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Blood Regulations

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the regulations*.)

Executive summary

Issue: Blood and blood components are currently regulated as drugs by a combination of provisions that are not specific to blood, found in several Divisions of Part C of the *Food and Drug Regulations* (FDR). Justice Krever's report to the Commission of Inquiry on the Blood System in Canada found that while blood and blood components used in Canada are safe, safety could be further improved. To achieve this, the Commission recommended that Health Canada outline regulatory requirements that are clear, intelligible, comprehensive and specific to blood. That current regulatory requirements for blood and blood components are being applied only to the blood operators, despite the fact that some hospital blood banks perform some of the same activities, is equally important. This creates a gap in Health Canada's regulatory oversight of these activities, which was also recognized by Justice Krever's recommendations. These recommendations are the main drivers for the new blood Regulations.

Description: The purpose of this initiative is to introduce in the *Food and Drugs Act* (FDA) specific Regulations for human blood and its components intended for transfusion or for further manufacturing into human drugs. The proposed regulatory framework would address the safety, efficacy and quality of blood and its components with requirements related to the donor suitability assessment, collection, testing, labelling, storage, distribution and importation, for all establishments performing these activities. The proposed regulatory initiative would consolidate the existing requirements in new Regulations specific for blood and its components, apply to all establishments that perform any of the regulated activities, and apply the level of oversight that is commensurate with the level of risk of the activities performed by each establishment. This would result in a more consistent and comprehensive safety and quality profile of blood and its components from the donor to recipient.

Cost-benefit statement: The proposed Regulations serve to codify the safety requirements described in the blood standards which were first published by the Canadian Standards Association in 2004 and recently updated in 2010. Since the key stakeholders committed to adopting the safety requirements in the blood standards, the regulated establishments would not experience any further costs as a result of the publication of the proposed Regulations. However, clearer regulatory requirements consolidated within the proposed Regulations would provide the necessary clarity,

transparency and flexibility to meet the challenges of the future, which would benefit the regulated establishments, the regulator and ultimately Canadians.

Business and consumer impacts: The proposed Regulations would consolidate all requirements that apply to blood that are currently located in three different Divisions of the FDA, thus simplifying and clarifying the requirements for both the regulator and the establishments. The proposed Regulations would also simplify the application and amendment processes for establishment licences (EL) currently required for blood operators to perform the regulated activities, thus decreasing their future costs. The addition of a new registration scheme for establishments that perform autologous blood collection, transformation activities or have pre-assessed donor programs would require the completion and submission of an application form to obtain their registration. Provisions for a delayed coming into force would allow establishments one year to update their processes in order to comply with the proposed regulatory requirements, and an additional three months to file the necessary applications.

Domestic and international coordination and cooperation: Since blood and its components are not sold within Canada, there are no domestic trade issues with the proposed Regulations. The proposed Regulations have a mechanism to allow blood to be imported in urgent circumstances when there may be insufficient allogeneic blood available in Canada. Since Canada's main trading partner for blood components is the United States, and the proposed Regulations align well with those of the United States, there is no anticipated impact on the supply of blood components imported from the United States for transfusion. As for source plasma that has been manufactured into blood products, these products would continue to be regulated under Division 8 of the FDR, and would not be affected by the proposed Regulations.

Performance measurement and evaluation plan: Because this initiative is largely a consolidation of existing regulatory requirements that apply to blood and is expected to have minimal impact on the blood system, the evaluation would focus on whether all establishments in Canada that handle blood for transfusion or for further manufacturing are being regulated and whether mandatory reporting of errors, accidents and adverse reactions is effective in identifying serious cases of interest to the regulator. Ongoing attention would be paid to the identification of situations within the blood system that could be unintended consequences related to the proposed Regulations.

Issue

Blood and blood components are currently regulated as drugs by a combination of provisions that are not specific to blood, found in the *Food and Drugs Act* (FDA) and several Divisions of Part C of the *Food and Drug Regulations* (FDR). Justice Krever's report to the Commission of Inquiry on the Blood System in Canada found that while blood and blood components used in Canada are safe, safety could be further improved. To achieve this, the Commission recommended that Health Canada outline regulatory requirements that are clear and intelligible, comprehensive and specific to blood, harmonized across Canada, and that allow for timely updating as new technologies or risks emerge.

That current regulatory requirements for blood and its components are being applied only to the blood operators (i.e. Canadian Blood Services and Héma-Québec) and Cangene (a private manufacturer collecting blood for the purpose of manufacturing drugs), despite the fact that some hospital blood banks perform some of the same activities, is equally important. This creates a gap in Health Canada's regulatory oversight of these activities, which was also recognized by Justice Krever's recommendations. These recommendations are the main drivers for the new blood Regulations.

Objectives

The purpose of this initiative is to introduce under the FDA specific Regulations for blood and its components intended for transfusion or further manufacturing into human drugs. The proposed

Regulations would apply to all establishments that handle blood, and allocate the level of oversight that corresponds to the level of risk of the activity being performed by each establishment. Having separate requirements that take into consideration the unique characteristics of blood would accommodate future innovation in transfusion sciences and clarify the requirements for both stakeholders and the regulator. The proposed Regulations would provide Health Canada's final response to the Krever Commission recommendations, and at the same time meet the broader departmental commitment to modernize regulations that have become outdated.

Interim approach — National blood safety standards

In response to Justice Krever's recommendation that the safety requirements for blood and its components be standardized, Health Canada contracted with the Canadian Standards Association (CSA) to develop the National Standard of Canada CAN/CSA-Z902 titled *Blood and blood components* (blood standards) which was first published in 2004 and updated in March 2010. The blood standards were developed following extensive consultation and the participation of the blood establishments, experts in the field of haematology, provincial and territorial representatives, interested stakeholders and Health Canada. Prior to their initial publication, the provincial and territorial governments committed to use the blood standards as the basis for their accreditation of hospital blood banks, thus harmonizing safety standards for the handling of blood and its components at the hospital blood banks under their jurisdiction. To ensure an easy transition for the newly regulated hospital blood banks performing the regulated activities, sections of the blood standards related to transformation activities (i.e. irradiation, washing or pooling), processing of autologous blood, pre-assessed donor programs and storage conditions for blood would be referenced in the proposed Regulations, thus making those requirements in the voluntary standards into law.

Amendments to existing legislation

The regulatory amendments propose to consolidate the applicable requirements under Division 1A and Division 2, and the regulatory requirements for plasma collected by plasmapheresis found in sections C.04.400 to C.04.423 of the FDR in the proposed Regulations specific for blood and its components. The plasmapheresis sections in Division 4, as well as the labelling requirement in subparagraph C.04.019(*b*)(ii), would also be repealed since these requirements would be found in the new Regulations. Schedule D to the FDA would be amended to combine all drugs that are blood or are made from blood into a single item in the schedule.

Description

The proposed regulatory initiative would consolidate the existing requirements into new Regulations specific for blood and its components, apply to all establishments that perform any of the regulated activities, and apply the level of oversight that is commensurate with the level of risk of the activities performed by each establishment.

The proposed Regulations would regulate the processing, labelling, storage, distribution and importation of blood and its components intended for transfusion or for further manufacturing into human drugs. Blood or blood components that are covered under other regulations, such as peripheral blood stem cells (covered under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*), blood used in clinical trials (covered in Division 5 of the FDR) or blood imported for the purpose of manufacturing drugs (covered in Division 8 of the FDR), would be exempted from these proposed Regulations.

Establishments that process or import allogeneic blood or its components (i.e. blood to be transfused into a person other than the donor), including processing of source plasma, would require an authorization and an establishment licence (EL) to conduct these activities, as well as a full quality management system (QMS). Establishments in this category would include the two blood operators and the private manufacturer of drugs from blood. This regulatory approach is consistent with the current level of oversight being applied to the regulation of these establishments under the existing provisions of the FDR, and would continue to allow for future innovations in transfusion medicine and manage emerging hazards to the blood system.

Establishments that collect blood for autologous transfusion (i.e. blood that is to be transfused back into the donor at a later time), have pre-assessed donor programs or perform transformation activities would require a registration to conduct these activities, as well as a full QMS. Establishments in this category would include the blood operators and some hospitals. The proposed Regulations would reference specific sections of the blood standards that apply to activities that are not regulated as part of an authorization, thus standardizing best practices across establishments while allowing for future innovations with respect to these activities.

Establishments that only transfuse the blood received from the collecting establishment or store and transport blood would only need to comply with the specific requirements associated with those activities, as specified in the proposed Regulations. Establishments in this category would include a majority of the hospital blood banks. These hospital blood banks would not need an authorization, EL or registration, nor do they need a full QMS.

