**86.** An establishment that has a pre-assessed donor program must ensure that the program has both of the following characteristics:

- (a) it is carried out under the supervision of a medical director; and
- (b) it is used only when
  - (i) no other alternative source of blood appropriate for the recipient is available, and
  - (ii) the recipient's physician requests the blood for use in the emergency treatment of their patient.

### Section 87 Donor identification code

Donor identification code

**87.** An establishment that has a pre-assessed donor program must assign a donor identification code at the time of the donor's acceptance into the program.

The donor identification code for a pre-assessed donor is specific to their participation in the Pre-Assessed Donor Program.

### Section 88 Regular donor assessment and testing

Regular donor assessment and testing

**88.** (1) An establishment that has a pre-assessed donor program must take both of the following steps every three months:

- (a) assess the suitability of every donor in the program in accordance with sections 40 to 44; and
- (b) take blood samples from every donor and test them for all of the following:
  - (i) the transmissible diseases and disease agents listed in sections 8.4.1 and 8.4.2 of the standard,
  - (ii) the ABO group,
  - (iii) the Rh factor, including weak D testing when appropriate, and
  - (iv) clinically significant antibodies.

Comparison of results

(2) The establishment must compare the results of the tests conducted under subparagraphs (1)(b)(ii) and (iii) with the last available results, if any, for that donor.

Discrepancies

(3) If the comparison indicates a discrepancy, the establishment must repeat the tests and must not collect any blood from that donor until the discrepancy is resolved.

## 88(1) Regular donor assessment and testing

**88(1)(a)** See sections 40 to 44 for donor suitability assessment guidance.

**88(1)(b)** Blood samples taken from a donor every three months must be tested for the infectious disease agents listed in clauses 8.4.1 and 8.4.2 of the CSA Blood Standard. Health Canada considers tests for the following infectious disease markers to be appropriate and effective in order to comply with clauses 8.4.1 and 8.4.2 of the Standard:

- a. antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2);
- b. hepatitis B surface antigen (HBsAg);
- c. total antibody to hepatitis B core antigen (anti-HBc, IgG and IgM);
- d. antibodies to hepatitis C virus (anti-HCV);
- e. antibodies to human T-lymphotropic virus type I and type II (anti-HTLV-I and anti-HTLV-II);
- f. syphilis using a non-treponemal or treponemal specific assay;
- g. WNV NAT
  - during times in the year when WNV is potentially transmissible to humans in Canada; and
  - for donors who have travelled to WNV endemic areas in the preceding 56 days.

**88(1)(b)(ii), (iii), (iv)** Blood samples taken from a donor every three months must be tested to determine the donor's blood type (i.e. ABO group and Rh type) and clinically significant red cell antibodies.

**88(1)(b)** Blood samples taken from a donor every three months may be tested to evaluate or provide information about the blood itself (e.g. red blood cell phenotyping) or to determine the human leukocyte antigen (HLA) type.

## Section 89 At each collection

At each collection

**89.** An establishment that collects blood from a pre-assessed donor must take all of the following steps at each collection:

- (a) assess the suitability of the donor;
- (b) assign a donation code to the blood collected and link the code in its records to the donor identification code; and
- (c) take a sample of blood from the donor and test it within 72 hours for all of the following:



- (i) the transmissible diseases and disease agents listed in sections 8.4.1 and 8.4.2 of the standard,
- (ii) the ABO group,
- (iii) the Rh factor, including weak D testing when appropriate, and
- (iv) clinically significant antibodies.

**89(a)** See sections 40 to 44 for donor suitability assessment guidance.

**89(b)** Each unit of blood must have a donation code assigned at the time of collection. Record-keeping procedures must allow for a link between the donation code and the donor identification code. For traceability purposes, the registered establishment must be able to quickly identify the donor of a specific donation and all other donations from the same donor. See section 1, the Interpretation section, for the definitions of *donation code* and *donor identification code*.

**89(c)** A registered establishment that collects blood from a pre-assessed donor must ensure that a blood sample is taken from the donor at the time of donation and is tested within 72 hours for the infectious disease markers specified under paragraph 88(1)(b).

If any test results for transmissible disease agents or markers are positive or repeat reactive from a pre-assessed donor, the licensed establishment that tested the blood must immediately notify the registered establishment that assessed the implicated donor.

## Section 90 Labelling

### Labelling

**90.** An establishment that collects blood from a pre-assessed donor must ensure that at least the donation code and the ABO group and, when appropriate, the Rh factor appear on the label of the blood.

## Section 91 When blood not transfused

### When blood not transfused

**91.** If blood that is collected from a pre-assessed donor is not transfused into an intended recipient in the emergency, the establishment that was to perform the transfusion must comply with the requirements of section 16.2.5 of the standard.

## Section 92 Importation in Urgent Circumstances

### Information — before importation

**92.** (1) An establishment may, in urgent circumstances, import allogeneic blood that was not processed in accordance with an authorization if it provides the Minister with all of the following information before the importation:

- (a) the information required by paragraphs 6(1)(a) and (j) with respect to each foreign establishment that processes blood that it proposes to import;
- (b) a copy of the circular of information for the blood that is proposed to be imported, or an equivalent document;

- (c) a copy of the donor screening questionnaire that is used by each foreign establishment that processes blood that it proposes to import, including a document that indicates how that questionnaire differs from the one referred to in section 41;
- (d) a description of how post-donation information described in paragraph 44(1)(b) is evaluated in the foreign jurisdiction;
- (e) a description of the conditions of storage and transportation of the blood that is proposed to be imported, both before and after its importation;
- (f) a description of how the establishment proposes to identify the blood as having been imported in urgent circumstances; and
- (g) a description of how errors, accidents and adverse reactions are investigated and reported in the foreign jurisdiction.

Information — at each importation

(2) At the time of each importation described in subsection (1), the establishment must provide the Minister with the following information:

- (a) a written justification that demonstrates the existence of urgent circumstances; and
- (b) a description of any further processing or labelling that may need to be done to the blood before its transfusion.

Meaning of “urgent circumstances”

(3) In this section, “urgent circumstances” means that there is an insufficiency of allogeneic blood in Canada that poses an immediate and substantial risk to public health.

## **92(1) Information — before importation**

If an establishment intends to include the importation of blood in urgent circumstances as a part of its emergency contingency plan, the establishment must meet requirements specific to this type of importation prior to the occurrence of the urgent circumstance.

**92(1)(a)** Health Canada requires the importing establishment to provide information about the foreign establishment, as required by paragraphs 6(1)(a) and (j), to the Blood Establishment Regulation Unit at the Biologics and Genetic Therapies Directorate, Health Canada. See subsection 6(1) of this guidance for contact information.

**92(1)(b)** The importing establishment must provide Health Canada with the following:

- the foreign establishment’s circular of information; or
- equivalent information about the blood components it proposes to import in urgent circumstances.

**92(1)(c)** The importing establishment must provide Health Canada with the following:

- the donor screening questionnaire from each foreign establishment from whom it proposes to import blood in urgent circumstances; and

- a document that describes the differences between each foreign establishment's donor screening questionnaire and the importing establishment's authorized donor screening questionnaire.

**92(1)(d)** The importing establishment must provide Health Canada with a description of how the foreign establishment evaluates post-donation information in its jurisdiction. The requirement for the evaluation of post-donation information in Canada is described in subsection 44(2) of the *Blood Regulations*.

**92(1)(e)** When planning for the importation of blood in urgent circumstances, the importing establishment must provide Health Canada with a description of the conditions of storage and transportation of the blood both before its importation and after its importation.

The conditions of storage and transportation include temperature, expiration and segregation.

**92(1)(f)** The importing establishment must describe to Health Canada the means the establishment will use to distinguish blood that is imported in urgent circumstances. This includes how the establishment will identify the blood imported in urgent circumstances when it distributes it to transfusing establishments.

**92(1)(g)** The importing establishment must provide Health Canada with a description of how errors, accidents and adverse reactions are investigated and reported in the foreign jurisdiction. Any errors, accidents or adverse reactions that occur as a result of processing by the foreign establishment should be reported according to the requirements of the foreign jurisdiction. If the foreign establishment is conducting an investigation into a serious error or accident with respect to blood that was imported into Canada, the importer in Canada should report the investigation to Health Canada.

## **92(2) Information — at each importation**

When an establishment imports blood in urgent circumstances, Health Canada must be provided with the following information for each importation:

- written documentation describing the urgent circumstances and why there is insufficient allogeneic blood in Canada; and
- a description of any further processing that the establishment may need to conduct before the blood may be transfused by establishments in Canada.

## 92(3) Meaning of urgent circumstances

Urgent circumstances make it impossible for a licensed establishment in Canada to rely on its own allogeneic blood supply or that of other establishments in Canada. The absence of a domestic solution to the situation brings about the justification to import blood in urgent circumstances. Note: *urgent circumstances* does not include blood for immunization of donors of plasma for further manufacture.

## Sections 93–123 Quality Management

### Sections 93–94 Quality Management System

#### Section 93 Organizational structure

##### Organizational structure

**93.** (1) A licensed or registered establishment must have an organizational structure that sets out the responsibility of management for all activities that the establishment conducts.

##### Oversight

(2) The establishment must have an effective quality management system, and must name an individual who has responsibility for it.

##### Periodic review

(3) The establishment must review its quality management system at regular intervals that are specified in the operating procedures, to ensure its continuing suitability and effectiveness.

**93(1)** Establishments conducting activities, for which an establishment licence or registration is required, must identify the hierarchical structure of the establishment with clear delineation of the areas of responsibility and lines of authority in a current organizational chart. These establishments must have an individual responsible for the quality management system. In addition, key personnel could include a Medical Director (as defined in section 1 of the Regulations), and an individual(s) responsible for operations (processing, transformation, importation), as applicable. The titles and areas of responsibility must be documented for all activities related to blood.

**93(2)** Establishments conducting activities, for which an establishment licence or registration is required, must ensure that their activities comply with the regulatory requirements. To ensure compliance these establishments must have a comprehensively designed and implemented quality management system and are subject to all requirements in subsection 94(1).

The quality management system is an integrated system of quality assurance that includes all matters that individually or collectively maximize the safety of blood. This system must encompass the following:

- be defined, documented, implemented and maintained by the establishment;

- include elements that enable the prevention, detection and correction of deficiencies that may compromise the safety of the blood;
- include an organizational structure that defines and documents the personnel responsible for all activities under these Regulations; and
- ensure that written policies, processes and procedures that cover the regulated activities are available and communicated to all relevant personnel.

The establishment must appoint an individual responsible for the quality management system, and this individual is responsible for ensuring that quality objectives are met. The attainment of the quality objectives requires the participation and commitment of personnel in many different departments and at all levels within the establishment.

The individual responsible for the quality management system may delegate duties and responsibilities to qualified personnel in accordance with subsection 98(1) of the Regulations, but remains accountable for those delegated duties and responsibilities.

**93(3)** Establishments conducting activities for which an establishment licence or registration is required, must review all elements of the quality management system at specified intervals to ensure its continuing suitability and effectiveness. The results of the review must be assessed. Any deficiencies or areas requiring improvement must be addressed and corrected, and a plan that includes goals, objectives and action plans should be developed and utilized.

## Section 94 Requirements

### Requirements

**94.** (1) The quality management system must include all of the following elements:

- (a) a quality assurance unit;
- (b) a quality control program;
- (c) a change control system;
- (d) a process control program, within the meaning of section 3.1 of the standard;
- (e) a system for process improvement through complaint monitoring and the implementation of corrective and preventive actions;
- (f) 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;
- (g) a program for the training and competency evaluation of personnel;
- (h) a proficiency testing program for the evaluation of the accuracy and reliability of test results;
- (i) a document control and records management system;
- (j) an internal audit system;
- (k) emergency contingency plans;
- (l) a system that uniquely identifies all critical equipment and supplies;
- (m) written specifications for all critical equipment, supplies and services;

- (n) a program for the preventive maintenance of critical equipment; and  
(o) a program for process validation.

Separation of functions

(2) The establishment's quality assurance unit must be a distinct organizational unit that functions and reports to management independently of any other functional unit.

Exception

(3) Subsection (2) does not apply in the case of a licensed establishment that only tests allogeneic blood or a registered establishment if the establishment ensures that any individual who conducts an internal audit does not have direct responsibility for the activities being audited

### **94(1)(a) Quality Assurance Unit**

Quality assurance includes the actions, planned and performed, to provide confidence that all systems and elements that influence the safety of blood are working as expected individually and collectively. A quality assurance unit consists of one or more individuals designated by the individual responsible for the quality management system, with defined authority and responsibility, to ensure compliance to the Regulations.

### **94(1)(b) Quality Control program**

The quality control program is a component of the quality management system that includes the activities and controls used to determine the acceptance of the establishment's products, supplies, and equipment, based on their specifications. Quality control must be conducted as per operating procedures.

Section 100 of the Regulations further specifies requirements for critical equipment and section 102 of the Regulations further specifies requirements for critical supplies.

### ***Licensed establishments***

A quality control program, that assesses the quality of blood, must be followed by every licensed establishment that collects allogeneic blood for transfusion. The following must be defined by each licensed establishment and authorized by Health Canada:

- the frequency of quality control testing, expressed as a percent of overall production;
- the minimum number of tests required specified over a period of time; and
- the acceptable criteria for quality control testing of each type of component.

The results of quality control testing must be analysed on an ongoing basis and appropriate corrective action taken when values deviate from acceptable limits.

### **Registered establishments**

Registered establishments that wash red blood cells must also conduct quality control testing. The tests that must be completed, acceptance criteria for each test, and the quantity of units to be tested must be defined in operating procedures. Registered establishments should follow Table 3 of the CSA Blood Standard for this purpose.

#### **94(1)(c) Change control system**

A change control system must be established and maintained to identify, document, review, approve and control all processes. Any changes to the processes, supplies, equipment and facilities that may impact the safety of blood must be properly documented, thoroughly evaluated, approved and managed. Any significant change may necessitate revalidation in accordance with the requirements of paragraphs 94(1)(d) and 94(1)(o).

These approvals are in addition to those required by Health Canada for licensed establishments as part of their Authorization.

#### **94(1)(d) Process control program, within the meaning of clause 3.1 of the standard**

Establishments must have a process control program that covers all stages of their regulated activities. Clause 3.1 of the CSA Blood Standard defines process control as “the management of processes and procedures that affect the quality of products and services, with the goal of ensuring that processes and procedures are performed consistently and as they were intended to be performed in order to produce predictable output.”

Policies and operating procedures must be in place to ensure all processes are conducted under controlled and defined conditions by qualified personnel.

#### **94(1)(e) A system for process improvement through complaint monitoring and the implementation of corrective and preventive actions**

The establishment must have a system for process improvement through complaint monitoring and the implementation of corrective and preventive actions. Corrective action focuses on eliminating causes of existing nonconformities in order to prevent recurrence whereas preventive action focuses on eliminating the causes of potential nonconformities in order to prevent occurrence. The establishment must also have policies, processes and operating procedures for the handling of complaints. All complaints must be reviewed, assessed by the appropriate department, documented and investigated in accordance with the establishment’s operating procedures, including identifying and implementing corrective and preventive actions, as applicable. All decisions and follow-up actions, taken as a result of a complaint investigation, must be recorded.



As part of the establishment's system for process improvement, if preventive action is required, the preventive actions must be implemented and monitored to reduce the likelihood of a recurrence and to take advantage of the opportunity for improvement. Once corrective and/or preventive actions are implemented, the effectiveness of these actions must be evaluated.

#### **94(1)(f) System for Identification and Investigation of Post-Donation Information, Errors/Accidents, Adverse Reactions and Conduct of Recalls**

Establishments must have defined processes and operating procedures to identify, gather information, and address any post-donation information (section 44 of the *Blood Regulations*), errors and accidents (sections 103 to 108 of the *Blood Regulations*), and adverse reactions (sections 109 to 116 of the *Blood Regulations*) that occur and for lookback/traceback programs. These operating procedures must outline the decision-making processes used in determining whether an investigation is warranted and the implementation of any corrective actions, as appropriate.

In the course of an investigation, non-conformances may be identified and corrective actions may be required. For non-conformances that may affect the safety of the blood, part of the corrective actions could include the identification, quarantine and recall of implicated blood, if applicable, until the investigation is completed and the issue is satisfactorily addressed. The type of corrective action is dependent upon the severity and nature of the non-conformance.

Establishments must have a system to effectively conduct prompt recalls of blood. With regards to the recall of blood distributed for further manufacturing into a drug for human use, this falls under the *Food and Drug Regulations*. Operating procedures must be in place to define steps for an effective removal of any non-conformant blood from distribution or use. Records must be kept to allow for the prompt identification and location of implicated blood. The procedures must identify the position(s) within the establishment responsible for (i) obtaining information on the implicated blood; (ii) initiating the recall; and (iii) reviewing distribution records necessary for recall coordination. The operating procedure should also outline the communication method to be used to notify all establishments to which the blood was distributed and, as such, are involved in the recall. All recalled blood must be identified and placed in quarantine until its disposition is determined.

The procedures must also describe reporting requirements for errors and accidents and adverse reactions to Health Canada as required in the *Blood Regulations* under sections 107, 108, 109, 113, 115, and 116.

Establishments must document all recalls and retain the documentation as per the requirements for record retention of investigations in sections 119 to 122 of the *Blood Regulations*.



### **94(1)(g) A program for the training and competency evaluation of personnel**

Establishments must have a written training program as well as a formal competency-evaluation program. Personnel must receive initial and on-going training appropriate to their job responsibilities related to activities regulated under the *Blood Regulations*, as defined in operating procedures. The requirements for these programs are described in subsection 98(2).

### **94(1)(h) Proficiency testing program for the evaluation of accuracy and reliability of test results**

Proficiency testing, an important aspect of the quality management system, monitors a establishment's ability to perform testing procedures within the predetermined acceptable limits of detection and accuracy through the analysis of unknown specimens.

The establishment must ensure that all personnel involved in testing participate in a proficiency testing program (e.g. on a rotational basis) using the establishment's routine testing procedures.

The results of proficiency testing must be reviewed by management and examined to identify trends that signal a systemic issue. When required, an establishment must apply corrective actions in order to rectify identified issues.

Records related to proficiency testing must be maintained, including test results, trend analyses and corrective actions taken.

### **94(1)(i) Document control and records management system**

Establishments must define, document and maintain operating procedures to control all quality documents and information relevant to the activities they conduct with respect to the *Blood Regulations*.

The distribution and maintenance of operating procedures and other quality documents, e.g. policies, forms, etc., must be controlled, so that only the current versions are available for use. Previous versions of quality documents must be removed, archived, and replaced with the current approved version. Obsolete quality documents must be removed and archived. A copy of every version of the operating procedures that was implemented must be retained in accordance with sections 119–122 of the *Blood Regulations*.

### **94(1)(j) Internal Audit System**

Internal audits must be performed on all regulated activities under the *Blood Regulations*, at intervals specified in the operating procedures, to verify the continuing effectiveness of the

quality management system. The audit will include an assessment of whether the operating procedures are being followed and the activities conducted consistently lead to the expected results and comply with the requirements of the *Blood Regulations*. The audit plan must include an assessment of all regulated activities. A typical period for conducting these audits is at a minimum every two years. These audits must be conducted in accordance with an established program and written procedures.

Audits can be performed by trained personnel, or by an external auditor (qualified third party) who is performing the audit on behalf of the establishment and is knowledgeable in the subject matter being audited. Auditors must not have direct responsibility for the procedures or processes they are auditing. For example, a supervisor responsible for component preparation must not audit any component preparation activities conducted by their own department.

Any establishment that contracts another establishment to perform any regulated activity on its behalf is responsible for establishing processes to periodically verify that the performance of those activities comply with the *Blood Regulations* and applicable operating procedures. For example, the establishment can assess another establishment's compliance by performing an audit on the other establishment or by reviewing audit reports from a third-party that are provided by that other establishment.

The findings from audits and follow-up actions required must be documented and subsequently reviewed by the individual responsible for the quality management system. Preventive and corrective actions must be implemented in a timely manner. Records of internal audits, including preventive and corrective actions, and audits of contracted establishments must be retained in accordance with the requirements for records in sections 119–121 of the *Blood Regulations*.

#### **94(1)(k) Emergency Contingency Plans**

Establishments must have emergency contingency plans in the event that processes are interrupted, such as in the case of a power outage or natural disaster.

The emergency plans must include a manual procedure to issue blood to hospitals and transfusion services from released inventory and must ensure that traceability requirements continue to be met, in the event that the computerized inventory system and/or its back-up system have malfunctioned. The emergency plans must include details for maintaining the safety of blood in storage. The emergency contingency plans must be reviewed periodically for their effectiveness. If applicable, the emergency power supply must be maintained and tested periodically for its readiness.

#### **94(1)(l) A system that uniquely identifies all critical equipment and supplies**

See section 1, the Interpretation section of this guidance document, for the definition of *critical*.

As part of the quality system, an establishment must have a system to identify, document and track all critical equipment and supplies. Within this system, each piece of equipment must have a unique identifier. A barcode system is one example of this type of system.

#### **94(1)(m) Written specifications for all critical equipment, supplies and services**

See section 1, the Interpretation section of this guidance document, for the definition of *critical*. Written specifications must be available for all critical equipment, supplies and services. Establishments must have defined processes and ensure that in the event of any changes to regulatory requirements or technology, the specifications continue to meet the applicable requirements of the *Blood Regulations*.

In cases where the specifications are not met, an establishment must have a system in place to ensure prompt effective remedial action, which could include the timely reporting of complaints, deviations or product defects to their supplier or service provider.

#### **94(1)(n) A program for preventive maintenance of critical equipment**

See section 1, the Interpretation section of this guidance document, for the definition of *critical*. Critical equipment must consistently meet its specifications in order to produce blood that is safe. Establishments must have a preventive maintenance program to keep the function of all critical equipment within required performance specifications.

The preventive maintenance program must have defined processes which include a predetermined schedule of technical services to verify that the performance and calibration of each piece of critical equipment meets the specifications identified in the manufacturer manual and/or the specifications required by the establishment's quality system. The processes must include the method to be used, frequency of calibration and action to be taken when equipment performance deviates from defined limits. This requirement applies to all equipment, instruments and measuring devices critical to ensuring that blood conforms to the *Blood Regulations*. Preventive maintenance must be conducted by qualified personnel.

The preventive maintenance schedule must be maintained and all records and reports of maintenance services, including actual test results indicating that equipment is qualified and calibrated according to the manufacturer's instructions, must be retained. Section 100 of the *Blood Regulations* describes the requirements for cleaning, validation and calibration of critical equipment.

#### **94(1)(o) A program for process validation**

Establishments must have a program in place to demonstrate that a specific process is capable of achieving planned results and predetermined specifications with a high degree of assurance.

A written validation plan could include testing methods, equipment to be used, validation procedures, acceptance criteria and supporting documentation.

The need for revalidation should be assessed when changes are made to a validated process. Depending on the nature and extent of the changes, e.g. changes that could affect the original validation, process characteristics and/or safety of the blood, a revalidation may be necessary. Documentation requirements will be the same for the initial validation of the process.

**94(2)** An individual may have more than one function, but the quality assurance unit must function and report to management independently of the individual(s) responsible for operations.

**94(3)** Licensed establishments that only test allogeneic blood or establishments that conduct activities requiring registration are not required to have a quality assurance unit that is a distinct organizational unit that functions and reports to management independently of any other unit, if the individual who conducts an internal audit does not have direct responsibility for the activities being audited.

## Sections 95–97 Operating Procedures

### Section 95 Operating procedures required

Operating procedures required

**95.** An establishment must have operating procedures for all of the activities that it conducts with respect to human safety and the safety of blood.

Operating procedures are an essential element of the quality management system that is composed of instructions that set out the processes for an establishment to follow in conducting its activities. Operating procedures provide personnel with instructions or directions, so that activities are performed and documented consistently and in compliance with regulatory requirements.

An establishment must develop and maintain written operating procedures describing the significant steps for each regulated activity that it conducts.

### Section 96 Requirements

Requirements

**96.** The operating procedures must meet all of the following requirements:

- (a) be in a standardized format;
- (b) be approved by a senior executive officer;
- (c) be readily accessible at all locations where the activities to which they relate are conducted; and
- (d) be kept up to date.

The format of each operating procedure should include:

- a. the title and purpose of the procedure;
- b. the unique number or code identifying the document and indicating the version;
- c. the date of implementation and the last revision date;
- d. the signature of the authorizing person and the date of authorization;
- e. appropriate page numbers;
- f. clear instructions to be followed that correspond to the tasks required to perform the activity and may include the completion of worksheets, forms or electronic fields;
- g. the responsible department for performing the operating procedure; and,
- h. references to publications cited, if applicable.

Operating procedures must be kept up-to-date. The procedures should be reviewed and/or revised periodically at a minimum every two years. The operating procedures must be reviewed by a knowledgeable person(s) and changed, as applicable: (i) after any amendment to the *Blood Regulations* or the referenced CSA Blood Standard; (ii) in response to audit findings; or (iii) as a result of corrective or preventive actions identified following an error, accident or adverse reaction.

All personnel responsible for carrying out a procedure must be trained prior to performing any task associated with a new or revised operating procedure. Operating procedures must be accessible at the location where individuals are conducting the activities.

In an urgent situation, a deviation from a current operating procedure is allowed if permitted by a senior executive officer or designate, and the deviation is documented, signed and dated. The reason for the deviation from the procedure must also be documented. For licensed and registered establishments, the deviation must be managed in accordance with the quality management system of the *Blood Regulations*.

The distribution and maintenance of operating procedures must be controlled, so that only the current versions are available for use. Previous versions of procedures must be removed, archived and replaced with the current approved version. Obsolete procedures must be removed and archived. Every version of the operating procedures that were implemented must be retained

in accordance with the requirements for record retention found in sections 119–122 of the Regulations.

## Section 97 Documented evidence

Documented evidence

**97.** An establishment must have documented evidence that demonstrates that the operating procedures that it uses in processing and transforming blood will consistently lead to the expected results.

An establishment's activities, processes and technical procedures used in the processing and transformation of blood must be

- validated by the establishment; or, as appropriate;
- established in standards developed by recognized and relevant professional organizations, based on established practice; or
- supported by current and relevant information available in the scientific literature.

## Sections 98–102 Personnel, facilities, equipment and supplies

### Section 98 Personnel

Personnel

**98.** (1) An establishment must have sufficient personnel, who must be qualified by their education, training or experience to perform their respective tasks, to conduct the establishment's activities.

Competency

(2) An establishment must have a program for the orientation and training, both initial and ongoing, of personnel and for the evaluation of their competency.

An establishment must prepare and maintain a current organizational chart with clear delineation of the lines of responsibility. A sufficient number of qualified personnel must be available to perform the tasks required. Their qualifications and responsibilities must be documented.

All personnel performing, or responsible for regulated activities, must be qualified in accordance with the establishment's policies, and have the necessary combination of education and/or experience. They must also receive training appropriate to their duties.

Personnel must receive initial and ongoing training, including remedial and retraining as necessary and appropriate for their duties. Training provided must be given by qualified personnel who have knowledge with regard to the functions involved. Training must be given in accordance with a training program for all personnel involved in activities carried out with

respect to blood. Training must be provided prior to the initiation of job duties or performing the tasks outlined in a new procedure or any revision of an existing procedure.

An establishment must have and maintain a program for the evaluation of the competency of personnel. The elements of a competency program may include, but are not limited to

- direct observation of performance;
- monitoring of records;
- written tests;
- assessment of knowledge of operating procedures and theory; and
- for personnel who normally perform routine testing, an assessment of performance through proficiency tests.

Records of the qualifications, training and continuing competency of personnel must be maintained. Training must be documented, include the date on which the training was conducted and should include the signature of the employee.

## Section 99 Facilities

### Facilities

**99.** A licensed or registered establishment must have facilities that permit all of the following:

- (a) the conduct of all of its activities;
- (b) the performance by personnel of their respective tasks using proper hygiene;
- (c) the cleaning of the facilities in a way that maintains sanitary conditions;
- (d) environmental controls that are appropriate to all areas where its activities are conducted;
- (e) controlled access to all areas where its activities are conducted; and
- (f) donor screening to be conducted in privacy.

Premises must be designed, constructed and adapted to suit the activities to be conducted. Their design and furnishing must minimize the risk of errors. Buildings must be maintained in good order. Facilities must have a donor screening area that allows for privacy when determining donor suitability. In addition, facilities must control access to all areas where its activities are conducted, as appropriate, and the entrance to the building should be monitored.

Premises should be designed to align with the process flow, so that operations can proceed in an orderly manner and include the following for control and security:

- a. a blood collection area, set up for safe blood withdrawal from donors;

- b. storage of critical supplies, including reagents and test kits, prior and following to quality assurance acceptance;
- c. an area for handling blood components and reagents not suitable for use or that have been recalled;
- d. area for preparing blood components and laboratory testing;
- e. area for labelling and releasing of components into inventory;
- f. storage areas as described in sections 69–72 of the *Blood Regulations* and associated guidance; and
- g. segregation control for biological waste.

Facilities must permit the conduct of activities using proper hygiene, with an emphasis on hand hygiene. Personnel hygiene procedures should also include the use of appropriate protective clothing.

The interior surfaces of the processing areas must be free of any cracks or holes and any porous surfaces must be sealed to allow efficient cleaning. The premises are to be maintained in a clean and sanitary condition. A written sanitation program should be available that addresses good housekeeping issues. An accidental spill clean-up procedure should be available and include instructions to dispose of blood spills as biohazardous material. The choice of cleaning supplies used in the processing or transformation areas should be reviewed to ensure they do not have any negative effects on the safety of the blood. In addition, a pest control program should be in place.

Where necessary, the building must be equipped with an appropriate HVAC (heating, ventilation and air conditioning) system to maintain temperature and air flow control.

The following considerations must be given when blood collection is conducted in a mobile clinic:

- (i) adequate environmental conditions;
- (ii) general cleanliness;
- (iii) provision of a secure supply of water and electricity;
- (iv) adequate space to enable the collection of blood from donors;



- (v) adequate control of access to blood, records and equipment; and
- (vi) an area for donor screening to be conducted in privacy.

## Section 100 Equipment

### Equipment

**100.** (1) A licensed or registered establishment must ensure that the critical equipment that it uses is cleaned and maintained and, as appropriate, validated for its intended purpose and calibrated.

### Repair or change

(2) The establishment must, whenever necessary after it repairs or makes any change to critical equipment, revalidate and recalibrate the equipment, as appropriate.

See section 1, the Interpretation section of this guidance document, for the definition of *critical* and for examples of critical equipment.

Equipment should be situated in a location that facilitates cleaning and maintenance. Cleaning must be performed according to established schedules to prevent contamination and maintain the safety of the blood. Cleaning procedures must address cleaning product residues that may potentially impact the safety of blood. The procedures must also include the cleaning and decontamination of any blood spills on the equipment, as applicable.

Equipment must also be validated and calibrated according to the manufacturer's instructions, to ensure that it consistently operates within established specifications. Schedules and procedures for the maintenance and calibration of equipment must be maintained and followed according to the specifications in the equipment manual. These procedures must include the frequency of calibration and include the actions to be taken when equipment performance deviates from defined limits. This requirement applies not only to the equipment, but also to all instruments and measuring devices used that are critical to ensuring that the blood conforms to the *Blood Regulations*. Paragraph 94(1)(n) describes the preventive maintenance of critical equipment.

If equipment has been repaired, moved, or modified, then re-calibration and/or revalidation must be conducted in accordance with the establishment's operating procedures and/or the manufacturer's manual before further use. In addition, where appropriate, measures should be taken to prevent unintended adjustments on the equipment or instrument that may impact its calibration settings.

All validation, qualification, calibration, maintenance and repair activities, including actual results, are to be documented and retained by the establishment.

If a licensed or registered establishment uses a computer system for regulated activities, it must be validated. There should be processes and operating procedures to support the maintenance and security of computer systems and their data. For an establishment that holds an Authorization, any modifications to the computer system must be authorized and documented as per the

requirements in sections 9, 10 and 12 of the *Blood Regulations*. Controls must be in place to limit access to the computer system data to ensure unauthorized changes are not made to software or data.

A registered establishment's program for the validation of computer systems should have a system acceptance test to address the following points:

- system functionality;
- system performance;
- critical parameters; and
- operating procedures.

The tests should ensure that the computer operates as indicated and meets the user requirements.

Data of a critical computer system must be backed up periodically and securely stored for data recovery. Computer validation records must be maintained and used as a reference for any system updates, changes and data recovery in case of system failures. Evidence must be presented that the equipment is performing to its specifications prior to the return to its regular use.

Any modifications, repairs and system updates to critical equipment must be assessed for a re-validation of the equipment.

## Section 101 Storage equipment

### Storage equipment

**101.** An establishment must use equipment to store blood that enables the establishment to meet the requirements of sections 69 to 72.

The storage equipment must be qualified and calibrated to demonstrate it can continuously maintain the on-going required temperature and any other appropriate storage conditions. A predetermined schedule for equipment maintenance must be established and adhered to in order to safeguard the safety of the blood being stored.

Storage equipment used to store blood, such as refrigerators, freezers and incubators must have measures in place to ensure continuous monitoring. Monitoring devices must be qualified, calibrated and maintained. Documentation that the blood was maintained under the appropriate environmental conditions must be retained. (For record retention requirements, refer to sections 117 to 122.) The storage equipment must also be secure against the entry of unauthorized persons.

The storage equipment should have an automated alarm system with audible signals for monitoring the required environmental conditions. For temperature monitoring, alarm activation points should be set at temperatures that allow sufficient time for appropriate corrective actions before the blood reaches unacceptable temperatures. The alarm warning should signal in a location that is continually monitored or staffed so that corrective actions can be taken immediately. If a manual system is employed, adequate measures must be in place for monitoring temperature and agitation devices to ensure that the safety of the blood is maintained.

The establishment must have operating procedures in place to maintain the above-mentioned equipment and a continuous temperature monitoring program for the stored blood. The operating procedures should describe the actions to be taken in the event of deviations from established temperature ranges or failure of agitation. Such events must be appropriately documented and investigated.

## Section 102 Supplies

### Supplies

**102.** A licensed or registered establishment must ensure that the critical supplies that it uses are validated or qualified, as applicable, for their intended use and must store them under appropriate environmental conditions.

The quality assurance unit must ensure that the critical supplies are validated or qualified, as applicable, prior to release of the supply. The release of the supply is based on established specifications and may include visual examination, lot specific release, and review of certificates of analysis. Only supplies that meet the documented requirements must be used. See section 1, the Interpretation section of this guidance document, for the definition of *critical* and for examples of critical supplies.

The conditions of use and storage of each supply must meet the conditions specified by the manufacturer. The expiry dates of supplies must be strictly observed.

## Sections 103–108 Error and Accident Investigation and Reporting

The regulatory requirements for errors and accidents, including investigation, reporting and record keeping, apply to all establishments, regulated under the *Blood Regulations*. This not only applies to those establishments that are licensed and/or registered with Health Canada, but also to those that are not required to be registered or licensed, but do conduct activities that fall under the *Blood Regulations*. The requirements with respect to the handling of errors and accidents are set out in sections 103–108 of the *Blood Regulations*.

Under the *Blood Regulations*, an *accident* means 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* means a deviation from the operating procedures or

applicable laws that could compromise human safety or the safety of blood. All definitions are found in the Interpretation section of the *Blood Regulations*.