In addition to the requirements described above, all establishments performing any of the regulated activities would need to comply with the requirements in the proposed Regulations related to operating procedures, record keeping, personnel, storage and the monitoring, investigation and reporting of serious adverse reactions and serious errors and accidents. Compliance and enforcement measures for all establishments performing any of the regulated activities would include compliance verification for cause and enforcement options available under the Act.

A brief summary of the key elements contained in the proposed Regulations follows.

Authorization

Establishments that process allogeneic blood and blood components for transfusion would be required to have an authorization from Health Canada. Also, establishments that process source plasma, which is plasma that is for further manufacturing into drugs for human use, would have to have an authorization to perform these activities. To obtain an authorization, establishments would submit an application to the Minister containing a detailed description of the proposed procedures and evidence to demonstrate that the blood or blood components meet the safety and efficacy requirements of the Regulations. If the Minister is satisfied that the application is complete and that the issuance of the authorization is not likely to compromise the safety, efficacy or quality of the blood or blood components or the safety of a donor or recipient, the Minister would issue the authorization. Once issued, an authorization would not need to be renewed but would be amended by Health Canada following review and approval of any proposed changes to the originally authorized processes and procedures.

Establishments that import blood for transfusion would have to obtain an authorization unless the blood is already the subject of another establishment’s authorization, and they would also require an EL. Establishments that only test allogeneic blood would be exempted from holding an authorization if they do not perform any other processing activities with respect to allogeneic blood, but would require an EL.

Establishment licensing

In addition to an authorization, establishments that process allogeneic blood or blood components for transfusion, or process source plasma, which is plasma that is for further manufacturing into drugs for human use, would require an EL issued under these proposed Regulations in order to perform these activities. To obtain an EL, the establishment would have to provide evidence to demonstrate that the establishment’s buildings, equipment and proposed practices and procedures meet the applicable requirements of the proposed Regulations, to maximize the safety, efficacy and quality of the blood and blood components. In addition, prior to receiving an EL, the establishment may undergo an inspection to assess its compliance with general good manufacturing practices (GMP), the quality management system and other applicable requirements of the proposed Regulations. Once an establishment had its EL, it would remain valid unless it were suspended or cancelled. However, licensed establishments would have to undergo routine inspections to assess their continued compliance with the requirements of these proposed Regulations in order to retain their EL.

Establishments that administer a pre-assessed donor program for allogeneic blood would be exempt from the EL or the authorization requirements if they do not process any other allogeneic blood or blood components. Rather, a registration would be required for pre-assessed donor programs.

Registration

Establishments that collect blood or blood components for autologous use, that perform transformation activities (i.e. irradiation, washing, or pooling) with respect to blood or blood components that have been determined safe for distribution or transfusion, or that administer a pre-assessed donor program would have to obtain a registration. To obtain a registration, an establishment would file an application that describes the activities it performs and the blood or blood components that it processes or transforms, along with a signed attestation that certifies that the establishment has sufficient evidence to demonstrate that it is in compliance with the proposed Regulations. If the establishment only performs activities that require a registration, an inspection would not be essential to initially obtain the registration, nor would it need an authorization. However, registered establishments may be subject to an inspection of their facilities and activities. Furthermore, establishments would be required to annually re-certify their continued compliance with the proposed Regulations in order to retain the registration.

Processing

Processing includes donor suitability assessment, collection, testing, and blood component preparation. The proposed Regulations would require establishments that process allogeneic blood and blood components to perform their activities in accordance with the processes/procedures approved by Health Canada in the authorization process. It is important to note that establishments that perform testing of allogeneic blood under contract for another establishment would be required to hold an EL and would have to perform the tests in accordance with the processes approved in the authorization of the contracting establishment.

Labelling

As an essential component of blood safety and the accurate identification of blood and blood components, labelling requirements for allogeneic, directed, designated and autologous donations, as well as labelling requirements for source plasma and recovered plasma, would be set out in the proposed Regulations. The proposed Regulations would require establishments that collect and distribute allogeneic blood for transfusion to prepare a circular of information that describes the composition and properties of the blood, the directions for storage and for use, and the indications, contraindications and a list of possible adverse reactions, and would ensure that the circular is available to anyone who requests it. To facilitate speedy and accurate identification of blood and its components intended for transfusion, certain key information would have to appear in machine-readable as well as eye-readable format for those components, including plasma for transfusion.

Storage and storage during transportation

To maximize the safety and quality of blood and its components, and thereby the safety of recipients, it is imperative that the appropriate storage temperature be maintained throughout all handling/storage and transportation. The proposed Regulations would include provisions outlining the acceptable storage conditions, including storage conditions during transportation of blood or blood components. Product handling requirements would also be described for situations when blood or blood components have been exposed to storage temperature variations.

Distribution

The proposed Regulations would require that establishments that collect blood or its components be satisfied that the blood has been processed in accordance with the Regulations and that it is safe, of good quality and effective, prior to distributing it. In addition, the proposed Regulations would describe the steps required to ensure that the blood that is distributed has not undergone any deterioration while it was in storage, and that all information required on the label is legible or retrievable from the establishments' records. Acceptable exceptions in the case of frozen

components that may have undergone thawing would also be described in the proposed Regulations.

Transformation

Transformation refers to the washing, pooling and irradiation of blood components after they have been determined safe for distribution or transfusion. It does not include component preparation or pathogen reduction technologies that are considered part of component preparation. The proposed Regulations would require that establishments use transformation methods that are safe and effective, and that components that undergo transformation be labelled to reflect the additional modifications. Specific sections of the blood standards that describe transformation requirements would also be referenced in the proposed Regulations.

Exceptional distribution

In emergency situations where an allogeneic blood or blood component that has been fully tested in accordance with an authorization is not immediately available, establishments would be allowed to distribute blood or blood components for transfusion if specific conditions are met. The proposed Regulations would require that an establishment first confirm that the intended recipient's physician accepts the use of the blood in the emergency treatment of their patient. Both the collecting establishment's medical director and the recipient's physician would also have to approve the emergency distribution in writing.

Under the exceptional distribution process, establishments that distribute blood or blood components for transfusion before the donor testing is complete would have to carry out any follow-up testing and notify the relevant establishment of the results as soon as possible after the distribution. Any blood or blood components distributed prior to completion of testing would be required to be clearly labelled to indicate that they have not been fully tested, and any such components that are not transfused into the intended recipient in the emergency would be prohibited from being stored or transfused into another recipient.

Pre-assessed donor programs

Establishments that administer a pre-assessed donor program for allogeneic blood would be exempt from the EL or the authorization requirements if they do not perform any other processing activity, but would require a registration. The use of pre-assessed donor programs would only be allowed in emergency situations when no alternate source of appropriate blood is available, and would require the oversight of a medical director and the confirmation that the intended recipient's physician accepts the use of the blood in the emergency treatment of their patient. The proposed Regulations would specify requirements related to donor suitability assessment, testing, and labelling, and any relevant time frames for these activities. Specific sections of the blood standards that describe the testing requirements and relevant time frames for pre-assessed donor programs, as well as the final disposition of the blood collected from such programs that is not transfused in the emergency for which it was collected, would also be referenced in the proposed Regulations. Establishments that test blood from pre-assessed donor programs would be required to obtain an EL.

Importation in urgent circumstances

In urgent circumstances, such as instances when there may be insufficient allogeneic blood available in Canada as a result of a catastrophic event, an establishment may import allogeneic blood for transfusion that has not been processed in accordance with an authorization if it provides the Minister the required information before the importation, and at the time of each importation. The establishment would also be required to be licensed to import blood.

Quality management system

To maximize the safety, efficacy or quality of blood or blood components, all licensed and registered establishments that process, transform or import blood or blood components would be required to have a quality management system that is an integrated system of quality assurance.

The proposed Regulations list the required elements of a quality system, including management functions and organizational structure and the need for periodic reviews of the quality system to ensure its continuing suitability and effectiveness.

All establishments, including hospitals that only store blood or blood components for transfusion, would be required to meet the provisions related to operating procedures for all regulated activities they perform, including provisions related to personnel, facilities, equipment, supplies, and computer systems. In addition, they would be required to maintain the records referred to in the proposed Regulations, use validated storage equipment that can maintain appropriate storage conditions, and meet the investigation and reporting requirements related to errors and accidents, adverse donor reactions, and adverse recipient reactions.