Establishments may suspect that an error or accident occurred during an activity that they conducted, or during an activity conducted by another establishment, and therefore, it is critical that all involved establishments communicate to ensure that all affected establishments are aware of the error or accident and any results of an investigation. In addition, when notifying other establishments with respect to errors and accidents, any verbal communications must be documented and written notices must be sent as soon as possible as per sections 103(4) and 104(6). When required to do so by the *Blood Regulations*, establishments must identify and quarantine any implicated blood, so as to prevent the transfusion or further distribution of the implicated blood and ensure that it is segregated from all other blood. As set out in the *Blood Regulations*, in sections 119, 120 and 122, all establishments must maintain records of distribution. At a minimum, as per section 118, these must contain the donation codes of the blood, so as to permit the rapid identification and location of all blood units.

## Sections 103–104      Errors and Accidents

### Section 103 Error or accident of another establishment

Error or accident of another establishment

**103.** (1) An establishment that has reasonable grounds to believe that the safety of blood may have been compromised by the occurrence of an error or accident during an activity conducted by another establishment must immediately take all of the following actions:

- (a) determine the donation codes of the implicated blood;
- (b) identify and quarantine any implicated blood in its possession; and
- (c) notify all of the following establishments:
  - (i) the establishment that collected the implicated blood,
  - (ii) the establishment from which it received the implicated blood, if different from the establishment mentioned in subparagraph (i), and
  - (iii) any establishment to which it distributed implicated blood.

Contents of notice

(2) The notice must include all of the following information:

- (a) the donation codes of the implicated blood;
- (b) a statement of whether the implicated blood is whole blood or blood components, and the names of the implicated blood components; and
- (c) the reason for the establishment's belief that the safety of the blood may have been compromised.

Action on receipt of notice

(3) An establishment that is notified under subparagraph (1)(c)(iii) or under this subsection must immediately notify to the same effect every establishment to which it distributed implicated blood and quarantine all implicated blood in its possession.

Written notice

(4) If a notice under this section is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

An establishment that has reasonable grounds to believe, based on the information available, that the safety of blood may have been compromised because of an error or accident that occurred during an activity conducted by another establishment (e.g. processing, transformation) must immediately follow the actions listed in subsection 103(1). The establishment must identify and quarantine any blood implicated in the error or accident and notify all relevant establishments without delay. In all cases, if a notice was provided verbally, a written notice must follow as soon as possible afterwards.

Under subsection 103(3), establishments that receive a notice under subparagraph 103(1)(c)(iii) or subsection 103(3), must quarantine all of the implicated blood in their possession.

Furthermore, they must forward the notice to any establishment to which they further distributed any implicated blood.

## Section 104 Establishment's own error or accident

Establishment's own error or accident

**104.** (1) An establishment that receives a notice under subparagraph 103(1)(c)(i) or (ii) or suspects that an error or accident that occurred during an activity it conducted may have compromised the safety of blood must immediately take all of the following actions:

- (a) determine the donation codes of the implicated blood;
- (b) identify and quarantine any implicated blood in its possession; and
- (c) determine whether there is sufficient evidence to warrant proceeding to an investigation into the suspected error or accident.

When no investigation — notice

(2) If the establishment determines that an investigation is not warranted, it must notify the establishment that sent it the notice under subparagraph 103(1)(c)(i) or (ii) that it will not be conducting an investigation and provide its reasons for that decision.

Action on receipt of notice

(3) An establishment that is notified under subsection (2) or under this subsection must immediately notify to the same effect every establishment to which it distributed implicated blood.

Notice of investigation

(4) If the establishment determines that an investigation is warranted, it must begin the investigation, notify every establishment and other person to which it distributed implicated blood, and include the following information in the notice:

- (a) the donation codes of all implicated blood; and
- (b) a description of the suspected error or accident and an explanation of how the safety of the implicated blood may have been compromised.

Action on receipt of notice

(5) An establishment that is notified under subsection (4) or under this subsection must

immediately notify to the same effect every establishment to which it distributed implicated blood and quarantine all implicated blood in its possession.

Written notice

(6) If a notice under this section is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

Section 104 addresses situations where establishments suspect that an error or accident occurred during an activity that they conducted, or when an establishment receives a notice that an error or accident could have occurred at their establishment.

Under subsection 104(1), upon receipt of the notice under subparagraph 103(1)(c)(i) or (ii), or when an establishment suspects that an error or accident occurred during an activity it conducted, the establishment must immediately determine the donation codes of the implicated blood and whether any other units of blood may be implicated in the same error or accident (e.g. other components with the same donation code, any other units that were subject to the same suspected processing, transformation or storage conditions). The establishment must also identify and quarantine any implicated blood in its possession and determine whether there is sufficient evidence to initiate an investigation.

### **(1) When an investigation is not warranted**

#### ***An establishment that receives a notice of a suspected error or accident:***

Under subsection 104(2), in cases where the establishment that collected or distributed the implicated blood receives a notice under subparagraph 103(1)(c)(i) or (ii) and does not have reasonable grounds to believe that the safety of the blood has been compromised by the error or accident during an activity it conducted it must notify the establishment from which it received the notice that it will not be conducting an investigation. The establishment must provide the reasons for not conducting an investigation and retain a documented, detailed rationale for that decision in its records. This is to ensure that all suspected errors and accidents are assessed.

In the event that an establishment had sent a notice under subparagraphs 103(1)(c)(i) and (ii), it must wait for a response to its notice by both implicated establishments prior to forwarding the decision that an investigation is not warranted and determining the disposition of the blood that it presently has under quarantine.

Under subsection 104(3), any establishment that receives a notice under subsection 104(2) or 104(3) must forward this notice to every establishment to which they distributed any implicated blood.

If a notice was provided verbally, a written notice must be sent as soon as possible afterwards.

***An establishment that suspected that an error or accident occurred during an activity it conducted:***

In the event that an establishment suspects an error or accident occurred during an activity it conducted that could compromise the safety of the blood, but then determines that an investigation is not warranted, it must document the decision and retain this decision and detailed rationale in its records.

**(2) When an investigation is warranted**

If the establishment determines that an investigation is warranted, in accordance with subsection 104(4), the establishment must notify all establishments or other persons (including blood product fabricators) to which it distributed implicated blood that it is conducting an investigation. In the notice, the establishment must list the donation codes of the implicated blood. In the notice, the establishment must also describe the suspected error or accident and include an explanation of how the safety of the implicated blood may have been compromised. If a notice was provided verbally, a written notice must follow as soon as possible.

**Sections 105–108      Investigation and Reporting**

**Section 105 Requirement to cooperate**

**Requirement to cooperate**

**105.** (1) An establishment must, on request, provide any establishment that is conducting an investigation with any relevant information in its possession in respect of blood that it distributed or transfused.

**Communication**

(2) When more than one establishment is affected by an error or accident or the investigation of one, each establishment must ensure that every other establishment that is so affected is kept informed of all relevant information and of all developments and issues that arise during the investigation.

Establishments must cooperate with any establishment that is conducting an investigation and provide any relevant information, as requested. This information includes, but is not limited to, an inventory list of implicated blood with their disposition (e.g. distributed, transfused, quarantined) and the names of establishments to which the implicated blood has been distributed.

In accordance with the *Blood Regulations*, it is critical that all involved establishments communicate to ensure that all affected establishments receive relevant information regarding the investigation. Therefore, it is expected that establishments notify the appropriate establishments, including any establishment to which they sent implicated blood, of any investigation of a suspected error or accident and of any developments and issues that arise during the investigation.



The establishment conducting an investigation must have mechanisms in place to communicate with all establishments that may have been impacted by the error or accident in a timely and accurate manner.

In the event that an establishment sends a notice under subparagraphs 103(1)(c)(i) and (ii), the establishment must wait for a response to the notice from both implicated establishments prior to determining the disposition of the blood that is presently under quarantine. If neither the establishment that collected the blood nor the establishment from which they received the blood proceeds to an investigation, communication between all affected establishments is expected to be maintained, so as to determine the disposition of the blood. In addition, any conclusions drawn by any of these establishments must be shared with all other implicated establishments.

## Section 106 Investigation results

### Investigation results

**106.** (1) An establishment that is conducting an investigation must notify in writing every establishment and other person to which it distributed implicated blood of the results of the investigation and of any action that is required to be taken.

### Notice to be forwarded

(2) An establishment that is notified under subsection (1) or under this subsection must send a copy of the notice to every establishment to which it distributed implicated blood.

The establishment must notify, in writing, all of the establishments or other persons (including blood product fabricators) that were previously notified under subsection 104(4) of the results of the investigation. Where it is determined that the safety of implicated blood has not been compromised, the establishment may make recommendations with regards to the disposition of the blood.

As stated in paragraph 4(7)(b) of the Prohibition section of the *Blood Regulations*, where the results of the investigation show that the safety of the implicated blood has been compromised, or the results are inconclusive, the implicated blood is not to be distributed or transfused.

Upon receipt of the notice under subsection 106(1) or subsection 106(2), the establishment must send a copy of the notice to every establishment to which they further distributed the implicated blood.

## Section 107 Reports to Minister

### Reports to Minister

**107.** (1) An establishment that is conducting an investigation into a suspected error or accident that is thought to have occurred during an activity that it conducted and that is identified after the blood is distributed or transfused must file the reports described in subsection (2) with the Minister if there is a reasonable probability that the error or accident could lead to a serious adverse reaction.

### Contents and timing



- (2) The reports must include the following information and be filed at the following times:
- (a) a preliminary report that includes all relevant information that is available, within 24 hours after the start of the investigation; and
  - (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 the 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.

Written notice

- (3) If the report under paragraph (2)(a) is given verbally, a written report must be filed as soon as possible afterwards.

Final report to Minister

- (4) On completion of an investigation, the establishment must file a final report with the Minister that contains all of the following information:
- (a) the results of the investigation;
  - (b) the final disposition of the blood that was the subject of the investigation and the reasons for that disposition; and
  - (c) any corrective actions taken and any other changes that are recommended to be made to relevant processes.

Section 107 applies to establishments that distribute blood and establishments that transfuse blood who are investigating suspected errors and accidents. For further guidance on *distribution*, please refer to section 1 Interpretation in this guidance document. The establishments are required to report to Health Canada all suspected errors or accidents that are identified after the distribution or transfusion of blood (as applicable) and if there is a reasonable probability that these could lead to a serious adverse reaction. This preliminary report must be filed with Health Canada within 24 hours of the start of an investigation. For example, an establishment that distributes blood for transfusion must provide Health Canada with a preliminary report of an error or accident that is identified after the distribution of blood, if there is a reasonable probability that the error or accident could lead to a serious adverse reaction. Establishments that transfuse blood must also report suspected errors or accidents identified after the transfusion of blood, if there is a reasonable probability that these could lead to a serious adverse reaction, as outlined in section 107.

The preliminary report must include all available information regarding the suspected error or accident. The information provided in the preliminary report could consist of, but is not limited to: a description of the E/A; risk assessments; number of implicated units of blood and/or blood components; corrective actions taken to date (including any notifications sent to establishments that received the implicated blood); and, any anticipated corrective actions. Corrective actions focus on eliminating causes of existing nonconformities in order to prevent recurrence.

Errors and accidents discovered before the distribution or transfusion of the blood are not required to be reported, but still need to be investigated by the appropriate establishment.

In the case of blood that has been imported into Canada, where the foreign establishment is conducting an error or accident investigation with respect to blood that was distributed to Canada — and if there is a reasonable probability that the error or accident could lead to a serious adverse reaction — the importer in Canada must report the investigation to Health Canada, as the foreign establishment is conducting the activities on its behalf.

## **Error and Accident Reporting**

All establishments are requested to provide the error and accident reports and any information required under this section to the appropriate Inspectorate Regional Program, to the attention of the Regional Manager, Inspectorate Program. Establishments with multiple sites across Canada are to send error and accident reports to the Ottawa location of the Health Products and Food Branch Inspectorate, to the attention of the Manager, Blood, Tissues, Organs and Xenografts (BTOX) Unit.

Please see below for the address information for the Inspectorate Regional Programs and the address information for error and accident reports directed to the Manager of the BTOX Unit.

### **INSPECTORATE PROGRAM, ATLANTIC REGION**

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Email [Insp.woc-coo@hc-sc.gc.ca](mailto:Insp.woc-coo@hc-sc.gc.ca)

Province: British Columbia

Reporting address for establishments with multiple sites across Canada:

Manager, Blood, Tissues, Organs and Xenografts Unit  
Health Products and Food Branch Inspectorate  
Graham Spry Building – 3rd Floor  
250 Lanark Ave  
Ottawa, Ontario K1A 0K9  
Tel 613-954-5011  
Fax 613-960-2156  
Email: [BTOX\\_STOX@hc-sc.gc.ca](mailto:BTOX_STOX@hc-sc.gc.ca)

An error and accident report form will be available on the Health Canada website. This form is primarily designed to facilitate submission of preliminary reports to Health Canada within 24 hours after the start of the investigation. Therefore, this form should not be used for the ongoing or the final investigation reports where more detailed and comprehensive information are to be reported. Although this form is recommended for preliminary reports, other formats will be accepted. It is acknowledged that all information may not be available at the time of initial reporting. In addition, it is highly recommended that where the transmission of information via fax is not successful, establishments contact the appropriate regional offices to obtain further contact information, or send the information electronically.

## **Investigation**

During an error or accident investigation, an establishment must determine whether any other blood is affected, the status of the implicated blood (e.g. the number of units distributed, quarantined or transfused) and the number of implicated establishments that were contacted. Establishments are to assess and implement any additional procedures or corrective actions required to mitigate the risk and to prevent similar occurrences.

## **Reports**

Reports must be provided to the appropriate Health Canada Inspectorate Regional Program in accordance with section 107. Following the preliminary report, the establishment is to provide the Inspectorate with a written update on any new information about the suspected error or accident within 15 days after the start of the investigation. The update is to include information regarding the status of all implicated blood units and the number of implicated establishments contacted. The report must also include information on the progress made in the investigation since the last report including root cause analysis, planned corrective actions and the steps taken to mitigate further risks, such as conducting a recall. Health Canada may also request an update at any time after the preliminary report.

Health Canada may request a recall based on the information received. A recall is the removal from further distribution or use of a distributed product that presents a risk to the health of Canadians or violates the *Food and Drugs Act* and its associated regulations. Please note that the 2014 amendment to the *Food & Drugs Act* provides the Minister with the authority to order a recall, as deemed necessary.

Upon completion of the investigation, the establishment is to notify and provide a final report to the appropriate Health Canada Inspectorate Regional Program. The final report must include the results of the investigation, specify any infectious agent(s), results of any tests performed, follow-up and corrective actions taken, and details of the final disposition of the blood, including but not limited to: number of units distributed, transfused, quarantined and discarded.

## **Scenario**

The following scenario is for illustrative purposes only and provides further guidance on the necessary steps to be followed by an establishment when a particular error or accident is suspected.

### ***Scenario #1***

In a regional hospital, Hospital A, after removing a red blood cell (RBC) unit from the refrigerator in order to perform compatibility testing for transfusion, the transfusion medicine laboratory noticed the unit was hemolyzed. This unit was part of a shipment received from a main hospital that contained six RBC units in total. Three of the six units had been further distributed by Hospital A to another regional hospital, Hospital B. The two remaining units located at Hospital A were not found to be hemolyzed. Hospital A had reasonable grounds to believe that the hemolysis was not caused during an activity conducted by them.

Hospital A is required to perform the following:

- Identify the donation code of the hemolyzed unit and the donation codes of the other RBC units in the same shipment;
- Quarantine the hemolyzed unit and the two remaining units;
- Immediately notify the establishment that collected the implicated units;
- Immediately notify the establishment (main hospital) from which they received the six units;
- Immediately notify the other regional hospital, Hospital B, to which it distributed the three units from the same shipment.

In the notice to the establishments above, Hospital A must provide the reason for its belief that the safety of blood may have been compromised.

Any verbal communications must be documented and written notices must be sent as soon as possible.

Upon receipt of the notice, Hospital B will verify the status of these units, and quarantine them.

The establishment that collected the blood and the main hospital that received the notification of a suspected error or accident from Hospital A must review the information received and these establishments are required to perform the following actions:

- Determine the donation codes of the implicated blood;
- Identify and quarantine any implicated units in their possession;
- If an investigation is not warranted, the establishment(s) must notify the establishment that sent the notice of the suspected error or accident to that effect and provide the reasons for the decision to not conduct an investigation;
- If an investigation is warranted, the establishment(s) where the error or accident occurred, must begin the investigation and notify every establishment and other person who received blood, including any blood product fabricators to which implicated blood was sent for further manufacturing. The notice will include the donation codes of the implicated blood and the relevant information regarding the error or accident and how the safety of the blood may have been compromised;
- As per section 105, establishments must cooperate with the establishment conducting the investigation. In addition, all establishments must communicate and provide all relevant information and developments on the investigation to every establishment that is involved with the error or accident;
- As per section 106, the establishment conducting the investigation must notify in writing to every establishment and other person who received implicated blood, of the results of the investigation. An establishment receiving this information must forward the notice to every establishment to which they sent the implicated blood;
- If there is a reasonable probability that the error or accident could lead to a serious adverse reaction, the establishment conducting the investigation must follow the requirements as set out in section 107 of the *Blood Regulations*.

## Section 108 Annual Report

### Annual report

**108.** (1) An establishment must prepare an annual report that summarizes all of the error and accident investigations that it conducted in the previous 12 months, including a concise critical analysis of those investigations, and must file it with the Minister on request.

### When to notify Minister

(2) If the analysis reveals a previously unidentified risk to the safety of blood, the establishment must notify the Minister immediately.

### Additional reports

(3) An establishment must, on the Minister's request, file additional reports described in subsection (1) in respect of the period specified in the request.

These requirements, found in section 108, apply to all establishments that are regulated under the *Blood Regulations*. Each establishment must prepare an annual report that includes all of the error and accident investigations that were conducted by their establishment in the previous 12 months. This includes all errors and accidents that fall under the scope of the *Blood Regulations*, identified before and after the distribution or transfusion of the blood.

The report could be separated into categories — e.g. types of errors and accidents, types of blood components, activities, areas, other categories, etc. The establishment must include an analysis of the investigations that clearly identifies any recurring issues and trends. These reports must be filed with Health Canada, upon request, and may be reviewed during the inspection by Health Canada. In addition, Health Canada may request that additional reports be prepared and submitted by the establishment, in respect of a specified time period designated by Health Canada.

If any previously unidentified risks are discovered through the preparation of the report, *or* at any point in time, the establishment must notify Health Canada immediately. Written notifications should be sent to the following address:

Manager, Blood, Tissues, Organs and Xenografts Unit  
Health Products and Food Branch Inspectorate  
Graham Spry Building - 3<sup>rd</sup> Floor  
250 Lanark Avenue  
Ottawa, Ontario K1A 0K9  
Tel 613-954-5011  
Fax 613-960-2156

## Sections 109–116      Adverse Reaction Investigation and Reporting

### Section 109      Adverse Donor Reactions

#### Section 109 Notice to Minister

Notice to Minister

**109.** (1) An establishment that has reasonable grounds to believe that a donor has experienced a serious adverse reaction during a donation or within 72 hours after a donation must notify the Minister of the adverse reaction within 24 hours after it learns of the death of the donor or within 15 days after it learns of the adverse reaction in any other case.

Contents of notice

(2) The notice must contain all of the following information:

- (a) a description of the adverse reaction;
- (b) any actions that were taken to address it; and
- (c) the outcome.

Written notice

(3) If a notice under this section is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

**109(1)** A serious adverse reaction in a donor may occur as a result of a whole blood or apheresis blood donation. When a serious adverse reaction in a donor occurs during a donation or within 72 hours after a donation and the reaction could impose a risk to the safety of the blood, the establishment that collected the blood must notify the Minister within 15 days. If a donor dies during a blood donation or within 72 hours after the donation, the establishment that collected the blood must notify the Minister within 24 hours after it learns of the death of the donor. A licensed or registered establishment should refer to section 1, the Interpretation section, for the definitions of *adverse reaction*, and *serious adverse reaction* when determining what must be reported as an adverse reaction in a donor.

**109(2)** When a licensed or registered establishment reports a donor's serious adverse reaction, the notice must contain, at a minimum, a description of the following:

- the adverse reaction;
- any actions that were taken to address it; and
- the outcome.

The licensed or registered establishment must describe any actions taken to address the serious adverse reaction, including treatment of the donor. The notice must include the final outcome of the donor's serious adverse reaction, i.e. whether the outcome is no deferral or temporary or indefinite deferral. The identity of the donor is not required in the notice.



The notice should also contain all of the following information:

- donor identification code;
- donation code;
- donor's age and sex; and
- a description of the reaction, including:
  - date, time, place;
  - donor type (allogeneic vs. autologous);
  - donation history (repeat vs. first time);
  - donation type (whole blood, plasmapheresis, cytapheresis);
  - clinical symptoms;
  - assessment of the reaction and relationship to the donation; and
  - sequelae.

In the event that all of the information above is not available at the time of reporting, a notice with all the information should be submitted to Health Canada as soon as possible after the initial report.

**109(3)** When a licensed or registered establishment provides verbal notice to Health Canada about a donor's serious adverse reaction, the establishment must also provide written notice to Health Canada without delay.

An establishment may use any adverse reaction or event reporting form to provide written notice to Health Canada as long as all reporting requirements are met.

The completed form must be faxed or emailed to Health Canada's Biologics and Genetic Therapies Directorate:

Blood Establishment Regulation Unit  
Office of Regulatory Affairs  
Biologics and Genetic Therapies Directorate

Health Canada  
Tel (613) 957-1722  
Fax (613) 948-3564

An establishment may email password protected scanned images of the form to [bgtd.ora@hc-sc.gc.ca](mailto:bgtd.ora@hc-sc.gc.ca).

## Sections 110–111 Adverse Recipient Reactions

Under the *Blood Regulations*, an unexpected adverse reaction or serious adverse reaction must be reported to Health Canada if it is associated with an undesirable response in the recipient to the transfused blood that indicates there is a risk to human safety or the safety of the blood. An establishment should refer to section 1, the Interpretation section, for the definitions of *adverse reaction*, *serious adverse reaction*, and *unexpected adverse reaction* when determining what must be reported as an unexpected adverse reaction or a serious adverse reaction to Health Canada. An adverse reaction caused by a blood labelling error that compromises the safety of the blood and leads to an adverse reaction in a recipient is an example of a reportable adverse reaction. Reportable adverse reactions in a recipient only apply to human blood collected from donors for the purpose of transfusion or for the immunization of source plasma donors (e.g. red blood cells for immunization). Adverse reaction reporting requirements under the *Blood Regulations* do not apply to blood products manufactured by a blood fabricator.

### Section 110 Required action

#### Required action

**110.** (1) Subject to section 111, an establishment that has reasonable grounds to believe that a recipient has experienced an unexpected adverse reaction or a serious adverse reaction must immediately take all of the following actions:

- (a) determine the donation codes of all implicated blood;
- (b) identify and quarantine any implicated blood in its possession;
- (c) if a preliminary inquiry indicates that the root cause of the adverse reaction is attributable to an activity that it carried out, conduct an investigation into the adverse reaction and notify any establishment to which it distributed implicated blood; and
- (d) if a 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:
  - (i) the establishment that collected the implicated blood,
  - (ii) the establishment from which it received the implicated blood, if different from the establishment mentioned in subparagraph (i), and
  - (iii) any establishment to which it distributed implicated blood.

#### Contents of notice

(2) The notice required by paragraphs (1)(c) and (d) must contain all of the following information:

- (a) a description of the adverse reaction;
- (b) an explanation of how the safety of the implicated blood may have been compromised, if

known;

(c) the donation codes of all implicated blood;

(d) a statement of whether the implicated blood is whole blood or blood components, and the names of the implicated blood components; and

(e) the name of any suspected transmissible disease or disease agent, if known.

Quarantine

(3) An establishment that is notified under subsection (1) or under this subsection must immediately notify to the same effect every establishment and other person to which it distributed implicated blood and quarantine any implicated blood in its possession.

Investigation

(4) An establishment that is notified under subparagraph (1)(d)(i) or (ii) must, if a preliminary inquiry indicates that the root cause of the adverse reaction is attributable to an activity that it carried out, conduct an investigation into the adverse reaction.

Written notice

(5) If a notice under this section is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

**110(1)** The Investigation Requirements Flow Chart (Flow Chart A), found in subsection 110(4) of this guidance, describes the steps to be taken once an unexpected adverse reaction or a serious adverse reaction occurs in a recipient.

Please note that section 110 requires action regarding an unexpected adverse reaction or a serious adverse reaction. In some instances the regulatory text does not specify *unexpected* or *serious* but always means *unexpected* or *serious* adverse reactions.

An establishment that has reasonable grounds to believe that a recipient has experienced an unexpected adverse reaction or a serious adverse reaction must immediately determine the donation codes, identify the implicated blood and quarantine the implicated blood (Flow Chart A (1)–(2)). The establishment must then conduct a preliminary inquiry to determine if the root cause analysis suggests the adverse reaction is attributable to an activity it carried out (Flow Chart A (3)). When an establishment has reasonable grounds to believe an unexpected adverse reaction or a serious adverse reaction has occurred due to an activity it carried out, the establishment must conduct an investigation and notify any establishment to which it distributed the implicated blood (Flow Chart A (8)–(9)).

When the unexpected adverse reaction or serious adverse reaction is due to an activity carried out by another establishment, the establishment must notify all of the establishments listed in 110(1)(d)(i)–(iii) (Flow Chart A (4)–(6)).

**110(2)** When notifying an establishment of an unexpected adverse reaction or a serious adverse reaction in a recipient, the notifying establishment must ensure that the notice to the

establishments listed in paragraph 110(1)(c) or (d) contains all of the required information in subsection 110(2). The notice should also include all of the following information:

- a. recipient's date of birth and sex;
- b. hospital identification;
- c. diagnosis, medical history;
- d. blood group, antibody screen;
- e. date, time, and place of transfusion;
- f. component transfused, donation code(s), blood group, collection date/pooling date, infusion start/stop time;
- g. description of adverse reaction, investigation, vital signs, treatment, culture of the recipient's blood and of the component transfused;
- h. assessment by transfusing establishment physician;
- i. establishment physician;
- j. outcome; and
- k. any other relevant information.

An establishment may use any adverse reaction or event reporting form to provide written notice as long as all notification requirements in subsection 110(2) of the *Blood Regulations* are met.

**110(3)** An establishment that receives a notice under subsection 110 (1), about an unexpected adverse reaction or a serious adverse reaction to transfused blood in a recipient, must immediately notify every other establishment and other person (including blood product fabricators) to which it distributed implicated blood (Flow Chart A (10)). An establishment may meet this requirement by forwarding the notice from the establishment that collected the implicated blood to the establishment that now has the implicated blood.

The establishment must quarantine — at once — any implicated blood components in its possession (Flow Chart A (11)).

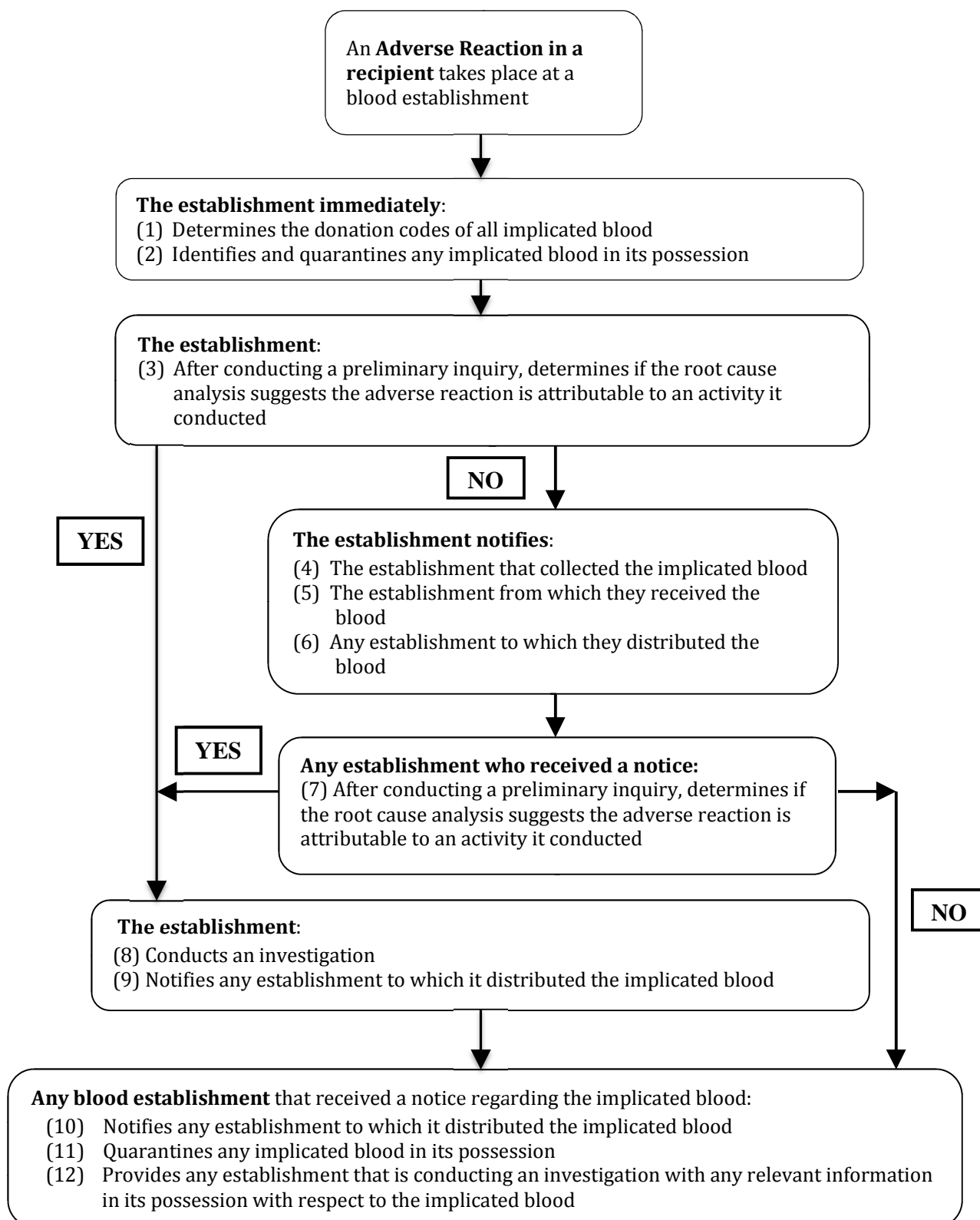
Establishments must cooperate with one another and provide any relevant information to the investigating establishment. Cooperation between establishments enables the investigating

establishment to determine the cause of the unexpected adverse reaction or serious adverse reaction when it is not clear whether the blood or an activity the investigating establishment conducted on the blood led to the adverse reaction in the transfusion recipient (Flow Chart A (12)). Refer to section 112 of the regulations regarding the requirement to cooperate.

**110(4)** An establishment that receives a notice, under 110(1)(d)(i) or (ii), about an unexpected adverse reaction or a serious adverse reaction to transfused blood must determine if the root cause of the adverse reaction was attributable to an activity it carried out (Flow Chart A (7)). If so, they must conduct an investigation into the adverse reaction (Flow Chart A (8)–(9)).

If it is unclear whether the root cause of the adverse reaction was an activity that the establishment carried out or an activity carried out by another establishment, the establishment should communicate with other establishments involved in the collection and distribution of the implicated blood in order to assist in this determination.

**Flow Chart A: Investigation Requirements**



## Traceback Investigation

The purpose of the traceback investigation is to identify the associated/implicated donor(s), retrieve available in-date components from those donors, and notify other consignees and recipients of those blood components. See 1.5 Definitions, *traceback*.

Establishments should conduct traceback investigation and reporting of unexpected adverse reactions or serious adverse reactions that are suspected to be transfusion-associated viral infections, such as HBV, HCV, HIV 1 and 2, HTLV I/II. Other transfusion-related infections may also trigger a traceback investigation.

The establishment conducting an investigation into the unexpected adverse reaction or serious adverse reaction associated with the implicated blood initiates a traceback investigation when it identifies any of the following:

- infection via transfusion is consistent with the timing of the recipient's diagnosis;
- the recipient did not originate from a lookback procedure;
- in the case of HTLV I/II infection, the recipient received cellular components; or
- in the case of HCV infection, when the recipient is not a hemophiliac or thalassemic patient transfused prior to May 1992.

The establishment conducting the investigation into the unexpected adverse reaction or serious adverse reaction associated with the implicated blood should initiate a traceback investigation of a suspected transfusion-related infection when it receives a report of a positive recipient from any of the following:

- Physician
- Establishment, such as a hospital, a licensed or a registered establishment
- Public Health Authority
- Information from a lookback procedure
- Compensation programme
- Transfusion recipient\*

\* If a transfusion recipient reports a transfusion-related infection, the establishment should have a *copy* of the test results to proceed with the traceback investigation.

A traceback investigation includes procedures for the following:

- a. determine donor status;
- b. notify donor;
- c. monitor donor, tests, and traceback investigation; and
- d. close traceback investigation.

During a traceback investigation, the establishment assesses the available information to determine the likelihood of transmission by the transfused components of a transfusion-associated viral infection. The medical director or the senior executive officer should be consulted, as needed, during an investigation. The establishment must defer the donor, when the outcome of confirmatory testing yields indeterminate or negative results, and consult the medical director or the senior executive officer for further action.

The medical director or senior executive officer should also be consulted in the following situations:

- if a report is received from a source other than those listed above;
- if a transfusion-related infection is other than HBV, HCV, HIV, HTLV; or
- if there are other clear risks for infection.

**Note:** When a traceback investigation identifies a donor who is confirmed positive for a transfusion-transmissible infectious agent, a lookback procedure should be carried out. A copy of the test results should be included in the documentation for the lookback procedure. (See section 56 and paragraph 94(1)(h) of this guidance document.) The establishment must record an indefinite deferral code in the donor's suitability assessment file. See subsections 44(2) and 56(1) for lookback procedure guidance.

**110(5)** When an establishment provides verbal notice to another establishment about a recipient's unexpected adverse reaction or serious adverse reaction, the establishment must also provide written notice without delay in accordance with information requirements in subsection 110(2).



## Section 111 Autologous donations

### Autologous donations

**111.** An establishment that both collects and transfuses the same autologous blood must, if it has reasonable grounds to believe that a recipient has experienced an unexpected adverse reaction or a serious adverse reaction, immediately quarantine any other blood from that donor in its possession and conduct an investigation into the adverse reaction and the implicated blood.

When the recipient of an autologous blood transfusion experiences an unexpected adverse reaction or a serious adverse reaction, the registered establishment that both collected and transfused the autologous blood must immediately take the following actions:

1. quarantine any other blood from the affected autologous blood donor in its possession; and
2. investigate the adverse reaction.

The investigation should determine the cause of the unexpected adverse reaction or serious adverse reaction, including the possibility of an error/accident, such as the transfusion of the wrong unit. See sections 103–108 of this guidance for error and accident investigation and reporting requirements.

## Sections 112–116 Investigation and Reporting of Adverse Recipient Reactions

### Section 112 Requirement to cooperate

#### Requirement to cooperate

**112.** An establishment must, on request, provide every establishment that is conducting an investigation with any relevant information in its possession in respect of blood that it distributed or transfused.

The establishment conducting the investigation is the establishment that after a preliminary inquiry has determined that the root cause of the adverse recipient reaction was attributable to an activity that they carried out (Flow Chart A (3) and (8)).

The establishment conducting the investigation may request relevant information from other establishments that distributed or transfused the implicated blood.

On request, an establishment must provide the investigating establishment with any information relevant to the investigation if they transfused or distributed blood that was later implicated in an adverse reaction in a recipient investigation. This information includes, but is not limited to, an inventory list of the implicated blood and its disposition (e.g. distributed, transfused, quarantined). (Flow Chart A (12)).

## Section 113 Notice to Minister

### Notice to Minister

**113.** (1) An establishment that is conducting an investigation must notify the Minister of the adverse reaction within 24 hours after it learns of the death of a recipient or within 15 days after it learns of any other unexpected adverse reaction or serious adverse reaction.