Errors and accidents

An establishment that has reasonable grounds to believe that an error or accident has occurred which could adversely affect the safety, efficacy or quality of blood or blood components, or the safety of the donor or recipient, would be required to do the following: determine the nature and scope of the error or accident; identify and quarantine all the implicated blood or blood components in its possession; and notify the establishment from which it received the implicated blood or its components, the collecting establishment, and any establishment to which it may have distributed implicated blood or blood components.

On receipt of a notice of an error or accident which could adversely affect the safety, efficacy or quality of blood or blood components, or the safety of the donor or recipient, the establishment would be required to initiate an investigation into the suspected error or accident if it determines that the error or accident occurred during an activity that it conducted. Within 24 hours after the start of such an investigation into an error or accident that is identified after the blood has been distributed or transfused, the investigating establishment would be required to notify the Minister in writing of the suspected cause of any serious error or accident if there is reasonable probability that the serious error or accident could lead to a serious adverse transfusion reaction. A written report would be required within 15 days after the start of the investigation, followed by a written update of the steps taken in the investigation every 15 days after that, until the final report is made.

Adverse donor reactions

An establishment that has reasonable grounds to believe that a donor has experienced an unexpected adverse reaction or a serious adverse reaction during or within 72 hours after the blood collection would be required to investigate and to notify the Minister. The proposed Regulations would require that the notice be made within 24 hours of the reaction in the case of a fatality, and within 15 days of the reaction in any other case. In the case of a verbal notice, the establishment would have to follow up as soon as possible with a written report including a description of the reaction, the corrective actions taken to address the reaction and the final outcome. The proposed Regulations would further specify the information required in the report to the Minister as well as the timing of the report, and describe follow-up actions to be taken by the establishment that processed the blood that is the subject of the investigation.

Adverse recipient reactions

The proposed Regulations would require that when a recipient experiences an unexpected adverse reaction or a serious adverse reaction, the reaction be investigated and reported to the Minister within 24 hours after the establishment becomes aware of the reaction in the case of a fatality and within 15 days after the establishment becomes aware of the reaction in any other case. In either case, if the report is made verbally, a written report must be provided as soon as possible after the verbal notice. The proposed Regulations further specify the information to be included in the final and annual summary reports to the Minister. In addition, the establishment that processed the blood that is the subject of the investigation would be required to notify all establishments to which it distributed the implicated blood of the result of the investigation.

Records

Establishments would be required to maintain records that are accurate, complete, legible, indelible and readily retrievable and are stored in a location that has appropriate environmental conditions and is secure against unauthorized entry. The proposed Regulations further require that the record keeping system be structured so that with the donor identification code or with the blood's donation code, the establishment can identify the donor and retrieve sufficient records to permit the recovery or recall of all distributed blood or blood components.

The proposed Regulations specify the retention period for records, requiring that records related to critical activities that could impact the safety, quality or efficacy of the blood be retained for 50 years, and records of less critical activities be retained for 10 years. All records related to autologous donations would be required to be retained for at least 10 years.

Transitional provisions and coming into force

Since these proposed Regulations would come into force one year after the day on which they are published in Part Ⅱ of the *Canada Gazette*, provisions are included that would allow establishments to continue to perform their activities while they update their processes in order to comply with the proposed regulatory requirements. During the one-year period, oversight of currently licensed blood operators/manufacturers would continue under the existing FDR.

Establishments that have previously filed sufficient safety and effectiveness information acceptable to the Minister under sections C.01A.005 to C.01A.007 and C.01A.014 of the FDR would be deemed to have an authorization under section 7 of the Regulations. Similarly, establishments that already hold an EL issued under section C.01A.008 of the FDR would be able to continue to operate until a new EL is issued under the Regulations provided that the establishment applies for an EL within three months after the Regulations come into force. In the meantime, any licence issued under the FDR would continue to be valid until an EL is issued or refused under section 19 of the Regulations.

In addition, establishments that are already performing any of the activities that require a registration, such as processing autologous blood and transformation activities, or that have pre-assessed donor programs, could continue these activities provided that they submit an application for a registration under section 29 of the Regulations within three months after the Regulations come into force.

International perspective

The proposed Regulations align well with the blood regulatory requirements, guidelines and policies of the United States, the European Union, the United Kingdom and Australia, including the overall approach of protecting the health of blood donors and recipients through oversight of the donor suitability assessment, collection, testing, storage, and distribution of blood and its components. Similarity with these international regulatory frameworks provides confidence that blood and its components from these countries meet the same high safety standards set by the proposed Canadian blood regulations.

These proposed Regulations compare with international regulatory frameworks in the following ways:

- Referencing sections of the CAN/CSA-Z902, *Blood and blood components* similar to Australia's standards-based regulatory framework;
- The United Kingdom regulatory system of authorization for the collection and testing of blood;
- Compliance and enforcement requirements, including licensure and inspections, in the United States, the European Union and Australia;
- The United States' adverse reaction reporting requirements; and
- Good Manufacturing Practices (GMP) requirements in the United States and the European Union align with the quality management system requirements included in the proposed Regulations.

In addition to requiring an EL under these proposed Regulations, establishments that import blood for transfusion would also have to obtain an authorization unless the blood is already the subject of another establishment's authorization. The proposed Regulations describe requirements for the importation of blood and its components for transfusion in the case of an emergency where no blood is available in Canada. In addition, the Canadian importer would have to apply for and obtain an EL for importation demonstrating that the blood is manufactured to meet the same high safety, quality and efficacy standards as any blood collected in Canada.

These proposed Canadian Regulations would not apply to the importation of blood and blood components into Canada for further manufacture — rather the requirements of Division 1A of the FDR would continue to apply to those products.

Regulatory and non-regulatory options considered

The options outlined below provide an overview of the alternatives that were considered.

Option 1: Leaving the existing Regulations in place (maintain the status quo)

The status quo is not considered to be a viable option. The existing regulatory requirements are located in multiple divisions of the FDR, namely, Division 1A, Division 2 and Division 4.

Since the current regulatory requirements were intended to apply to pharmaceuticals, it is not immediately clear how they apply to blood since they are not specific for blood. The current regulatory requirements are being applied only to the blood operators/manufacturers that handle blood, despite the fact that some hospital blood banks perform some of the same activities. For these reasons, this option would not address the Krever report's recommendations to consolidate all requirements related to blood, and provide regulatory oversight over all establishments that handle blood.

The new regulatory framework for blood and its components would apply to all establishments performing any of the regulated activities, and consolidate and clarify the requirements specific to blood and its components for the regulated establishments.

Option 2: Amend the existing Regulations to include requirements specific for blood and blood components

Amending the existing Regulations is not considered to be a viable option. The scope of the existing Regulations applies to all drugs, including pharmaceuticals and biological drugs. Amending the existing Regulations would mean that stakeholders would still be required to consult multiple divisions in the FDR to determine what requirements apply to them. In addition, adding specific requirements to the existing divisions would greatly complicate the Regulations so as to make them difficult to understand for the regulated establishments. In addition, this option would not address the Krever report's recommendation to provide regulatory oversight over all establishments that handle blood.

Option 3: Develop new regulations specific for blood and blood components

The development of new regulations specific for blood or blood components was considered the best option. The objectives of the new regulatory framework include outlining clear and intelligible requirements; allowing for timely updating of the requirements as new technologies/products/issues emerge; and achieving greater harmonization in Canada related to the collection, handling and post-market surveillance of blood and blood components. To achieve this harmonization and avoid duplication, the existing regulatory requirements for plasma collected by plasmapheresis (found in sections C.04.400 to C.04.423 of the FDR) would be merged into the proposed Regulations so that all the requirements for whole blood and other blood components collected for transfusion or further manufacturing would be consolidated.

One of the elements of this regulatory framework was the development of safety standards for blood and blood components. The blood standards were developed following extensive collaboration with experts in the field of haematology, the blood establishments and federal and

provincial government stakeholders. The blood standards are aimed at maintaining and enhancing the quality and safety of blood collection, testing, labelling, storage and transfusion. Establishments collecting/handling blood or blood components can obtain a copy of the blood standards, which have been published and are available for purchase from the CSA.

With the proposed, specific Regulations, Health Canada would be better able to fulfil its mandate of protecting the health and safety of Canadians who donate or receive blood or blood components.