### Written notice

(2) If a notice under this section is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

**113(1)** The Reporting of an Adverse Reaction Flow Chart (Flow Chart B), found at the end of section 116, describes the steps to be undertaken once an establishment determines that they must conduct an investigation into an unexpected adverse reaction or a serious adverse reaction.

The investigating establishment must notify Health Canada of an adverse reaction that results in a fatal event within 24 hours of learning of the recipient's death. Although a preliminary notification may be sent within 24 hours, the investigating establishment must provide Health Canada with a subsequent notice containing any additional information without delay. For all other unexpected adverse reactions or serious adverse reactions, the investigating establishment must provide a notice to Health Canada within 15 days of learning of the adverse reaction (Flow Chart B, Step 1).

An unexpected adverse reaction or a serious adverse reaction in a recipient must be reported if the investigating establishment suspects that the adverse reaction is associated with the safety of the transfused blood. Clinical judgement should be exercised by a qualified health care professional from the establishment to determine if the adverse reaction in the recipient is related to the transfused blood, rather than one of treatment selection or disease progression.

### ***Examples of Errors or Accidents that could lead to an Adverse Reaction in a Recipient***

An error or accident could lead to an adverse reaction in a recipient. In the example where a transformation error or accident may have led to an adverse reaction in a recipient, the registered establishment who carried out the transformation on the implicated blood would investigate and report the adverse reaction to Health Canada. If it is suspected that a storage error or accident led to an adverse reaction in a recipient, then the establishment where the storage error or accident occurred would investigate and report the adverse reaction to Health Canada.

**113(2)** If an establishment provides verbal notice to Health Canada about an unexpected adverse reaction or a serious adverse reaction in a recipient, the establishment must also provide written notice to Health Canada without delay.

As long as all reporting requirements are met, an establishment may use any adverse reaction reporting form to provide mandatory written notice to Health Canada about an unexpected adverse reaction or a serious adverse reaction in a blood transfusion recipient.

The completed form must be faxed or emailed to Health Canada's Biologics and Genetic Therapies Directorate:

Blood Establishment Regulation Unit  
Office of Regulatory Affairs  
Biologics and Genetic Therapies Directorate  
Health Canada  
Tel (613) 957-1722  
Fax (613) 948-3564

An establishment may email password protected scanned images of the adverse reaction reporting form to [bgtd.ora@hc-sc.gc.ca](mailto:bgtd.ora@hc-sc.gc.ca).

## Section 114 Results of investigation

Results of investigation

**114.** (1) The establishment that is conducting an investigation must notify in writing every establishment and other person to which it distributed implicated blood of the results of the investigation and of any action that is required to be taken.

Notice to be forwarded

(2) An establishment that is notified under subsection (1) or under this subsection must send a copy of the notice to every establishment to which it distributed implicated blood.

**114(1)** The establishment conducting the investigation must communicate in writing, to every establishment or other person (including blood product fabricators) to which it distributed implicated blood, the results of the investigation and any required actions. The results of the investigation notification should reference the original notification (Flow Chart B, step 2).

**114(2)** When an establishment receives the results of an investigation, they must forward the results to any other establishment to which they distributed implicated blood. It is not necessary for the establishment to add any additional information to the results of the investigation notification.

## Section 115 Final report to Minister

Final report to Minister

**115.** On completion of the investigation, the establishment must file a final report with the Minister that contains all of the following information:

- (a) the results of the investigation;
- (b) the final disposition of the blood that was the subject of the investigation and the reasons for that disposition; and
- (c) any corrective actions taken and any other changes that are recommended to be made to relevant processes.

The investigating establishment must file a final report to Health Canada concerning the recipient's adverse reaction and containing all of the information required in section 115. When

the information is inconclusive, the establishment may also provide comments based on their evaluation (Flow Chart B, step 3).

## Section 116 Annual Report

Annual report

**116.** At the end of each year, an establishment must prepare an annual report that summarizes all of the final reports that it filed in the year, including a concise critical analysis of the investigations that were the subjects of those reports, and must file it with the Minister on request.

Establishments that conduct adverse reaction investigations must prepare an Annual Adverse Reaction Report (Flow Chart B, step 4) summarizing all of the final reports concerning unexpected adverse reactions or serious adverse reactions in recipients that were filed during the year, including a concise critical analysis of the final adverse reaction investigation reports.

The annual report should include the following:

- an executive summary;
- the established degree of relationship of adverse reaction to the transfused blood;
- 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 a trend analysis over time;
- traceback and lookback annual summary statistical reports; and
- overall conclusions and opportunities for improvement.

When requested by the Minister, an establishment may file an annual adverse reaction report that was prepared for other purposes, such as an annual hemovigilance report, as long as it includes the information required and described in section 116 above.

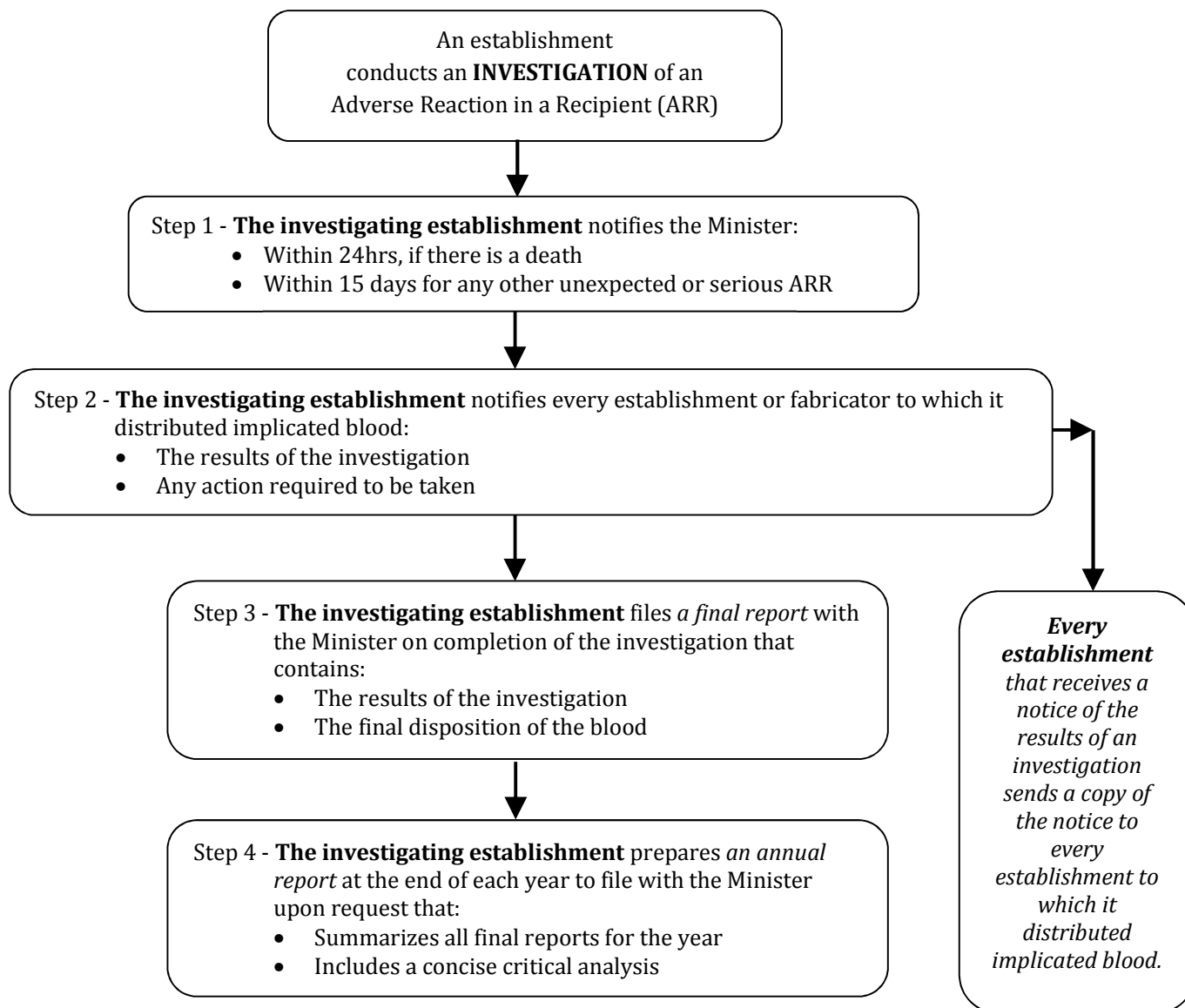
When requested by the Minister the annual report must be faxed or emailed to Health Canada's Biologics and Genetic Therapies Directorate:

Blood Establishment Regulation Unit  
Office of Regulatory Affairs  
Biologics and Genetic Therapies Directorate  
Health Canada  
Tel (613) 957-1722  
Fax (613) 948-3564

An establishment may email password protected scanned images of the adverse reaction reporting form to [bgtd.ora@hc-sc.gc.ca](mailto:bgtd.ora@hc-sc.gc.ca).

Appendix A provides a summary of all annual reporting requirements for blood establishments.

**Flow Chart B: Reporting an Adverse Reaction in a Recipient**



## Sections 117–123      Records

Establishments must retain records, including the ones produced prior to coming into force of the *Blood Regulations*, in accordance with the regulatory requirements as set out in the *Blood Regulations*.

### Section 117 Record quality

Record quality

**117.** Records kept by an establishment must be accurate, complete, legible, indelible and readily retrievable.

Records are a critical component of any quality management system as they provide documented evidence of compliance. Records must be accurate, complete and legible. Upon coming into force of the *Blood Regulations* and during the transitional period (see sections 126–128 for transitional provisions), records must be maintained concurrently with the performance of each significant step in the processing, importation, transformation, storage, distribution (including exceptional distribution), investigation of errors and accidents and adverse reactions of blood, so that all steps can be clearly associated with the person who conducted the step, time/date and location of such activities. In addition, for processing and transformation records, the lot number of critical supplies and the identity of the critical equipment associated with the activities must be part of the records.

All records must identify the person who conducted the activities and the dates of the various entries. Establishments must ensure that the records are accurate. For example, all manual transcriptions of test results must be independently verified in situations where the transcribed document is the permanent record.

Any handwritten entry of information must be made using indelible ink. Any correction, entry of information, or notation made after the original date of record completion must be clearly crossed out, initialled or signed and dated to indicate a change has been made to the original information.

All establishments must retain records in an easily understandable and retrievable format. Records must be accessible at all times. All establishments must be able to quickly and efficiently retrieve blood traceability information.

Records must consistently be maintained in a manner to preserve their completeness and integrity over time. Establishments may decide to use microfiche, microfilm or other means of retaining permanent records. The establishment must verify the transfer of information to microfiche, microfilm or other media used to retain information. The accuracy of the transfer of information should be verified by someone other than the individual who transferred the information.

An establishment that keeps electronic records must have an electronic system validated for its intended use to ensure the maintenance of the data integrity of those records. Any changes to the electronic system must be evaluated, documented and approved prior to implementation to ensure the integrity of the data and that the records can be retrieved during the required retention period. A history of any changes to electronic records must be available in an audit trail.

An establishment must be able to retrieve and print a hard copy of information that is stored in an electronic record.

One standardized format for dates (e.g. YYYY-MM-DD or MM-DD-YYYY) should be used for all records. Where this is not possible, records should clearly indicate the date format if not readily apparent.

### Section 118 Donation code part of all records

Donation code part of all records

**118.** An establishment must ensure that the donation code is a component of all of its records that relate to the processing, distribution, transformation and transfusion of blood.

Each unit of blood has a donation code that uniquely identifies it. The donation code enables the traceability of a given unit of blood and any associated information about that unit of blood throughout any processing or transformation steps and the chain of distribution. The donation code must be a part of all records related to the processing, distribution, transformation and transfusion of the unit of blood. A blood component will be identified by the specific component code associated with the donation code.

### Section 119 Retention periods — allogeneic blood

Retention periods — allogeneic blood

**119.** (1) An establishment that collects allogeneic blood must keep the records set out in column 1 of the table to this section for the period set out in column 2.

Calculation of record retention period

(2) The record retention period begins on the day on which the record is created, except for the personnel records set out in item 28 of the table, in which case the period begins on the last day on which the employee was last employed by the establishment.

All establishments that collect allogeneic blood must ensure that records are retained according to the Table to section 119, Records and Retention Periods. See clause 20.2.5 of the CSA Blood Standard for guidance concerning the reconciliation of donation codes (item 3 of the Table to section 119).



## Table to Section 119 — Records and Retention Periods — allogeneic blood

TABLE TO SECTION 119  
RECORDS AND RETENTION PERIODS

Item	Column 1 Records	Column 2 Retention period
1.	Donor identification code	50 years
2.	Donation code	50 years
3.	Reconciliation of donation codes	10 years
4.	Donor suitability assessment	5 years
5.	Determinations of donor unsuitability — indefinite	50 years
6.	Determinations of donor unsuitability — temporary	10 years
7.	Collection — date of donation	50 years
8.	Collection — donor apheresis	5 years
9.	Collection — record of donation	5 years
10.	Lot number and name of manufacturer of container and other critical supplies for each donation	1 year
11.	Test results for transmissible disease testing, ABO group and Rh factor, and clinically significant antibody testing	50 years
12.	Blood component preparation	10 years
13.	Blood storage temperature monitoring	5 years
14.	Destruction or other disposition of blood	50 years
15.	Distribution	50 years
16.	Shipping documents	1 year
17.	Exceptional distribution	50 years
18.	Importation in urgent circumstances	50 years
19.	Post-donation information	10 years
20.	Complaints and their investigation	5 years
21.	Internal audit reports	5 years
22.	Quality control testing	5 years
23.	Maintenance, validation, qualification and calibration of critical equipment	3 years
24.	Critical supplies, including their qualification	3 years
25.	Proficiency testing	5 years
26.	Every version of the operating procedures that was implemented, other than those related to donor suitability assessments	10 years
27.	Every version of the operating procedures related to donor suitability assessments	50 years
28.	Personnel qualifications, training and competency evaluation	10 years
29.	Investigations and reports of errors and accidents	10 years
30.	Investigations and reports of adverse reactions	10 years

## Section 120 Retention periods — autologous blood

Retention periods — autologous blood

**120.** (1) An establishment that collects autologous blood must keep the records set out in column 1 of the table to this section for the period set out in column 2.

Calculation of record retention period

(2) The record retention period begins on the day on which the record is created, except for the personnel records set out in item 18 of the table, in which case the period begins on the last day

on which the employee was employed by the establishment.

All establishments that collect autologous blood must ensure that records are retained according to the Table to section 120, Records and Retention Periods.

### Table to Section 120 — Records and Retention Periods — autologous blood

TABLE TO SECTION 120 RECORDS AND RETENTION PERIODS		
Item	Column 1 Records	Column 2 Retention period
1.	Donor identification code	10 years
2.	Donation code	10 years
3.	Collection — donor record	5 years
4.	Lot number and name of manufacturer of container and other critical supplies for each donation	1 year
5.	Test results for transmissible disease testing, ABO group and Rh factor	10 years
6.	Blood component preparation	10 years
7.	Blood storage temperature monitoring	5 years
8.	Destruction or other disposition of blood	10 years
9.	Distribution	10 years
10.	Shipping documents	1 year
11.	Complaints and their investigation	5 years
12.	Internal audit reports	5 years
13.	Quality control testing	5 years
14.	Maintenance, validation, qualification and calibration of critical equipment	3 years
15.	Critical supplies, including their qualification	3 years
16.	Proficiency testing	5 years
17.	Every version of the operating procedures that was implemented	10 years
18.	Personnel qualifications, training and competency evaluation	10 years
19.	Investigations and reports of errors and accidents	10 years
20.	Investigations and reports of adverse reactions	10 years

### Section 121 Retention periods — transformation

Retention periods — transformation

**121.** (1) An establishment that transforms blood must keep the records set out in column 1 of the table to this section for the period set out in column 2.

Calculation of record retention period

(2) The record 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.

All establishments that transform blood must ensure that records are retained according to the Table to section 121, Records and Retention Periods.

**Table to Section 121 — Records and Retention Periods — transformation**

TABLE TO SECTION 121 RECORDS AND RETENTION PERIODS		
Item	Column 1 Records	Column 2 Retention period
1.	Donation code	10 years
2.	Records of washing, pooling and irradiation of blood	10 years
3.	Lot number 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

## Section 122 Retention periods — transfusion

Retention periods — transfusion

**122.** (1) An establishment that transfuses blood must keep the records set out in column 1 of the table to this section for the period set out in column 2.

Calculation of record retention period

(2) The record retention period begins on the day on which the record is created, except for the personnel records set out in item 11 of the table, in which case the period begins on the last day on which the employee was employed by the establishment.

All establishments that transfuse blood must ensure that records are retained according to the Table to section 122, Records and Retention Periods.

**Table to Section 122 — Records and Retention Periods — transfusion**

TABLE TO SECTION 122 RECORDS AND RETENTION PERIODS		
Item	Column 1 Records	Column 2 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	50 years

	blood, including identification of recipient	
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

## Section 123 Storage of records

### Storage of records

**123.** An establishment must store records in a location that has appropriate environmental conditions and that is secure against the entry of unauthorized persons.

Record storage areas must maintain the integrity of the records. Environmental parameters for storage, such as temperature, must be appropriate and controlled to the extent necessary in order to safeguard the integrity of the type of records being stored. The humidity should also be controlled as appropriate and as required. Access to the storage area must be restricted to authorized persons.

If records are copied off-site, the establishment must have a signed contract with the service provider. The contract must include specific requirements, such as transport to the site, copy quality, retrieval information, and storage conditions. Where relevant, the contract must describe specific requirements for the destruction of the original document.

## Section 124 POWERS OF INSPECTORS

### Making visual recordings

**124.** An inspector may, in the administration of these Regulations, take photographs and make recordings of any of the following:

- (a) any article that is referred to in subsection 23(2) of the Act;
- (b) any place where the inspector believes on reasonable grounds any article referred to in paragraph (a) is processed, transformed or stored; and
- (c) anything that the inspector believes on reasonable grounds is used or is capable of being used in the conduct of an establishment's activities.