Benefits and costs

Costs and benefits for the national blood standards

A cost-benefit analysis was completed in 2003 to assess the impact of the implementation of the blood standards on establishments, governments and consumers. Establishments were asked to quantify the gaps between their current practices and what the blood standards prescribe in the following categories: building, testing, personnel, equipment, computerization/record keeping/reporting, and audits, training and developing standards of practice. The costs were broken into initial and ongoing costs to recognize that some costs would be recurring and some would not. The analysis estimated that the level of benefits for meeting the requirements of the blood standard over the next 20 years would range between $3.3 and $4.4 billion (at 8% discount rate). This greatly exceeds the total costs estimated at $438.55 million over the same period (discounted at 8%).

However, the scope of the blood standards is significantly broader than that of the sections of the standards being referenced in these proposed Regulations — specifically sections related to activities that are within federal jurisdiction such as processing of autologous blood, transformation activities, and pre-assessed donor programs. During the development of the blood standards, key stakeholders such as the blood operators and representatives of the provincial/territorial governments, committed to adopting the blood standards. It is therefore expected that these establishments would have already undertaken the efforts required to comply with the blood standards, and that these establishments would only experience relatively minor costs associated with maintaining their already updated processes.

Costs and benefits for the proposed Regulations

Estimated costs

The proposed Regulations serve to codify the safety requirements described in the blood standards which were first published by the CSA in 2004 and recently updated in 2010. Since the key stakeholders committed to adopting the safety requirements in the blood standards, the regulated establishments would not experience any further costs as a result of the publication of the proposed Regulations. It is therefore expected that establishments would today only experience the costs associated with maintaining their already updated processes.

The proposed Regulations would introduce a novel registration scheme for establishments that perform autologous blood collection, transformation activities or have pre-assessed donor programs, which includes both the blood operators and some hospital blood banks. To obtain a registration, establishments would be required to complete and submit an application form within three months of the final Regulations coming into force. There would be no fee associated with the registration process, so the only negligible cost would result from the short time taken to complete and submit the form.

Estimated benefits

The objective of the proposed Regulations is to make official and codify the improvements in blood safety resulting from establishments adopting the blood standards. Benefits from implementing the proposed Regulations would also accrue from greater clarity and consistency in safety procedures performed by all establishments across the country, thus strengthening Health Canada’s legislative authority to continue to monitor the safety of processes carried out in all

establishments that handle blood and blood components. Clearer regulatory requirements consolidated within the proposed Regulations would provide the necessary flexibility for the blood system to meet the challenges of the future, which would benefit the regulated establishments, the regulator and the Canadian public.

Based on the analysis above, Health Canada has concluded that implementing the proposed Regulations would have a positive net benefit. A comparison of the costs and benefits for each stakeholder group follows.

1. Blood operators/manufacturers

Costs

- There would be no fee attached to the application process for an authorization, an EL or a registration.
- Blood operators/manufacturers that process allogeneic blood would require time to prepare and submit the paperwork associated with an application for an authorization and an EL required in the proposed Regulations. There would be no additional costs since the licensing scheme in the proposed Regulations is similar to that in the current Regulations.
- Blood operators that process autologous blood, have pre-assessed donor programs or perform blood transformation activities would need to maintain their quality system, submit an application for a registration, update their information as it changes, and annually re-certify their continued compliance with the proposed Regulations.

Benefits

- There would be a transition period during which establishments may continue to perform their activities while they apply for an EL or a registration.
- These proposed Regulations would clarify and consolidate the current requirements for the blood operators/manufacturers, while not placing additional regulatory burdens on these establishments.
- Elimination of the current requirement for annual renewal of EL should greatly reduce the paperwork burden on blood operators/manufacturers without adversely affecting the safety or quality of blood or blood components. The safety of the donors and the quality and safety of blood and blood components would not be compromised in meeting the needs of blood operators.

2. Hospital blood banks

Costs

- There would be no costs associated with obtaining a registration.
- Hospital blood banks that process autologous blood, perform blood transformation activities, or that have pre-assessed donor programs would need to implement a quality management system, submit an application for a registration, update their information as it changes, and annually re-certify their continued compliance with the proposed Regulations.
- The proposed Regulations would formalize the current practice of investigating adverse reactions and errors and accidents, and report those that are “serious” to Health Canada.

Benefits

- There would be a transition period during which hospital blood banks may continue to perform their activities while they apply for a registration, if required.
- Implementation of a quality system at hospital blood banks that process autologous blood, perform blood transformation activities, or that have pre-assessed donor programs can be expected to result in continuously improving processes in these establishments.
- Referencing the blood standards in the proposed Regulations for activities performed at hospital blood banks related to processing of autologous blood, blood transformation activities, or those related to pre-assessed donor programs would make those requirements

in the voluntary standard into law, thus resulting in consistent safety practices across the country.
- Standardized storage and handling requirements for blood and blood components would maximize the safety, efficacy and quality of the blood throughout the distribution chain.

3. Canadian public (donors and recipients)

Costs

- The public would not pay a direct cost for the investments some establishments may be required to make in order to comply with the proposed Regulations.

Benefits

- Standardization of blood safety requirements across the country may further improve the already high level of public confidence in the safety of the blood system, potentially resulting in greater numbers of Canadians willing to become blood donors.

- The benefit to blood and blood component donors is the confirmation in Regulations of current requirements that must be met by establishments to protect donors' health and safety. The health and safety of donors is a major concern for Health Canada, since there cannot be a national blood system without healthy dedicated donors.

- The benefit to the patient receiving blood and blood components from a donor pool that is protected by clear regulatory requirements with respect to volume limits, donor safety and transmissible disease testing is that there is a greater likelihood of a safer product when the donor pool is stable and consistent.

- Blood safety requirements would be standardized across Canada, and across the supply chain, from the blood operator to the end user.

- The proposed Regulations would clarify Health Canada's legal authority to take compliance and enforcement action in the best interests of the Canadian public, should the need arise.

4. Health Canada

Costs

Health Canada would require additional time to review and approve the new authorization, EL and registration submissions and inspect establishments under the proposed Regulations. These applications, amendments and ongoing compliance and enforcement activities would be managed with existing resources at Health Canada.

Benefits

- Clear and consistent requirements would simplify Health Canada's oversight of all establishments under the proposed Regulations.
- The transition period provided during which establishments may continue to perform their activities while they apply for an EL or a registration would allow Health Canada the time necessary to process the applications and issue the ELs and registrations.
- The proposed Regulations provide the Department's final response to recommendations in the Krever report.
- The proposed Regulations would clarify Health Canada's legal authority to take compliance and enforcement action, should the need arise.

An analysis of the costs and benefits associated with the implementation of the blood standards is available upon request.

Rationale

The cost-benefit analysis conducted in 2003 estimated that the benefits of implementing the blood standards would greatly outweigh the associated costs. With the publication of the blood standards in 2004, key stakeholders committed to adopting the blood standards and have since aligned their processes with those described in the standards. Thus the baseline for this regulatory initiative is a blood system that has been improved and is safe. The proposed Regulations serve to codify the current best practices described in the blood standards, clarifying the regulatory requirements so that the blood system remains flexible enough to cope with future technological developments and challenges, and continues to be one of the safest systems in the world. As a result of having already adopted the blood standards, Health Canada has determined that the cost-benefit ratio associated with establishments implementing the proposed Regulations would be similarly favourable to that estimated for the implementation of the blood standards.

Canada's proposed stand-alone blood regulations compare well with international regulatory authorities that have separate regulations for blood and blood components, and have included hospital blood banks in their regulatory frameworks. Furthermore, the proposed Regulations specific for blood and blood components address Justice Krever's recommendations, which were the main drivers for the development of these proposed Regulations. Despite some concerns of possible overlap of some provincial requirements for hospitals, stakeholders are supportive of having separate regulations that take into consideration blood and blood components' unique characteristics since it would clarify the requirements for both stakeholders and the regulator.

Consultation

Over the past decade, stakeholders have been given the opportunity to provide input on these developing regulations through a series of public consultations and communication activities across Canada.

Informing stakeholders

As part of Health Canada's renewal process in 1994, the Blood Regulatory Renewal Project was launched to enhance the blood regulatory framework. In addition, the establishment of the External Advisory Committee on the Blood Regulations (EAC-BR) in 1997 allowed Health Canada to take advantage of the knowledge of external experts in the field of hematology, transfusion medicine, infectious diseases, nursing and ethics, as well as of former provincial and territorial medical officers of health and community and patient groups, in identifying emerging diseases and technological advances that could impact the safety, quality or efficacy of blood and its components.

In November 2001, Health Canada published an information kit titled "Toward a Renewed Regulatory Framework for Whole Blood and Blood Components Intended for Transfusion." The information kit clearly detailed Health Canada's proposal for new Blood Regulations under the FDA to be based on the safety requirements listed in the national blood standards and to include surveillance and adverse-reaction reporting components, as well as a compliance monitoring and enforcement strategy.

The information kit also explained that the CSA's process for developing national standards requires public review. To fulfill this requirement, copies of the draft blood standards were sent to provincial and territorial representatives, blood operators, hospital blood banks, hospitals and all individuals who had expressed a desire to comment on the draft. Over 1 000 comments were received through the public review process and were referred to the CSA Technical Committee for consideration. The national standards have now met the requirements of the Standards Council of Canada. Namely, they were drafted through a consensus-development process, and extensive opportunity has been afforded to Canadians to express their opinions or concerns about these new national blood standards. The blood standards were first published in 2004 by the CSA and were recently updated in March 2010.

The information kit was sent to all known establishments and interested individuals, providing information on the progress of the development of the blood standards. The extensive public

consultation process on the blood standards offered an opportunity for Canadians to express their opinions or concerns, and was considered sufficient to move forward with the Regulations.

On July 26, 2004, a letter and a question and answer document on the development of a renewed regulatory framework for whole blood and blood components were sent to stakeholders and posted on Health Canada's Web site. This step was followed by an update to inform stakeholders on the progress of the developing blood regulatory framework, which was made available online on August 23, 2006, as "Advance Notice — Update on the Development of a Regulatory Framework for Whole Blood and Blood Components."

A series of meetings was held across Canada with provincial and territorial government representatives in the fall of 2006 and into early 2007 to present the proposal for a new framework and to solicit their input. These face-to-face meetings were held in Toronto, Winnipeg, Regina, Edmonton, Vancouver, Québec, Halifax, Whitehorse, Yellowknife and Iqaluit. These consultations were complemented by broad, online stakeholder consultation on the proposed new regulatory framework for blood and blood components conducted from May to June 2007.

During the course of these consultations, provincial and territorial government representatives indicated that the goals of the regulatory framework are realistic and consistent with what hospitals have been achieving through their own initiatives, and that the governments support the need for national regulations for blood and blood components. Hospital blood bank representatives expressed concerns regarding the potential impact of storage and transportation on the safety of blood and blood components, which were recognized and would be addressed by specific requirements in the proposed Regulations. Concerns were also expressed related to the potential duplication of reporting, accreditation and inspection activities currently performed in hospitals by other levels of government. However, Health Canada will continue to clarify that while the proposed Regulations may have some similar requirements to those of provincial or accreditation agencies, the focus of the Regulation remains the safety of blood and blood components. This focus will continue to be communicated to stakeholders as the proposed Regulations are finalized. A detailed summary of these consultations was published in October 2007, and the consultation report can be found at www. hc-sc.gc.ca/dhp-mps/pubs/biolog/2007-consult-blood-sang/indexeng.php.

The latest update to stakeholders on the blood regulatory framework, titled "Notice to Stakeholders — Update — Upcoming Blood Regulations and the CSA National Blood Standards" was sent on May 10, 2011, and is available at www.hc-sc.gc.ca/dhp-mps/brgtherap/reg-init/blood-sang/blood_notice-sang_avis-eng.php.

Plasmapheresis Regulations

The need to update and harmonize the existing provisions respecting Human Plasma Collected by Plasmapheresis (Plasmapheresis Regulations), located in Part C, Division 4, of the *Food and Drug Regulations*, was identified as a priority sub-project of the Blood Regulatory Project in April of 1995, at which point the process for identifying and analyzing the necessary changes and drafting the proposed amendments was initiated.

On April 27, 2002, a notice of intent was published in the *Canada Gazette*, Part Ⅰ, informing stakeholders of Health Canada's intent to amend the existing Plasmapheresis Regulations as a part of its response to Justice Krever's report on the status of Canada's blood supply. During the 60-day comment period, only four responses were received, which were taken into consideration in the development of the regulatory amendments.

The proposed amendments to the Plasmapheresis Regulations were pre-published in the *Canada Gazette*, Part Ⅰ, on September 3, 2005. The responses to the comments received following the 75-day comment period on the proposed amendments were published with the final Regulations in the *Canada Gazette*, Part Ⅱ, on December 27, 2006. Further consultation with stakeholders occurred during the development of the associated guidance document *Human Plasma Collected by Plasmapheresis*. Comments and suggestions received from the consultation on the draft version of the guidance document were reviewed and considered in the finalization of this document, released in February 2008.

Recent information-sharing activities

Two presentations were made at the annual Canadian Society for Transfusion Medicine (CSTM) Conference, in June of 2009 and in May of 2011, to inform stakeholders regarding the ongoing development of the *Blood Regulations*. The CSTM is the largest gathering of transfusion medicine specialists and includes the blood operators and the Canadian Transfusion Medicine Laboratories.

A notice to stakeholders was sent and posted on the Health Canada Web site in April of 2011 to inform stakeholders of the intent to publish the proposed Regulations in the *Canada Gazette*, Part I, in the fall. In addition, in July of 2011, an update on the development of the proposed *Blood Regulations* was published in the Ontario Accreditation Newsletter, which reaches the Ontario Laboratory Accreditation members.

In summary, the consultation mechanisms employed in the development of the proposed Regulations have permitted extensive opportunity for stakeholder engagement and feedback. As the regulatory framework for blood and blood components evolves, Health Canada continues to communicate both in writing and in face-to-face meetings with provincial and territorial government representatives, blood operators and hospital representatives to discuss the impact of the proposed Regulations on their jurisdictions and operations. These key stakeholders have been very involved throughout the development of the blood standards, and both welcome and support the clarity and flexibility that the proposed regulatory framework would provide.

Implementation, enforcement and service standards

These proposed Regulations do not alter existing compliance provisions under the FDA. Compliance and enforcement measures for all establishments performing any of the regulated activities include compliance verification for cause, and existing enforcement options available under the Act. This practice would continue under the proposed Regulations.

For establishments that collect allogeneic blood and blood components, test or import allogeneic blood, an inspection may be required prior to the issuance of an EL and on an ongoing basis. The inspection verifies compliance with all the requirements in the Regulations.

Compliance and enforcement options also include Health Canada inspections for establishments that only process autologous blood, have pre-assessed donor programs or perform transformation activities. In addition to these establishments being registered, they would be inspected on a priority basis according to specific criteria such as the risk level of the activities that they perform as well as their compliance history.

Hospitals performing the lowest risk activities — storage and transportation of blood and blood components for transfusion — would not need to register. Rather, these establishments may be inspected for cause or on a priority system based on the risk associated with the activities that they perform.

Performance measurement and evaluation

Because this initiative is largely a consolidation of existing regulatory requirements that apply to blood and is expected to have little impact on the blood system, the evaluation would focus on whether all establishments in Canada that handle blood for transfusion or for future manufacturing are being regulated and whether mandatory reporting of errors, accidents and adverse reactions is effective in identifying serious cases of interest to the regulator. Ongoing attention would be paid to the identification of situations within the blood system that could be unintended consequences related to the proposed Regulations.

Evaluating whether the initiative has been successful in regulating all establishments that handle blood intended for transfusion or further manufacturing has two components. The first relates to determining whether all establishments that perform activities that require an authorization, an EL or a registration under the proposed Regulations have been identified and issued the appropriate paperwork. The second relates to determining whether regulatory requirements are adequately understood by all the regulated establishments, including hospitals that would not require a

registration, but must still comply with the requirements for storage, record keeping, and the investigation of error and accident and adverse reaction, and reporting those that are considered serious.

To evaluate whether all establishments that process or transform blood or that have pre-assessed donor programs are being regulated, the ratios for actual and anticipated authorization, licensing and registration would be measured immediately following the end of the implementation period to determine whether these establishments have been captured in the authorization, licensing and registration system. This data would be readily available from the Health Products and Food Branch Inspectorate, and Health Canada expects that all establishments that should be captured by the proposed Regulations would be identified and aware of their responsibilities to meet the regulatory requirements following implementation efforts.

To evaluate whether the Regulations are adequately understood, inquiry, inspection and/or compliance data would be assessed following the implementation period to determine whether there are any trends associated with non-compliance that might suggest that sections of the Regulations are not understood by all or particular groups of regulated parties. The evaluators do not expect to find any such trends or unclear sections.