## Section 125 CONSEQUENTIAL AMENDMENT

**125.** Section 18 of the *Regulations Amending the Food and Drug Regulations (1475 — Good Manufacturing Practices)*<sup>1</sup> is replaced by the following:

**18.** *The Food and Drug Regulations*, as they read immediately before the coming into force of these Regulations, continue to apply in respect of whole blood and blood components until the day before the day on which subsection 3(2) of the *Blood Regulations* comes into force.

## Sections 126–128 TRANSITIONAL PROVISIONS

### Section 126 Deemed Authorization

Deemed authorization

**126. The information that is required by section 6 to be included in an application for an authorization and that was filed with and accepted by the Minister under sections C.01A.005 to C.01A.007 and C.01A.014 of the *Food and Drug Regulations* before the day on which these Regulations come into force is deemed to be an authorization issued by the Minister under section 7 of these Regulations.**

Establishments that process blood, who were formerly regulated under the *Food and Drug Regulations*, have received from Health Canada notices of approval for changes to processes at their establishments. The sum of these notices — received prior to the coming into force of the *Blood Regulations* — are considered to be the establishment's Authorization under the new *Blood Regulations* and, as such, the establishment is not required to apply for a new Authorization. However, establishments will be required to file applications for amendments to their Authorization as described in section 9 of the *Blood Regulations*.

### Section 127 Licence continued

Licence continued

**127. If an establishment files an application for a licence under section 18 — without regard to paragraphs (1)(j) and (k) — within three months after the day on which these Regulations come into force, any licence that was issued to the establishment under section C.01A.008 of the *Food and Drug Regulations* before that day is continued until a licence is either issued under section 20 or refused under section 21 of these Regulations.**

### Temporary Establishment Licence

An establishment holding a valid Establishment Licence under the *Food and Drug Regulations* will have it considered a temporary Establishment Licence when the *Blood Regulations* come into force, as long as the establishment files an application for an Establishment Licence under the *Blood Regulations* within 3 months of this date. The temporary Establishment Licence will be replaced with an official Establishment Licence when the application for an Establishment Licence is processed and approved.

### Inspection requirements

At the time of coming into force of the *Blood Regulations*, if an establishment holds an Establishment Licence under the *Food and Drug Regulations* for activities now subject to the *Blood Regulations*, a new inspection will not be required prior to the issuance of an Establishment Licence under the *Blood Regulations* for the previously licensed activities.

If applying to add new activities after the coming into force of the *Blood Regulations*, the establishment may be subject to inspection, and may not begin these activities until such time as a revised Establishment Licence is issued.

## Foreign establishment compliance evidence

In accordance with paragraph 18(1)(k), evidence demonstrating compliance to these regulations is required for each foreign establishment that the establishment in Canada intends to have on its Establishment Licence. However, if the establishment in Canada already holds a valid Establishment Licence under the *Food and Drug Regulations* containing foreign establishments (with valid compliance), they do not need to re-file compliance evidence that was previously filed in order to have those foreign establishments listed on their Establishment Licence under the *Blood Regulations*.

If applying to add new foreign establishments after the coming into force of the *Blood Regulations*, the establishment must file valid compliance evidence for those foreign establishments and have them listed on their official Establishment Licence under the *Blood Regulations* before the new foreign establishments may undertake activities on their behalf.

## Section 128 Delayed registration

Delayed registration

**128. (1) An establishment that, before the day on which these Regulations come into force, conducts any of the activities mentioned in section 30 may continue to do so without a registration if it files an application for registration under section 31 within three months after that day.**

Duration

**(2) Subsection (1) applies until the determination of the application under section 32.**

## Section 129 Coming into force

One year after publication

**129. (1) These Regulations — except subsections 4(4) to (6), paragraph 64(1)(b) as it applies to registration numbers, and section 125 — come into force one year after the day on which they are published in the *Canada Gazette*, Part II.**

Subsections 4(4) to (6) and paragraph 64(1)(b)

**(2) Subsections 4(4) to (6) and paragraph 64(1)(b), as it applies to registration numbers, come into force six months after the day on which these Regulations come into force.**

Section 125

**(3) Section 125 comes into force on the day on which these Regulations are registered.**

## APPENDIX A: Summary Table of Annual Reporting Requirements for Blood Establishments

Report Title	Blood Regulations section	Who prepares the report	When to file report	Where to file report
Authorization – Other Changes – Annual Report	12	Establishments who hold an Authorization	To be decided in consultation with Health Canada	Blood Establishment Regulation Unit, Office of Regulatory Affairs, Biologics and Genetic Therapies Directorate, Health Canada
Annual Report of Error and Accident Investigations	108	At the end of a 12 month period, establishments who have conducted an investigation into Errors and Accidents throughout the year	Upon request by the Minister	Indicated in request by Minister
Annual Report of Adverse Reactions in Recipients	116	At the end of each year, establishments who have conducted an investigation into a serious or unexpected adverse reaction in a blood transfusion recipient	Upon request by the Minister	Indicated in request by Minister

## APPENDIX B: Pre-Registration Self-Assessment Tool for Establishments applying for a Blood Establishment Registration

Establishments should refer to section 30 of the *Blood Regulations* to determine if they are conducting activities that require them to register with Health Canada.

Before applying for a Registration number, Health Canada strongly recommends that establishments complete this self-assessment tool to determine whether their practices meet the requirements of the *Blood Regulations*. This tool is designed to facilitate the identification of areas that the establishment may need to address in order to be compliant with the *Blood Regulations*. Establishments are not required to file this self-assessment with Health Canada nor will it be reviewed during an inspection. The completion of this form alone is not considered as a record of compliance with the internal audit requirements under paragraph 94(1)(j).

Please note that this tool does not supersede the requirements of the *Blood Regulations*. Each section of this document should be read in conjunction with the relevant sections of the *Blood Regulations*. For an interpretation of the sections listed below, please refer to the appropriate sections in this Guidance Document. Several terms used in this self-assessment tool are defined in the *Blood Regulations*. Please refer to the definitions in section 1, the Interpretation section, of the *Blood Regulations*.

<i>Blood Regulations</i> Section	Requirements	Assessment
<b>A. Processing Activities for Autologous Blood</b>		
<b>Collection</b>		
46	Is there a donor identification code assigned to each donor?	Yes <input type="checkbox"/> No <input type="checkbox"/>
47	Is there a donation code assigned to every unit of blood collected? Is the donation code linked in the records to the donor identification code?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
48	Is it ensured that the blood containers are labelled as per section 63 of the <i>Blood Regulations</i> at the time of the collection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
49(1)	Is blood being collected in the following way? (a) use of aseptic methods (b) use of collection equipment that is licensed under the <i>Medical Devices Regulations</i> (c) use of containers that are licensed under the <i>Medical Devices Regulations</i> and free from	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>



	defects or damage (d) lot number of the container is being documented and linked to the donation code	Yes <input type="checkbox"/> No <input type="checkbox"/>
49(2)	Is each container used only once?	Yes <input type="checkbox"/> No <input type="checkbox"/>
50	At the time of collection, are samples for testing obtained in a way that avoids contamination of the donated blood and the samples?	Yes <input type="checkbox"/> No <input type="checkbox"/>
51	(a) Does the blood collection comply with the criteria set out in clause 12.2.1 of the CSA Blood Standard? (b) Is the volume of the blood collected and volume of the anticoagulant adjusted based on the donor's weight, when appropriate?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Testing</b>		
53	Is the blood tested using appropriate and effective tests for the transmissible diseases and disease agents specified in clause 12.3.1.2 of the CSA Blood Standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>
54(1)	At the time of each donation, is the blood being tested to identify both of the following: (a) the ABO group; and (b) the Rh factor, including weak D testing when appropriate?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
54(2)	Are the results from paragraphs 54(1)(a) and (b) compared with the last available results for that donor?	Yes <input type="checkbox"/> No <input type="checkbox"/>
54(3)	If the comparison in subsection 54(2) indicates a discrepancy, are the tests described in 54(1) repeated and the blood is not transfused until the discrepancy is resolved?	Yes <input type="checkbox"/> No <input type="checkbox"/>
55(a)	Is the blood being tested with test kits that are licensed under the <i>Medical Devices Regulations</i> either for diagnosis or screening?	Yes <input type="checkbox"/> No <input type="checkbox"/>
56(2)	Is the donor's physician informed of the test results described in clause 12.3.1.6 of the CSA Blood Standard by the establishment that collects the blood?	Yes <input type="checkbox"/> No <input type="checkbox"/>
58	Are the blood components prepared in accordance with clauses 7.1.3, 7.2, 7.3.1, 7.3.2, 7.5.1.1 (without regard to the reference Table 3 of the CSA Blood Standard), 7.5.1.2 and 7.5.1.5, clause 7.5.2.1 (a) to (c) and clause 7.5.2.2 of the CSA Blood Standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Labelling</b>		
60	Is the information appearing on the label of blood containers or the circular of information printed in	Yes <input type="checkbox"/> No <input type="checkbox"/>

	either English or French?	
61	Do the labels meet the following requirements? (a) all information is accurate, and presented clearly and legibly (b) they are made using only adhesives and inks that are non-permeable to the blood container (c) they are permanently affixed to the blood container (d) tags are firmly attached to the blood container	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
63	At the time of collection, is the donation code permanently marked on the label of every blood container?	Yes <input type="checkbox"/> No <input type="checkbox"/>
64(1)	Does the following information appear on the label of the blood? (a) establishment's name and civic address (b) the establishment's licence number, if it has one, or its registration number (c) donation code (d) a statement of whether the donation is whole blood or a blood component, and if it is a component, its name (e) ABO group and Rh factor, when appropriate (f) approximate volume of the whole blood collection (g) approximate volume of the contents of the container (h) name of the anticoagulant or additive in the container (i) recommended storage temperature (j) expiry date and, if applicable, the time (k) warning that the blood could transmit infectious agents, in the case of blood for transfusion	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
64(2)	Does the following additional information appear on the label of autologous blood? (a) the statement "For Autologous Use Only" (b) a symbol or words to indicate the blood is a biohazard if the donor tested positive for a disease or disease agent listed in clause 12.3.1.2 of the CSA Blood Standard (c) if the unit of blood was not tested in accordance with clause 12.3.1.2 of the CSA Blood Standard, an indication to that effect	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
65	Is the establishment that divides blood into aliquots for transfusion, ensuring that the following appears on the label of each aliquot container: (a) donation code;	Yes <input type="checkbox"/> No <input type="checkbox"/>

	(b) name of the blood component; (c) a code that identifies the aliquot; (d) when appropriate, the ABO group and Rh factor; and (e) expiry date?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
68	Is it verified that the information added to the label is accurate and complete?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Autologous Activities:</b>		
<b>B. Storage</b>		
69(1)(b)	Is the collected blood stored in accordance with the storage and expiration criteria specified in Table 2 of the CSA Blood Standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>
69(2)	Is the blood received from another establishment stored in accordance with the directions on the label and with any directions that are specified in writing by the establishment that collected it?	Yes <input type="checkbox"/> No <input type="checkbox"/>
70	Does the storage location have appropriate environmental conditions and is it secure against the entry of unauthorized persons?	Yes <input type="checkbox"/> No <input type="checkbox"/>
71	Is blood intended for autologous, designated or directed use segregated from the blood intended for other allogeneic use?	Yes <input type="checkbox"/> No <input type="checkbox"/>
72	Is blood that is untested, incompletely tested, tested positive or repeat reactive, segregated from blood that has been determined safe for distribution or autologous transfusion?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Storage:</b>		
<b>C. Distribution</b>		
73(2)	Before distributing blood for transfusion, does the establishment that collected autologous blood determine that it is safe for transfusion if it is satisfied that the blood has been processed in accordance with the <i>Blood Regulations</i> ?	Yes <input type="checkbox"/> No <input type="checkbox"/>
74(1)	Prior to distributing blood for transfusion, is there an examination of the container to verify that	

	(a) the information on the label is legible; (b) the integrity of the blood container is intact; (c) there are no signs of deterioration or contamination of the blood; and (d) any frozen blood components show no signs of thawing?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
74(2)	Is the blood prevented from distribution for transfusion if (a) the donation code is missing or illegible; (b) any information — other than the donation code — that is required by the <i>Blood Regulations</i> to appear on the label of blood is missing or is illegible, unless the missing or illegible information can be retrieved from the establishment's records; (c) the container is defective or damaged to the extent that it does not protect the blood against external conditions; or (d) there are signs of deterioration or contamination of the blood?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>  Yes <input type="checkbox"/> No <input type="checkbox"/>  Yes <input type="checkbox"/> No <input type="checkbox"/>
75	When the blood is shipped: (a) Are the blood containers examined before shipping to verify the integrity of the container and the legibility of the labels? (b) Are the shipping containers used capable of resisting damage and maintaining the safety of the blood?	Yes <input type="checkbox"/> No <input type="checkbox"/>  Yes <input type="checkbox"/> No <input type="checkbox"/>
76	Is it ensured that blood for transfusion being shipped is stored during transportation in accordance with the criteria specified in Table 2 of the CSA Blood Standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Distribution:</b>		
<b>D. Transformation Activities of Allogeneic or Autologous Blood</b>		
77	Are the transformation methods used by the establishment safe and effective?	Yes <input type="checkbox"/> No <input type="checkbox"/>
78(1)	Is the washing of blood done in accordance with clauses 7.5.2.3 and 7.5.3 of the CSA Blood Standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>
78(2)	For washed blood, is the label amended to add the mention of the washing and any new expiry date	Yes <input type="checkbox"/> No <input type="checkbox"/>

	and time?	
79(1)	Is the pooling of blood components done in accordance with clauses 7.11.1 and 7.11.3 of the CSA Blood Standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>
79(2)	Does the information specified in clauses 10.8.2 and 10.8.3 of the CSA Blood Standard appear on the label of the pooled blood components?	Yes <input type="checkbox"/> No <input type="checkbox"/>
80	Is the irradiation of blood done in accordance with clauses 7.12.2 to 7.12.6 of the CSA Blood Standard?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Transformation Activities:</b>		
<b>E. Pre-Assessed Donor Program (PADP) Processing Activities</b>		
86	(a) Is the PADP carried out under the supervision of a medical director? (b) Is it only used when (i) no other alternative source of blood appropriate for the recipient is available, and (ii) the recipient's physician requests the blood for use in the emergency treatment of their patient?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
87	Is a donor identification code assigned to every donor at the time of acceptance into the PADP?	Yes <input type="checkbox"/> No <input type="checkbox"/>
88(1)	Are the following occurring every three months? (a) donors are assessed as per sections 40 to 44 of the <i>Blood Regulations</i> (b) blood samples from every donor are tested for all of the following: (i) the transmissible diseases or disease agents listed in clauses 8.4.1 and 8.4.2 of the CSA Blood Standard (ii) ABO group (iii) the Rh factor including weak D testing when appropriate (iv) clinically significant antibodies	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
88(2)	Does the establishment ensure that the results of the tests conducted under subparagraphs 88(1)(b)(ii) and (iii) are compared with the last available results, if any, for that donor?	Yes <input type="checkbox"/> No <input type="checkbox"/>
88(3)	If the comparison in subsection 88(2) indicates a discrepancy, are these tests repeated and any blood	Yes <input type="checkbox"/> No <input type="checkbox"/>

	not collected from that donor until the discrepancy can be resolved?	
89	<p>Are the following occurring at each collection?</p> <p>(a) suitability of the donor is assessed  Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(b) a donation code is assigned to the blood collected and linked to the donor's identification code in the records.  Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(c) a blood sample is taken from the donor and tested within 72 hours for the following:  Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(i) transmissible diseases or disease agents specified in clauses 8.4.1 and 8.4.2 of the CSA Blood Standard  Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(ii) the ABO group  Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(iii) the Rh factor, including weak D testing when appropriate  Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(iv) clinically significant antibodies  Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
90	Does the donation code, ABO group and, when appropriate, Rh factor always appear on the label of the blood?	Yes <input type="checkbox"/> No <input type="checkbox"/>
91	If the blood collected from a pre-assessed donor is not transfused into an intended recipient in the emergency, are the requirements in clause 16.2.5. of the CSA Blood Standard being followed?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Donor Suitability Assessment</b>		
40	<p>In conducting the donor suitability assessment, does the establishment verify the following:</p> <ul style="list-style-type: none"> <li>• whether the potential donor has been previously determined unsuitable?</li> <li>• the reason why the potential donor has been previously determined unsuitable, if applicable?</li> <li>• the duration that the donor was determined to be unsuitable, if applicable?</li> </ul>	Yes <input type="checkbox"/> No <input type="checkbox"/>
41	<p>Are the following steps being performed during a donor suitability assessment?</p> <p>(a) obtain information from the donor by use of a questionnaire or similar means about their identity, their medical history, and their social history to the extent that it is relevant in determining the presence of risk factors for diseases transmissible by blood  Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>(b) provide the donor with information about the risks associated with donating blood and the risks to the recipient of contracting a transmissible disease  Yes <input type="checkbox"/> No <input type="checkbox"/></p>	
42	Is the donor deemed unsuitable to donate when any of the information obtained under sections 39 to 41	Yes <input type="checkbox"/> No <input type="checkbox"/>