To evaluate the effectiveness of mandatory reporting of errors, accidents and adverse reactions, the number of these reports received following publication of the proposed Regulations would be compared to the baseline of those received prior to the coming into force of the proposed Regulations. Analysis of this data would take place annually, beginning one year after the final Regulations come into force. The expectation is an initial increase in reporting, followed by a decline as reporting requirements are fully understood and then a levelling off.

Environmental scanning would be ongoing to identify any issues or situations within the blood system that could be unintended consequences of this initiative.

Contact

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PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to section 30 (see footnote a) of the *Food and Drugs Act* (see footnote b), proposes to make the annexed *Blood Regulations*.

Interested persons may make representations concerning the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice and be addressed to Liz Anne Gillham-Eisen, Unit Manager, Office of Policy and International Collaboration, Director General's Office, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Department of Health, Address Locator: 0702B, Health Protection Building, 200 Tunney's Pasture Driveway, Ottawa, Ontario K1A 0K9 (fax: 613-952-5364; email: bgtd.opic@hc-sc.gc.ca).

Ottawa, March 1, 2012

JURICA ČAPKUN
Assistant Clerk of the Privy Council

BLOOD REGULATIONS

INTERPRETATION

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 the safety of a donor or recipient or the safety, quality or efficacy 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 transfused blood.

"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 the purpose of transfusion to the same individual at a later time.

"blood"
« *sang* »

"blood" means human blood, and includes blood components.

"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, software, supplies and services, means that the equipment, software, supply or service could, if it does not meet its specifications, compromise the safety of donors or recipients or the safety, quality or efficacy of blood.

"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 selected by the recipient.

"distribute"
« *distribution* »

"distribute" does not include to transfuse.

"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.

"error"
« *manquement* »

"error" means a deviation from the operating procedures or applicable laws that could compromise the safety of a donor or recipient or the safety, quality or efficacy 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.

"executive manager"
« *dirigeant* »

"executive manager", in respect of an establishment, means the individual who has the authority to implement the quality management system in the establishment.

"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"
« *procédure d'opération* »

"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 and procedures 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 89 to 94 from whom blood is taken in an emergency and is transfused before completion of the testing.

"processing"
« *traitement* »

"processing" means any of the following activities:

(*a*) donor suitability assessment;

(*b*) collection;

(*c*) testing; and

(*d*) blood component preparation.

"scientific director"
« *directeur scientifique* »

"scientific director", in respect of an establishment, means the individual who is responsible for all technical procedures carried out by the establishment and for the application of the operating procedures that relate to them.

"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.

"source plasma"
« *plasma destiné au fractionnement* »

"source plasma" means plasma that is collected by plasmapheresis and that is used in the manufacture of a drug for human use.

"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.

"transformation"
« *transformation* »

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

"transfusion"
« *transfusion* »

"transfusion", in respect of the administration of blood, includes by injection.

"unexpected adverse reaction"
« *effet indésirable imprévu* »

"unexpected adverse reaction" means an adverse reaction that is not identified among the possible adverse reactions in the circular of information.

APPLICATION

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.

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*;

(*c*) blood that is imported for use in the manufacture of a drug for human use; and

(*d*) blood that is of a rare phenotype and that is imported pursuant to a prescription.

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.

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.

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 95, allogeneic blood that has not been processed in accordance with an authorization; and

(*b*) distribute or transfuse such blood if it is imported in accordance with section 95.

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 89 to 94.

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.

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 or serious adverse reaction are inconclusive or show that there has been a compromise to the safety, quality or efficacy of the blood.

AUTHORIZATIONS, ESTABLISHMENT LICENCES AND REGISTRATIONS

AUTHORIZATIONS

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 95, an establishment that imports blood for transfusion must have an authorization to do so, unless the blood is already the subject of another establishment's 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 the executive manager and contain all of the following information:

(*a*) the applicant's name and civic address, and its postal address if different, and if the establishment has more than one location, the civic address of each building in which it proposes to conduct its activities;

(*b*) the name, telephone number, fax number and email address 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 list of the blood and blood components that the establishment proposes to process or import;

(*e*) a list of the activities that are proposed to be conducted in each building;

(*f*) a detailed description of the establishment's facilities, including its buildings and all critical equipment, software, supplies and services that it proposes to use in the conduct of its activities;

(*g*) a detailed description of the processes and procedures 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;

(*h*) a draft of each proposed label and circular of information;

(*i*) evidence that any foreign establishment that it proposes to have conduct any of its processing activities is licensed in the foreign jurisdiction; and

(*j*) sufficient evidence to demonstrate that the proposed processes and procedures will not compromise the safety of donors or recipients and will result in blood that can be determined safe for distribution, of good quality and efficacious.

Site inspection

(2) During the review of an application, the Minister may carry out an inspection at 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, blood and blood samples that the Minister determines are necessary to complete the Minister's review of the application, by the date specified in the request.

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 is satisfied that the establishment has provided sufficient evidence to demonstrate that issuance of the authorization will not compromise the safety of donors or recipients or the safety, quality or efficacy of blood.

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.

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 the safety of donors or recipients or the safety, quality or efficacy 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)(*d*);

(*b*) the deletion of or a change to any authorized process or procedure;

(*c*) the addition of a process or procedure described in paragraph 6(1)(*g*);

(*d*) a change to the description of the establishment's facilities referred to in paragraph 6(1)(*f*); or

(*e*) the addition or deletion of, or a change to, critical equipment, software, supplies or services.

Emergency changes

10. (1) In an emergency, if it becomes necessary 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 the safety of donors or recipients or the safety, quality or efficacy 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 giving that 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.

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 the safety of donors or recipients or the safety, quality or efficacy 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 may, by notice in writing, require the establishment to submit an application to amend its authorization and to cease or reverse the implementation of the change, as the case may be.

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 reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or to the safety, quality or efficacy of blood; or

(*b*) the establishment fails to provide the Minister, on written request, with sufficient evidence to demonstrate that its processes and procedures will not compromise the safety of donors or recipients and will result in blood that can be determined safe for distribution, of good quality and efficacious, 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 in writing 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 reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or the safety, quality or efficacy 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 in writing 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 the safety of donors or recipients or to the safety, quality or efficacy of blood.

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 and procedures will not compromise the safety of donors or recipients and will result in blood that can be determined safe for distribution, of good quality and efficacious, 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 period within which it must be taken; and

(*c*) gives the establishment a reasonable opportunity to be heard in writing 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 reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or the safety, quality or efficacy 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;

(*b*) if applicable, indicates that the establishment must take corrective action and specifies the period within which it must be taken; and

(*c*) gives the establishment a reasonable opportunity to be heard in writing concerning the suspension.

Reinstatement

(5) Subject to subsection (6), the Minister must reinstate the authorization if the establishment provides the Minister with sufficient evidence to demonstrate that its processes and procedures will not compromise the safety of donors or recipients and will result in blood that can be determined safe for distribution, of good quality and efficacious, within the following periods:

(*a*) in the case of a suspension under subsection (1), 90 days after the day on which the suspension is effective; or

(*b*) in the case of a suspension under subsection (3), the period specified in the notice sent under subsection (4).

Partial reinstatement

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

Cancellation

15. (1) The Minister must cancel an authorization in either of the following circumstances:

(*a*) the establishment fails to provide the Minister with the evidence required by subsection 14(5) within the specified period; or

(*b*) the establishment's licence is cancelled under section 27.

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.

ESTABLISHMENT LICENCES

Establishment licence required

16. (1) An establishment that processes allogeneic blood — except, subject to subsection (2), blood from a pre-assessed donor — or that imports blood for transfusion 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.

Application for establishment licence

17. (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 the executive manager 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, telephone number, fax number and email address 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 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 the safety of donors or recipients or the safety, quality or efficacy of blood;

(*k*) in the case of an importer, the information described in paragraphs (*a*) and (*f*) to (*j*) with respect to every foreign establishment that processes or distributes blood that they propose to import; and

(*l*) in the case of an establishment that proposes to import blood in urgent circumstances, all of the information required by subsection 95(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.

Inspection

18. (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 an inspector, on written request, with any information that the inspector determines is necessary to complete the inspection, by the date specified in the request.

Issuance

19. 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 is satisfied that the application provides sufficient evidence to demonstrate that issuance of the licence will not compromise the safety of donors or recipients or the safety, quality or efficacy of blood.

Refusal

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

Changes requiring application to amend licence

21. (1) Before making any change that affects the information provided under any of paragraphs 17(1)(*f*) to (*i*), (*k*) and (*l*), the establishment must, subject to paragraph 22(*b*), file with the Minister an application to amend the licence.

Applications

(2) Sections 17 to 20 apply to an application to amend a licence, with any necessary modifications.

Administrative changes — notice

22. 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 17(1)(*a*) to (*e*); and

(*b*) within 30 days after the cessation of any licensed activity.

Changes requiring amendment of licence by Minister

23. 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 17(1)(*f*) to (*k*);

(*b*) the Minister receives a notice from the establishment under paragraph 22(*a*) concerning a change to the information provided under paragraph 17(1)(*a*);

(*c*) the Minister receives a notice from the establishment under paragraph 22(*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 in its licence application under any of paragraphs 17(1)(*f*) to (*k*).

New or amended terms and conditions

24. (1) The Minister may add terms and conditions to the licence or amend its terms and conditions in either of the following circumstances:

(*a*) the Minister has reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or to the safety, quality or efficacy of blood; or

(*b*) the establishment fails to provide the Minister, on written request, with information that demonstrates 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 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 in writing 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 reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or to the safety, quality or efficacy 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 in writing 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 the safety of donors or recipients or to the safety, quality or efficacy of blood.

Additional information

25. 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.

Suspension

26. (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 17 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 an establishment 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 period within which it must be taken; and

(*c*) gives the establishment a reasonable opportunity to be heard in writing concerning the suspension.

Urgent circumstances

(3) Despite subsection (2), the Minister may immediately suspend all or part of an establishment licence if she or he has reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or to the safety, quality or efficacy 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;

(*b*) if applicable, indicates that the establishment must take corrective action and specifies the period within which it must be taken; and

(*c*) gives the establishment a reasonable opportunity to be heard in writing concerning the suspension.

Reinstatement

(5) Subject to subsections (6) and (7), the Minister must reinstate the licence if the establishment provides the Minister with sufficient evidence to demonstrate that it is in compliance with these Regulations, within the following period:

(*a*) in the case of a suspension under subsection (1), 90 days after the day on which the suspension is effective; or

(*b*) in the case of a suspension under subsection (3), the period specified in the notice sent under subsection (4).

Exception — compliance history

(6) 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

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

Cancellation

27. (1) The Minister must cancel an establishment licence in any of the following circumstances:

(*a*) the establishment notifies the Minister under paragraph 22(*b*) that it has ceased all activities under the licence;

(*b*) the establishment fails to provide the Minister with the evidence required by subsection 26(5) within the specified period;

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

REGISTRATION

Requirement to register

28. Except for an establishment that only tests blood, 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.

Application for registration

29. (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 another name, that other name;

(*c*) the name, telephone number, fax number and email address 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 any processing activities that the establishment conducts in respect of autologous blood and a list of the blood or blood components that it processes;

(*f*) a list of any transformation activities that the establishment conducts and a list of all the blood or blood components that it transforms;

(*g*) a statement of whether the establishment has a pre-assessed donor program;

(*h*) the civic address of every building in which it conducts its activities and a list of the activities that are 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 the executive manager, 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.

Registration

30. (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 the safety of donors or recipients or the safety, efficacy or quality of blood.

Changes — notice

31. An establishment must notify the Minister in writing of any change to the information provided under section 29, within 30 days after the change is made, and in the case of a change to the information provided under any of paragraphs 29(1)(*e*) to (*i*), include in the notice another statement described in paragraph 29(1)(*j*).

Amendment by Minister

32. The Minister may amend an establishment's registration to remove from it any activity if she or he has reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or to the safety, quality or efficacy of blood.

Annual statement of compliance

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

Additional information

34. 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.

Cancellation

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

(*a*) the Minister receives a notice under section 31 that the establishment has ceased all of its activities that are the subject of the registration;

(*b*) information provided by the establishment under section 29 proves to be false or misleading;

(*c*) the establishment has not complied with a request for additional information made under section 34;

(*d*) the establishment fails to complete any corrective action within the required period; or

(*e*) the Minister has reason to believe that the establishment is not in compliance with these Regulations or that the safety of donors or recipients or the safety, quality or efficacy 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 period within which it must be taken; and

(*c*) gives the establishment a reasonable opportunity to be heard in writing concerning the cancellation.

Urgent circumstances

(3) Despite subsection (2), the Minister may immediately cancel a registration if she or he has reason to believe that it is necessary to do so to prevent a compromise to the safety of donors or recipients or to the safety, quality or efficacy 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 period within which it must be taken; and

(*c*) gives the establishment a reasonable opportunity to be heard in writing 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.

PROCESSING

DONOR SUITABILITY ASSESSMENT

Non-application — autologous donations

36. Sections 37 to 42 do not apply to an autologous donation.

Licensed establishments

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

Past unsuitability

38. 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.

Donor screening

39. In conducting a donor suitability assessment, an establishment must take all of the following steps:

(*a*) have the donor complete a screening questionnaire to provide information 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;

(*b*) inform the donor of the risks associated with donating blood and of the risks to the recipient of contracting a transmissible disease, and obtain the donor's consent to the donation; and

(*c*) except in the case of a pre-assessed donor, provide the donor with an opportunity to indicate confidentially if they believe that, despite the information that they provided on the screening questionnaire, their blood should not be used.

Exclusion criteria

40. (1) An establishment must determine that a donor is unsuitable to donate if any of the information obtained under sections 37 to 39 indicates that the safety of the donor or recipients or the safety, quality or efficacy of blood could be compromised.

Exception — directed donations

(2) Despite subsection (1), a directed donation may take place even if the criteria for the frequency of donation, hemoglobin level or recent delivery are not met if both the medical director and the recipient's physician agree.

When donor determined unsuitable

41. 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.

When donor determined suitable

42. (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 or quality of donated blood, or

(ii) the donor later 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 and quality 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 or quality of the blood might 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.

COLLECTION

Licensed establishments

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

Donor identification code

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

Donation code

45. 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.

Labelling of containers

46. Subject to section 59, an establishment that collects blood must ensure that sample containers and blood containers are labelled in accordance with sections 63 and 64 at the time of the collection.

Collection procedures

47. An establishment that collects blood must conduct the collection in the following way:

(*a*) use aseptic methods;

(*b*) use blood containers described in section 48;

(*c*) use collection equipment that is licensed under the *Medical Devices Regulations*;

(*d*) use anticoagulants and additives for which a drug identification number has been assigned under the *Food and Drug Regulations*; and

(*e*) record the container lot number in the records and link it to the donation code.

Containers

48. (1) An establishment that collects blood must use blood containers that are

(*a*) licensed under the *Medical Devices Regulations*;

(*b*) capable of inspection of their contents;

(*c*) pre-labelled by the manufacturer with the following information:

(i) the lot number of the container, and

(ii) the name and volume of any anticoagulant or additive in the container and its drug identification number; and

(*d*) free from defects or damage.

Reuse of containers prohibited

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

Samples

49. 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.

Autologous donations

50. An establishment that collects autologous blood must

(*a*) adjust the volume of the blood collected and the volume of anticoagulant based on the donor's weight; and

(*b*) comply with the criteria set out in paragraphs 12.2.1(*a*) (without regard to the reference to "clause 12.5") and (*b*) of the standard.

TESTING

Authorization

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

Autologous donations — testing for transmissible diseases

52. An establishment must test autologous blood using appropriate and effective tests for the diseases and disease agents listed in section 12.3.1.2 of the standard.

ABO and Rh

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

(*a*) the ABO group;

(*b*) the Rh factor, including weak D testing when appropriate; and

(*c*) except in the case of autologous donations, clinically significant antibodies.

Comparison of results

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

Discrepancies

(3) If the comparison performed under subsection (2) indicates a discrepancy, the establishment must repeat the tests and must not distribute or transfuse the blood until the discrepancy is resolved.

Frequency of transmissible disease testing

54. An establishment that collects blood must test a sample of the blood for transmissible diseases and disease agents

(*a*) in the case of an allogeneic donation, at every donation; and

(*b*) in the case of an autologous donation, in accordance with section 12.3.1.2 of the standard.

Licensed diagnostic devices

55. When testing blood, an establishment must use *in vitro* diagnostic devices that are licensed under the *Medical Devices Regulations* for the following purposes:

(*a*) in the case of allogeneic blood, for screening donors; and

(*b*) in the case of autologous blood, either for diagnosis or for screening donors.

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 blood from the same donor in the establishment's possession; and

(*c*) notify every person to which it distributed any 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 abnormal test results.

BLOOD COMPONENT PREPARATION

Licensed establishments

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

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.

LABELLING

Non-application — pre-assessed donors

59. Sections 60 to 69 do not apply to the labelling of blood collected from a pre-assessed donor.

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.