	of the <i>Blood Regulations</i> indicates that human safety or the safety of blood could be compromised?	
43	<p>If a donor is determined unsuitable to donate:</p> <ul style="list-style-type: none"> <li>• Is the blood not collected from that donor?</li> <li>• Is the donor informed of the reasons why he or she is not suitable to donate?</li> <li>• Is the donor informed of the date, if any, when he or she will again be suitable to donate?</li> </ul>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
44(1)	<p>Once the donor is determined suitable, does the establishment take the following steps:</p> <p>(a) Assign a donor identification code to the donor, if the donor does not already have one; and</p> <p>(b) Instruct the donor to inform the establishment</p> <p>(i) if he or she develops an illness or condition that may potentially compromise the safety of any donated blood within the time periods set out in the establishment's operating procedures;</p> <p>(ii) or, if the donor has any reason to believe that his/her blood should not be used after the donation?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
44(2)	On receipt of any post-donation information under paragraph (1)(b), is the information evaluated by the establishment to reassess the safety of the current and any other donation made by the donor and to the donor's suitability for future donations?	Yes <input type="checkbox"/> No <input type="checkbox"/>
44(3)	If the reassessment shows that the safety of the blood may have been compromised and the blood has already been distributed, does the establishment notify every person to which the blood was distributed to that effect, and if the person is an establishment, does the notice specify that the blood must not be distributed or transfused?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Collection</b>		
47	<p>Is there a donation code assigned to every unit of blood collected?</p> <p>Is the donation code linked in the records to the donor identification code?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
49(1)	<p>Does the establishment ensure that the collection of blood is being conducted in the following way:</p> <p>(a) use of aseptic methods;</p> <p>(b) use of collection equipment that is licensed under the <i>Medical Devices Regulations</i>;</p> <p>(c) use of containers that are licensed under the <i>Medical Devices Regulations</i> and free from defects</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>

	or damage; and (d) lot number of the container is documented in the establishment's records and linked to the donation code?	Yes <input type="checkbox"/> No <input type="checkbox"/>
49(2)	Is each blood container used only once?	Yes <input type="checkbox"/> No <input type="checkbox"/>
50	At the time of collection, are samples for testing obtained in a way that avoids contamination of the donated blood and the samples?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Testing</b>		
17(2)	Has the establishment ensured that the testing laboratory possesses an establishment licence from Health Canada to test blood for transmissible diseases or disease agents?	Yes <input type="checkbox"/> No <input type="checkbox"/>
55 b)	Is the blood being tested with test kits that are licensed under the <i>Medical Devices Regulations</i> for donor screening?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Pre-Assessed Donor Program Activities:</b>		
<b>F. Quality Management System (applicable to all registered establishments)</b>		
93(1)	Is there an organizational structure that sets out the responsibility of management for all activities that the establishment conducts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
93(2)	Does the establishment have an effective quality management system and name an individual who has responsibility for it?	Yes <input type="checkbox"/> No <input type="checkbox"/>
93(3)	Does it review the quality management system at regular intervals specified in the operating procedures, to ensure its continuing suitability and effectiveness?	Yes <input type="checkbox"/> No <input type="checkbox"/>
94(1)	Is there a quality management system in place that includes the following elements: (a) a quality assurance unit; (b) a quality control program; (c) a change control system; (d) a process control program, within the meaning of clause 3.1 of the CSA Blood Standard; (e) a system for process improvement through complaint monitoring and the implementation of corrective and preventive actions; (f) a system for the identification and investigation of post-donation information, errors and accidents	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>



	<p>and adverse reactions, including the implementation of corrective action and the conduct of recalls;</p> <p>(g) a personnel training and competency-evaluation program;</p> <p>(h) a proficiency testing program to evaluate the accuracy and reliability of test results;</p> <p>(i) a document control and records management system;</p> <p>(j) an internal audit system;</p> <p>(k) emergency contingency plans;</p> <p>(l) a system that uniquely identifies all critical equipment and supplies;</p> <p>(m) written specifications for all critical equipment, supplies and services;</p> <p>(n) a program for preventive maintenance of critical equipment;</p> <p>(o) a program for process validation?</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
94(3)	Unless any individual who conducts an internal audit does not have direct responsibility for the activities being audited, is the establishment's quality assurance unit a distinct organizational unit that functions and reports to management independently of any other functional unit?	Yes <input type="checkbox"/> No <input type="checkbox"/>
95	Are there operating procedures for all of the activities the establishment conducts with respect to human safety and the safety of blood?	Yes <input type="checkbox"/> No <input type="checkbox"/>
96	<p>Do the operating procedures meet all of the following requirements?</p> <p>(a) in a standardized format</p> <p>(b) approved by a senior executive officer</p> <p>(c) readily accessible at all locations where the relevant activities are conducted</p> <p>(d) kept up-to-date</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
97	Is there documented evidence that demonstrates that the operating procedures used in the processing and transforming of blood will consistently lead to the expected results?	Yes <input type="checkbox"/> No <input type="checkbox"/>
98(1)	Are there sufficient personnel who are qualified by education, training or experience to perform their respective tasks to conduct the establishment's activities?	Yes <input type="checkbox"/> No <input type="checkbox"/>
98(2)	Is there a program for the orientation and training, both initial and ongoing, of personnel and for the evaluation of their competency?	Yes <input type="checkbox"/> No <input type="checkbox"/>
99	Do the facilities permit all of the following:	

	(a) the conduct of all of the activities; (b) the performance by personnel of their respective tasks using proper hygiene; (c) the cleaning of the facilities in a way that maintains sanitary conditions; (d) environmental controls appropriate to all areas where its activities are conducted; (e) controlled access to all areas where activities are conducted; and (f) privacy for donor screening?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
100(1)	Is the critical equipment cleaned and maintained and, as appropriate, validated for its intended purpose and calibrated?	Yes <input type="checkbox"/> No <input type="checkbox"/>
100(2)	After repairs or any changes are made to critical equipment, is the equipment revalidated and recalibrated, as appropriate?	Yes <input type="checkbox"/> No <input type="checkbox"/>
101	Does the equipment used to store blood allow compliance with the storage requirements of sections 69 to 72 of the <i>Blood Regulations</i> ?	Yes <input type="checkbox"/> No <input type="checkbox"/>
102	Are the critical supplies validated or qualified, as applicable, for their intended use and stored under appropriate environmental conditions?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Quality Management System:</b>		
<b>G. Error and Accident Investigation and Reporting (applicable to all establishments)</b>		
103–108	Has the establishment read and understood the requirements of error and accident investigation and reporting?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Error and Accident Investigation and Reporting:</b>		
<b>H. Adverse Reaction Investigation and Reporting (applicable to all establishments)</b>		
109–116	Has the establishment read and understood the requirements of adverse reaction investigation and reporting?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Adverse Reaction Investigation and Reporting:</b>		

<b>I. Records (applicable to all registered establishments)</b>		
117	Are the records accurate, complete, legible, indelible and readily retrievable?	Yes <input type="checkbox"/> No <input type="checkbox"/>
118	Is the donation code a component of all the records related to the processing, distribution, transformation and transfusion of the blood?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b><i>Records for establishments that collect allogeneic blood</i></b>		
119(1)	<p>Are the following records relating to allogeneic blood, including PADP activities, retained for the amount of time specified from the date they were created?</p> <ol style="list-style-type: none"> <li>1. Donor identification code for 50 years</li> <li>2. Donation code for 50 years</li> <li>3. Reconciliation of donation codes for 10 years</li> <li>4. Donor suitability assessment for 5 years</li> <li>5. Determination of indefinite donor unsuitability for 50 years</li> <li>6. Determination of temporary donor unsuitability for 10 years</li> <li>7. Collection – date of donation for 50 years</li> <li>8. Collection – donor apheresis for 5 years</li> <li>9. Collection – record of donation for 5 years</li> <li>10. Lot number and name of manufacturer of container and other critical supplies for each donation for 1 year</li> <li>11. Test results for transmissible disease testing, ABO group and Rh factor, and clinically significant antibody testing for 50 years</li> <li>12. Blood component preparation for 10 years</li> <li>13. Blood storage temperature monitoring for 5 years</li> <li>14. Destruction or other disposition of blood for 50 years</li> <li>15. Distribution for 50 years</li> <li>16. Shipping documents for 1 year</li> <li>17. Post-donation information for 10 years</li> <li>18. Complaints and their investigation for 5 years</li> <li>19. Internal audit reports for 5 years</li> <li>20. Quality control testing for 5 years</li> <li>21. Maintenance, validation, qualification and calibration of critical equipment for 3 years</li> <li>22. Records related to critical supplies, including</li> </ol>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>

	<p>their qualification for 3 years</p> <p>23. Proficiency testing for 5 years</p> <p>24. Every version of the operating procedures that was implemented, other than those related to donor suitability assessments, for 10 years</p> <p>25. Every version of the operating procedures related to donor suitability assessment for 50 years</p> <p>26. Personnel qualifications, training and competency evaluation for 10 years</p> <p>27. Investigations and reports of errors and accidents for 10 years</p> <p>28. Investigations and reports of adverse reactions for 10 years</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
119(2)	Are the records related to personnel qualifications, training and competency evaluation being stored for 10 years from the last date on which the employee was last employed?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Records for establishments that collect autologous blood</b>		
120(1)	<p>Are the following records relating to autologous donation retained for the amount of time specified from the date they were created?</p> <p>1. Donor identification code for 10 years</p> <p>2. Donation code for 10 years</p> <p>3. Collection - donor record for 5 years</p> <p>4. Lot number and name of manufacturer of container and other critical supplies for each donation for 1 year</p> <p>5. Test results for transmissible disease testing, ABO group and Rh factor for 10 years</p> <p>6. Blood component preparation for 10 years</p> <p>7. Blood storage temperature monitoring for 5 years</p> <p>8. Destruction or other disposition of blood for 10 years</p> <p>9. Distribution for 10 years</p> <p>10. Shipping documents for 1 year</p> <p>11. Complaints and their investigation for 5 years</p> <p>12. Internal audit reports for 5 years</p> <p>13. Quality control testing for 5 years</p> <p>14. Maintenance, validation, qualification and calibration of critical equipment for 3 years</p> <p>15. Critical supplies, including their qualification for 3 years</p> <p>16. Proficiency testing for 5 years</p> <p>17. Every version of the operating procedures that</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>

	<p>was implemented for 10 years</p> <p>18. Personnel qualifications, training and competency evaluation for 10 years</p> <p>19. Investigations and reports of errors and accidents for 10 years</p> <p>20. Investigations and reports of adverse reactions for 10 years</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
120(2)	Are the records related to personnel qualifications, training and competency evaluation being stored for 10 years from the last date on which the employee was last employed	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Records for establishments that transform blood</b>		
121(1)	<p>Are the following records relating to transformation retained for the amount of time specified from the date they were created?</p> <p>1. Donation code for 10 years</p> <p>2. Records of washing, pooling and irradiation of blood for 10 years</p> <p>3. Lot number and name of manufacturer of critical supplies for each transformation for 1 year</p> <p>4. Complaints and their investigation for 5 years</p> <p>5. Internal audit reports for 5 years</p> <p>6. Quality control testing for 5 years</p> <p>7. Maintenance, validation, qualification and calibration of critical equipment for 3 years</p> <p>8. Critical supplies, including their qualification for 3 years</p> <p>9. Every version of the operating procedures that was implemented for 10 years</p> <p>10. Personnel qualifications, training and competency evaluation for 10 years</p> <p>11. Investigations and reports of errors and accidents for 10 years</p> <p>12. Investigations and reports of adverse reactions for 10 years</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
121(2)	Are the records related to personnel qualifications, training and competency evaluation being stored for 10 years from the last date on which the employee was last employed by the establishment?	Yes <input type="checkbox"/> No <input type="checkbox"/>
123	Are the records stored in a location that has appropriate environmental conditions and that is secure against the entry of unauthorized persons?	Yes <input type="checkbox"/> No <input type="checkbox"/>
<b>Comments for Records:</b>		

## **APPENDIX C: Repealed Food and Drug Regulations C.04.400–C.04.423 Human Plasma Collected by Plasmapheresis**

This appendix provides the requirements of the *Food and Drug Regulations* C.04.400–C.04.423 *Human Plasma Collected by Plasmapheresis*. These requirements are the baseline of the authorized criteria for licensed establishments previously held to these requirements prior to the repeal of these sections of the *Food and Drug Regulations*. These baseline requirements will change once an application for an amendment to an Authorization is submitted by an establishment and approved by Health Canada.

### *Human Plasma Collected by Plasmapheresis*

#### Interpretation

**C.04.400.** The following definitions apply in this section and in sections C.04.401 to C.04.423.

“accident” means an unexpected event that is not attributable to a deviation from a fabricator’s procedures or applicable laws and that could adversely affect the safety of a donor or the safety, efficacy or quality of plasma. (*accident*)

“donor” means a person aged 17 years or older who has given their name to a fabricator for the purpose of participating in plasmapheresis with that fabricator. (*donneur*)

“error” means a deviation from a fabricator’s procedures or applicable laws that could adversely affect the safety of a donor or the safety, efficacy or quality of plasma. (*manquement*)

“fabricator” means a person who is the holder of an establishment licence issued under these Regulations that authorizes the person to fabricate source plasma. (*manufacturier*)

“personal identifier” means a unique group of letters, numbers or symbols, or any combination of them, that is assigned to a donor by a fabricator. (*identificateur personnel*)

“physician” means a person who is entitled to practice the profession of medicine under the laws of the province in which the person provides medical service in connection with plasmapheresis or specific immunization. (*médecin*)

“physician substitute” means a person who  
(a) acts under the general supervision and direction of a physician; and  
(b) is authorized to provide the services that may be provided by a physician substitute under sections C.04.401 to C.04.423, according to the applicable laws of the province in which the person provides any of those services. (*substitut*)

“plasmapheresis” means a process during which:  
(a) blood is taken from a donor from which plasma is separated; and

(b) red blood cells and formed elements from the blood are returned to the donor.  
(*plasmaphérèse*)

“plasmapheresis session” means a meeting between a fabricator and a donor held for the purpose of proceeding with plasmapheresis. (*séance de plasmaphérèse*)

“serious adverse reaction” means an unexpected and undesirable response in a donor, associated with plasmapheresis or specific immunization, that results in any of the following consequences for the donor:

- (a) hospitalization;
- (b) persistent or significant disability or incapacity;
- (c) a medical or surgical intervention to preclude a persistent or significant disability or incapacity;
- (d) a life-threatening condition; or
- (e) death. (*effet indésirable grave*)

“source plasma” means human plasma collected by plasmapheresis that is intended for use in producing a drug for human use. (*plasma destiné au fractionnement*)

“specific immunization” means the administration of an immunogen to a donor with the intention of eliciting an immune response in their blood for the purpose of plasmapheresis.  
(*immunisation spécifique*)

“unique identifier” means a unique group of letters, numbers or symbols, or any combination of them, that is assigned by a fabricator to source plasma or red blood cells to be used in specific immunization. (*identificateur unique*)

SOR/78-545, s. 1; SOR/85-1022, s. 1; SOR/2006-353, s. 1.

## Prohibitions

### **C.04.401.** No person shall

- (a) sell source plasma unless it has been fabricated, tested, packaged/labelled and stored in accordance with sections C.04.402 to C.04.423; or
- (b) fabricate source plasma from blood collected from a person who is not suitable to participate in plasmapheresis according to sections C.04.402 to C.04.423.

SOR/78-545, s. 1; SOR/85-1022, s. 2; SOR/2006-353, s. 1.

## Fabricator’s Responsibility

**C.04.402.** (1) A fabricator shall ensure that a person who provides services to them in connection with plasmapheresis or specific immunization is qualified by education and by training or experience to provide the services.



(2) The fabricator shall ensure that the premises used for donor screening, plasmapheresis or specific immunization are designed, constructed and maintained in a manner that permits medical information to be communicated in confidence.

SOR/78-545, s. 1; SOR/85-1022, s. 2; SOR/97-12, s. 47; SOR/2006-353, s. 1.

#### Consent and Preliminary Evaluation

**C.04.403.** (1) A fabricator shall not begin plasmapheresis with a donor unless

(a) the fabricator has informed the donor of what is involved with plasmapheresis, including the risks to the donor's health associated with plasmapheresis and with participating in plasmapheresis more frequently than once every eight weeks; and

(b) after paragraph (a) has been satisfied, the fabricator obtains from the donor

(i) a written acknowledgement that the information specified in paragraph (a) has been provided to them, and

(ii) in accordance with the applicable laws governing consent, written informed consent to participate in plasmapheresis.

(2) A fabricator shall not begin the specific immunization of a donor unless

(a) a physician has selected the immunogen to be administered to the donor and informed the donor of

(i) the name and nature of the selected immunogen,

(ii) the proposed frequency and the maximum number of specific immunization injections the donor is expected to receive, and

(iii) what is involved with specific immunization, including the risks to the donor's health associated with specific immunization and with receiving the selected immunogen; and

(b) after paragraph (a) has been satisfied, the fabricator obtains from the donor

(i) a written acknowledgement that the information specified in paragraph (a) has been provided to them, and

(ii) in accordance with the applicable laws governing consent, written informed consent to receive the selected immunogen.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

**C.04.404.** (1) A fabricator shall not proceed with plasmapheresis or specific immunization unless a physician or physician substitute has determined the donor's suitability to participate in plasmapheresis more frequently than once every eight weeks based on the donor's medical history and a medical examination of the donor.



(2) If the donor is determined to be suitable, the fabricator shall document the following information:

- (a) the fact that the donor is suitable to participate in plasmapheresis more frequently than once every eight weeks;
- (b) the donor's name and personal identifier;
- (c) the name and signature of the physician who makes the determination, or supervises the physician substitute making the determination; and
- (d) the date of the determination.

(3) The fabricator shall not proceed with plasmapheresis or specific immunization if the most recent determination under subsection (1) in respect of the donor was made more than

- (a) 30 days before the date set for the donor's first participation in plasmapheresis or specific immunization; or
- (b) one year before any other date set for the donor's participation in plasmapheresis or specific immunization.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

#### Specific Immunization

**C.04.405.** (1) No one other than a physician or physician substitute shall administer an immunogen to a donor for the purpose of specific immunization.

(2) A physician shall monitor the donor's response to the immunogen to determine if the donor can continue to receive specific immunization.

(3) If the donor cannot continue to receive specific immunization, the fabricator shall cease to provide it to the donor until a physician determines that the donor can receive specific immunization using the same or another immunogen.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

#### Evaluation Before Collection

**C.04.406.** (1) At the beginning of each plasmapheresis session, a physician or physician substitute shall determine if the donor is suitable to participate in plasmapheresis.

(2) If the donor is determined to be temporarily not suitable to participate in plasmapheresis based on the criteria set out in Table 1 or any other medical reason justifying a determination of temporary non-suitability, the fabricator shall cancel the session, inform the donor of the reason why they are temporarily not suitable and indicate the date when the donor may continue to participate in plasmapheresis.

(3) If the donor is determined to be not suitable to participate in plasmapheresis for an indefinite period based on the exclusion criteria set out in Table 2 or any other medical reason justifying a determination of indefinite non-suitability, the fabricator shall cancel the session and inform the donor of the reason why they are not suitable to participate in plasmapheresis for an indefinite period.

TABLE 1

Item	Criteria
1.	Weight of less than 50 kg
2.	Temperature outside of normal limits
3.	Blood pressure above 100 mmHg diastolic or 180 mmHg systolic
4.	Haemoglobin level of less than 125 g/L of blood or haematocrit value of less than 0.38 L/L of blood
5.	Total protein level of less than 60 g/L of blood
6.	Substantial blood loss
7.	Prior donation of plasma or other blood components
8.	Pregnancy
9.	History of medical or surgical procedures
10.	History of convulsions requiring medical treatment
11.	Ability to answer questions compromised by alcohol or drug use
12.	Prior transfusion of blood, blood components or a blood product, or prior transplantation of a cell, tissue or organ other than dura mater
13.	Skin infection at the site of the phlebotomy
14.	Sign or symptom of infection
15.	Risk of infection with HIV, hepatitis B virus or hepatitis C virus based on, but not limited to, a history of acupuncture, skin piercing, tattooing, accidental needle-stick injury or occasional sexual relations with a person at risk of having any of those infections
16.	Current or past use of medication that poses a risk to a recipient of a product manufactured from source plasma

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| 17. | Receipt of a live attenuated vaccine   |
| 18. | Animal bite requiring prophylaxis for rabies or for which the need for post-exposure prophylaxis has not been assessed |
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TABLE 2

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Item	Exclusion Criteria
1.	Abnormal cardiovascular function or serious or chronic cardiovascular disease
2.	Abnormal respiratory function or serious or chronic respiratory disease
3.	Bleeding disorder that poses a risk to the donor in relation to plasmapheresis
4.	Serious disease or medical condition of the liver, kidneys, another organ, a system or blood
5.	Persistent abnormal plasma proteins including monoclonal or polyclonal gammopathy
6.	Current or past use of medication that poses an ongoing risk to a recipient of a product manufactured from source plasma
7.	History of recurrent fainting associated with the donation of blood or plasma
8.	History, signs or symptoms of injectable drug abuse such as skin punctures, scars or sharing needles to inject drugs
9.	History, signs or symptoms of AIDS or HIV infection
10.	Risk of HIV infection based on sexual practices
11.	History, signs or symptoms of a chronic or persistent infection or parasitic disease transmissible by blood
12.	History, signs or symptoms of hepatitis, other than hepatitis A
13.	Cancer, other than non-melanoma skin cancer or insitu cervical cancer
14.	Risk factor for Creutzfeldt-Jacob disease (CJD) or its variant (vCJD) based on, but not limited to, the receipt of dura mater transplant or a treatment using a human pituitary hormone
15.	Positive test result for any transmissible disease agent

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SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

### Plasma Protein Composition

**C.04.407.** (1) Before beginning plasmapheresis with a donor, a fabricator shall take a blood sample from the donor to determine the plasma protein composition of the donor's blood by means of a serum protein electrophoresis test or an equivalent test.

(2) A blood sample shall be taken within seven days before the donor's first plasmapheresis session at which the fabricator proceeds with plasmapheresis.

(3) If 21 days have elapsed from the taking of the sample without a physician examining the test result, the fabricator may not proceed with plasmapheresis until a physician examines the test result.

(4) If a physician concludes that the plasma protein composition of the donor's blood is not within normal limits, the fabricator may not proceed with plasmapheresis until a physician determines that the plasma protein composition of the donor's blood is within normal limits.

(5) If the fabricator has not taken a blood sample from the donor as required under subsection (1) for more than four months, the fabricator may not proceed with plasmapheresis until the blood sample is taken from the donor.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

### Ongoing Review of Collection Records

**C.04.408.** (1) A physician shall determine if a donor is suitable to continue to participate in plasmapheresis more frequently than once every eight weeks, based on the test results and collection records for the donor that have been made or received by the fabricator within the preceding four months.

(2) The determination shall be made at least every four months after the date of the initial determination that the donor is suitable under section C.04.404.

(3) If the donor is determined to be temporarily not suitable to participate in plasmapheresis the fabricator shall inform the donor of the reason why they are temporarily not suitable and indicate the date when the donor may continue to participate in plasmapheresis.

(4) If the donor is determined to be not suitable for an indefinite period, the fabricator may not proceed with plasmapheresis and shall inform the donor of the reason why they are not suitable.

(5) If the requirement of subsection (2) is not met, the fabricator may not proceed with plasmapheresis until the determination is made.

SOR/78-545, s. 1; SOR/85-1022, s. 3; SOR/2006-353, s. 1.

### Plasmapheresis Procedures

**C.04.409.** A fabricator who conducts a plasmapheresis session shall

- (a) use aseptic methods and a sterile collection system licensed under the *Medical Devices Regulations*;
- (b) ensure that all surfaces intended to come into contact with blood or plasma are pyrogen free;
- (c) ensure that the donor's skin where the phlebotomy is to be made is
  - (i) determined to be free from lesion, rash or other source of infection, and
  - (ii) cleaned and disinfected; and
- (d) ensure that emergency medical personnel are capable of attending to the medical needs of the donor within 10 minutes after being contacted by the fabricator.

SOR/78-545, s. 1; SOR/85-1022, s. 4; SOR/2006-353, s. 1.

### Maximum Volumes and Minimum Intervals

**C.04.410.** (1) A fabricator shall not collect plasma from a donor in a total amount, excluding anticoagulant solution, that exceeds

- (a) if the donor's weight is 50 kg or more but less than 68 kg,
    - (i) 625 mL or 640 g in respect of a single plasmapheresis session, and
    - (ii) 11.5 L in respect of all plasmapheresis sessions during the preceding six months;
  - (b) if the donor's weight is 68 kg or more but less than 80 kg,
    - (i) 750 mL or 770 g in respect of a single plasmapheresis session, and
    - (ii) 15.5 L in respect of all plasmapheresis sessions during the preceding six months; and
  - (c) if the donor's weight is 80 kg or more,
    - (i) 800 mL or 820 g in respect of a single plasmapheresis session, and
    - (ii) 18.5 L in respect of all plasmapheresis sessions during the preceding six months.
- (2) The fabricator shall have written procedures that describe
- (a) the minimum waiting period for a donor between donations of plasma and between a donation of plasma and a donation of blood or other blood components; and
  - (b) the maximum number of plasma donations a donor may make in a given period.

SOR/78-545, s. 1; SOR/85-1022, s. 5; SOR/95-203, s. 1; SOR/2006-353, s. 1.

### Anticoagulant Solution

**C.04.411.** (1) During plasmapheresis, the fabricator shall mix an anticoagulant solution with the blood collected from the donor.

(2) The anticoagulant solution shall have a valid drug identification number under these Regulations that indicates the solution is suitable for use in plasmapheresis.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

### Samples for Testing

**C.04.412.** (1) During a plasmapheresis session, the fabricator shall take a sample of blood or plasma in a manner that does not contaminate the sample or the source plasma.

(2) When the sample is taken, the fabricator shall clearly and permanently label the sample container with the unique identifier assigned to the source plasma.

(3) The fabricator shall ensure that the person who labels the sample container is the same person who labels the container holding the source plasma under subsection C.04.416(2).

SOR/78-545, s. 1; SOR/2006-353, s. 1.

**C.04.413.** (1) The fabricator shall test a sample taken under section C.04.412 to detect evidence of the following disease agents:

(a) HIV types 1 and 2;

(b) hepatitis B virus;

(c) hepatitis C virus; and

(d) syphilis.

(2) The fabricator shall retain the source plasma collected at the plasmapheresis session until all the test results are determined to be negative or non-reactive.

(3) In the case of a positive or reactive test result for any disease agent referred to in subsection (1), the fabricator shall

(a) clearly and permanently label the container holding the source plasma collected at the session with

(i) the statement “Caution: Not for Manufacturing Use” or “Précaution : Non destiné à la fabrication”, and

(ii) the hazard symbol for Biohazardous Infectious Material set out in Schedule II to the Controlled Products Regulations; and

(b) segregate and dispose of the source plasma.

(4) In the case of a positive or reactive test result for syphilis, the fabricator may not proceed with plasmapheresis until a subsequent test shows that the donor is not infected with syphilis and a physician determines that the donor can continue to participate in plasmapheresis.

(5) In the case of a positive or reactive test result for a disease agent referred to in subsection (1), other than syphilis, the fabricator shall discontinue plasmapheresis and inform the donor of the reason why they are not suitable to participate in plasmapheresis for an indefinite period.

SOR/78-545, s. 1; SOR/97-12, s. 48; SOR/2006-353, s. 1.

### Preservatives and Additives

**C.04.414.** No person shall add a preservative or additive to source plasma.

SOR/78-545, s. 1; SOR/85-1022, s. 6; SOR/2006-353, s. 1.

### Containers

**C.04.415.** A fabricator shall place source plasma in a container

(a) in respect of which a medical device licence has been issued under the *Medical Devices Regulations* for the purpose of collecting and storing plasma;

(b) that permits visual, electronic or automated inspection of the plasma;

(c) that has been visually inspected at the plasmapheresis session and found to be intact; and

(d) that has not been previously used for any purpose, including holding source plasma from the same donor.

SOR/78-545, s. 1; SOR/85-1022, s. 6; SOR/2006-353, s. 1.

### Labelling

**C.04.416.** (1) Sections C.01.004 and C.04.019 do not apply to source plasma.

(2) A fabricator shall clearly and permanently label the container used to hold source plasma with

(a) the unique identifier assigned to the source plasma in the container;

(b) the statement “Source Plasma” or “Plasma destine au fractionnement”;

(c) the statement “Caution: For Manufacturing Use Only” or “Précaution : À utiliser uniquement pour la fabrication”;

(d) the quantity of the source plasma;

- (e) the name and quantity of the anticoagulant solution used during the plasmapheresis;
  - (f) the expiry date of the source plasma, expressed in an unambiguous format;
  - (g) subject to subsection C.04.413(3), a statement indicating that the source plasma tests negative for the disease agents for HIV, hepatitis B and hepatitis C;
  - (h) if the source plasma was collected from a donor who has received specific immunization, a statement indicating the immunogen that was used;
  - (i) the name, address and establishment licence number of the fabricator; and
  - (j) a statement indicating that the source plasma must be stored at a temperature of -20°C or colder.
- (4) The unique identifier shall be placed on the container at the time of collection.

SOR/78-545, s. 1; SOR/85-1022, s. 7; SOR/2006-353, s. 1.

### Storage

**C.04.417.** (1) In respect of the storage of source plasma, including storage during transportation, a fabricator shall ensure that the storage environment

- (a) is designed to maintain a temperature of -20°C or colder; and
  - (b) remains consistently at a temperature of -20°C or colder.
- (2) If the temperature of the environment rises above -20°C, the fabricator shall record the following information:
- (a) the reason for the elevated temperature;
  - (b) the source plasma affected; and
  - (c) the final disposition of the source plasma.
- (3) If the temperature of the environment rises to between - 20°C and +10°C, the fabricator shall clearly and permanently label the container of the source plasma with the statement “Source Plasma — Salvaged” or “Plasma destiné au fractionnement — recyclé”.
- (4) Subsection (3) does not apply if the temperature of the environment rises to between -20°C and -5°C for a single period lasting less than 72 hours.
- (5) If the temperature of the environment rises above +10°C, the fabricator shall dispose of the source plasma.
- (6) Paragraph (1)(b) and subsections (2) to (5) do not apply in respect of the storage of source plasma during transportation, if the transportation is not conducted by the fabricator.



SOR/78-545, s. 1; SOR/85-1022, s. 8; SOR/2006-353, s. 1.

**C.04.418.** (1) A fabricator shall inspect each container of source plasma to determine if the container and its label are intact and if there are any indications that the source plasma has been subject to thawing.

(2) The fabricator shall dispose of the source plasma if the inspection shows that

(a) the container is defective or damaged to the extent that it does not provide protection against external factors that could result in deterioration or contamination of the source plasma;

(b) the unique identifier assigned to the source plasma is missing or illegible;

(c) any information required under paragraphs C.04.416(2)(b) to (i) is missing or illegible, unless the missing or illegible information can be retrieved from the fabricator's records; or

(d) the source plasma has been subject to thawing.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

#### Records

**C.04.419.** (1) A fabricator shall use and maintain a recordkeeping system according to which the fabricator shall

(a) assign a personal identifier to each donor;

(b) keep on the donor's file a photograph of the donor or some other reliable means of identification; and

(c) assign a unique identifier to the source plasma collected by the fabricator at each plasmapheresis session.

(2) The system shall be structured so that a fabricator may, based on a personal identifier or a unique identifier, identify the donor and retrieve sufficient records to permit the traceability and recall of source plasma.

(3) The fabricator shall keep the records referred to in subsection (2) indefinitely.

SOR/78-545, s. 1; SOR/85-1022, s. 9; SOR/2006-353, s. 1.

**C.04.420.** (1) For each donor, the fabricator shall keep

(a) the original or a copy of the donor's acknowledgement and consent under paragraphs C.04.403(1)

(b) and (2)(b), if any;

(b) the original or a copy of any determinations, examinations, test results, reports and written notices made under sections C.04.401 to C.04.423;

(c) for each specific immunization given by the fabricator to the donor, a record indicating

(i) the date and location of the immunization,

(ii) the physician or physician substitute who administered the immunogen, and

(iii) for the immunogen injected, its name and manufacturer's name, the quantity and expiry date and either the immunogen's lot number and drug identification number or, if the immunogen is red blood cells, its unique identifier;

(d) for each plasmapheresis session held by the fabricator for the donor, a record indicating

(i) the date and location of the session,

(ii) the volume of source plasma collected,

(iii) the unique identifier assigned to the source plasma,

(iv) the volume of red blood cells collected that was not returned to the donor, including the volume of red blood cells collected during sampling,

(v) for the anticoagulant solution used, its name, its manufacturer's name and its lot number and drug identification number, and

(vi) for the container used, the manufacturer's name and the container's lot number and expiry date.

(2) The fabricator shall maintain a summary of all accidents, errors, serious adverse reactions and recalls of source plasma involving the fabricator.

(3) The fabricator shall maintain temperature records made under subsection C.04.417(2).

SOR/78-545, s. 1; SOR/85-1022, s. 10; SOR/97-12, s. 61; SOR/2006-353, s. 1.

#### Information to the Minister

**C.04.421.** (1) A fabricator shall notify the Minister of any serious adverse reaction

(a) within 24 hours after the fabricator becomes aware of the occurrence, in the case of a fatality; and

(b) within 15 days after the fabricator becomes aware of the occurrence, in any other case.

(2) In the case of a verbal notice under subsection (1), the fabricator shall submit a written report of the serious adverse reaction to the Minister within 24 hours after submitting the notice.

(3) The notice, if in writing, or the written report shall include a description of the serious adverse reaction and any steps taken to address it.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

**C.04.422.** If a fabricator recalls source plasma for a reason involving product safety, the fabricator shall provide the Minister with a written report stating the reason for the recall, the number of units involved and the location from which the units were recalled.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

**C.04.423.** In order to prevent injury to the health and safety of donors and recipients of products manufactured from source plasma, a fabricator shall, on request, provide the Minister with a copy of any record pertaining to plasmapheresis, specific immunization or source plasma that is required by sections C.04.401 to C.04.422 to be kept by the fabricator.

SOR/78-545, s. 1; SOR/2006-353, s. 1.

## **APPENDIX D: Health Canada Guidance Documents and Directives superseded by the *Guidance Document: Blood Regulations***

Please note that other guidance documents and directives as well as any associated forms (not listed) that provide further interpretation of the *Food and Drug Regulations*, Part C, Division 1A, 2 and 4 no longer apply to blood that is the subject of the *Blood Regulations*.

*Guidance for Industry: Management of Blood Establishment Submissions*

*Guidance Document: Human Plasma Collected by Plasmapheresis*

*Annex 14 to the Current Edition of the GMP Guidelines — Schedule D Drugs, Human Blood and Blood Components (GUI-0032)*

*Information Letter I.L. No. 816 November 1, 1995, 2. Health Canada Policy a) Donors considered to pose a risk of CJD b) Donor Deferral c) Withdrawal/quarantine of In-date Blood Products (November 1, 1995)*

*D98-01: Implementation of Pre-storage Leukoreduction of Cellular Blood Components (November 2, 1998)*

*D99-01: Donor Exclusion to Address Theoretical Risk of Transmission of variant CJD through the Blood Supply (August 17, 1999)*

*D99-02: Donor Exclusion to Address Theoretical Risk of Transmission of variant CJD through the Use of Commercial Blood Products (August 17, 1999)*

*D2000-01: Donor Exclusion to Address Theoretical Risk of Transmission of variant CJD through the Blood Supply (August 30, 2000)*

*D2001-001: Donor Exclusion to Address Theoretical Risk of Transmission of variant Creutzfeldt-Jakob Disease (vCJD) through the Blood Supply: United Kingdom, France & Western Europe (August 30, 2001)*

*Additional Donor Exclusion Measures to Address the Potential Risk of Transmission of variant Creutzfeldt-Jakob Disease (vCJD) through the Blood Supply (April 22, 2005)*

*D2006-01: Implementation of blood donor screening measures to reduce the theoretical risk of transmission of simian foamy virus and possibly other yet unidentified simian viruses by transfusion (May 15, 2006)*

*Information Letter Regarding Syphilis Testing and Deferral Requirements for History of Parasitic Disease for Donors of Source Plasma for Further Manufacturing (September 2, 2010)*