General requirements

61. Labels must meet all of the following requirements:

(*a*) all information on the label must be accurate and must be presented clearly and legibly;

(*b*) all information on the label that is in machine-readable code must also appear in text;

(*c*) labels must be formulated using only adhesives and inks that will not permeate the container;

(*d*) labels must be permanently affixed to the container; and

(*e*) any tags must be firmly attached to the container.

Circular of information

62. 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.

Same individual to label

63. An establishment that collects blood must ensure that the same individual labels the primary container, the sample containers and any secondary containers at the time of the collection.

Donation code

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

Contents of label

65. (1) An establishment that collects blood 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 there is one, or its registration number;

(*c*) the donation code;

(*d*) whether the donation is whole blood or a blood component, and if it is a component, its name;

(*e*) the ABO group of the blood and, when appropriate, its Rh factor;

(*f*) except in the case of apheresis, the approximate volume of the whole blood collection;

(*g*) the approximate volume of the contents of the container;

(*h*) the name of any anticoagulant or additive in the container;

(*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 may transmit infectious agents; and

(*l*) in the case of allogeneic blood for transfusion, a direction to refer to the circular of information for indications, contraindications, warnings and a list of possible adverse reactions.

Machine-readable code — allogeneic blood

(2) In addition to the information required by subsection (1), in the case of allogeneic blood for transfusion, the establishment must ensure that all of the following information appears on the label in machine-readable code:

(*a*) the name of the establishment;

(*b*) the donation code;

(*c*) the expression "whole blood" or the name of the blood component; and

(*d*) the ABO group and Rh factor of the blood.

Autologous blood

(3) 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;

(*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; and

(*d*) if known, the name of the intended transfusing establishment.

Recovered plasma

(4) In addition to the information required by subsection (1), in the case of plasma that is derived from a whole blood donation but that will be used in the manufacture of a drug for human use, the establishment must ensure that the collection date and the expression "Recovered plasma" appear on the label.

Source plasma

(5) In addition to the information required by subsection (1), the establishment must ensure that all of the following information appears on the label of source plasma:

(*a*) the expression "Source plasma";

(*b*) the statement "Caution: For Manufacturing Use Only";

(*c*) the name and volume of the anticoagulant added during the collection; and

(*d*) if the donor received specific immunization, the name of the immunogen that was used.

Aliquots

66. Except for purposes of immunization, an establishment that divides blood into aliquots for transfusion must ensure that the labels on the aliquot containers set out all of the following information:

(*a*) the donation code;

(*b*) the name of the blood component;

(*c*) a code that identifies the aliquot;

(*d*) the ABO group of the blood and, when appropriate, its Rh factor; and

(*e*) the expiry date.

Designated donations

67. (1) In addition to the information required by section 65, 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.

Directed donations

68. In addition to the information required by section 65, 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.

Label verification

69. An establishment that labels blood must verify that all of the information that they added to the label is accurate and complete.

STORAGE

Criteria — collecting establishment

70. (1) An establishment that collects blood must store the blood, including during transportation, in accordance with the following:

(*a*) in the case of a licensed establishment, the authorization; and

(*b*) in the case of a registered establishment, the storage, transport and expiration criteria specified in Table 2 of the standard.

Criteria — receiving establishment

(2) An establishment that receives blood from another establishment must store the blood, including during any further transportation, in accordance with the directions on the container.

Platelets

71. An establishment that stores platelets must do so in accordance with section 9.4.6 of the standard.

Storage location

72. An establishment that stores blood must do so in a location that has appropriate environmental conditions that maintain its safety, quality and efficacy and that is secure against the entry of unauthorized persons.

Segregation — autologous, designated and directed donations

73. 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.

Segregation — untested or positive or reactive test results

74. An establishment that stores blood must segregate the following blood from all other blood:

(*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.

Storage during transportation

75. 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.

DISTRIBUTION

Determination of safety — allogeneic blood

76. (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, of good quality and efficacious if 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 if the establishment is satisfied that the blood has been processed in accordance with these Regulations.

Verification

77. (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 factors; or

(*d*) there are obvious signs of deterioration or contamination of the blood.

Exception — frozen blood components for transfusion

(3) If frozen blood components show signs of thawing, the establishment may distribute the blood for transfusion if it amends the expiry date in accordance with Table 2 of the standard and relabels the container accordingly.

Exception — frozen blood components for manufacture

(4) If the storage temperature of frozen blood components rises above the authorized temperature, the establishment may distribute the blood for use in the manufacture of a drug for human use if the label is amended to indicate that rise of temperature.

Shipping containers

78. 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, quality and efficacy of the blood.

TRANSFORMATION

Transformation methods

79. An establishment that transforms blood must do so using safe and effective methods.

Anticoagulants and additives

80. An establishment that transforms blood must use anticoagulants and additives for which a drug identification number has been assigned under the *Food and Drug Regulations*.

Washing

81. (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.

Pooling

82. (1) An establishment that pools blood components must do so in accordance with sections 7.11.1, 7.11.3 and 7.11.4 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.

Irradiation

83. An establishment that irradiates blood must do so in accordance with sections 7.12.2 to 7.12.6 of the standard.

EXCEPTIONAL DISTRIBUTION, PRE-ASSESSED DONOR PROGRAMS AND IMPORTATION IN URGENT CIRCUMSTANCES

EXCEPTIONAL DISTRIBUTION

Conditions

84. An establishment may distribute or transfuse allogeneic blood for transfusion for which the test results for 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, of good quality and efficacious is not immediately available; and

(*b*) the recipient's physician, based on their clinical judgment, accepts the use of the blood in the emergency treatment of their patient.

Notice of exceptional distribution

85. (1) A notice of exceptional distribution must be completed in writing as soon as possible after the distribution and must contain all of the following information:

(*a*) the donation code;

(*b*) an indication of whether the blood was whole blood or a blood component, and if it was a component, its name;

(*c*) a list of the test results that were not available at the time of the distribution;

(*d*) the name of the establishment that distributed the blood and the justification for the distribution;

(*e*) the name of the recipient's physician;

(*f*) the name of the establishment where the transfusion is performed; and

(*g*) the date and time of the distribution and the signatures of the recipient's physician and the medical director of the establishment that distributed the blood.

Notice in establishment's records

(2) An establishment that distributes blood under section 84 must keep a copy of the notice of exceptional distribution in its records.

Notice in recipient's file

(3) The recipient's physician must keep a copy of the notice of exceptional distribution in the recipient's file.

Labelling

86. An establishment that distributes blood under section 84 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.

Follow-up

87. An establishment that distributes blood under section 84 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 where the transfusion took place with all of the relevant test results as soon as they become available.

When blood not transfused

88. If blood that is the subject of an exceptional distribution is not transfused into the intended recipient in the emergency, the transfusing establishment must not store the blood or transfuse it into another recipient.

PRE-ASSESSED DONOR PROGRAMS

Program characteristics

89. A pre-assessed donor program of an establishment must have 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, based on their clinical judgment, accepts the use of the blood in the emergency treatment of their patient.

Donor identification code

90. 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.

Regular donor assessment and testing

91. An establishment that has a pre-assessed donor program must take the following steps every three months:

(*a*) assess the suitability of every donor in the program in accordance with sections 38 to 42; and

(*b*) take blood samples from every donor and test them for the transmissible diseases and disease agents listed in sections 8.4.1 and 8.4.2 of the standard.

At each collection

92. 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 from the donor and test it within 72 hours for the transmissible diseases and disease agents listed in sections 8.4.1 and 8.4.2 of the standard.

Labelling

93. 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.

When blood not transfused

94. If blood that is collected from a pre-assessed donor is not transfused into an intended recipient in the emergency, the establishment that collected the blood must comply with the requirements of section 16.2.5 of the standard.

IMPORTATION IN URGENT CIRCUMSTANCES

Information — before importation

95. (1) An establishment may, in urgent circumstances, import allogeneic blood for transfusion 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*), (*g*) and (*i*) 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 required by section 39;

(*d*) a description of the conditions of storage and transportation of the blood that is proposed to be imported, both before and after its importation;

(*e*) a description of how the establishment proposes to identify the blood as having been imported in urgent circumstances; and

(*f*) 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 insufficient allogeneic blood in Canada as a result of a catastrophic event.

QUALITY MANAGEMENT

QUALITY MANAGEMENT SYSTEM

Executive manager

96. (1) A licensed or registered establishment must have an executive manager.

Organizational structure

(2) A licensed or registered establishment must have an organizational structure that sets out the management responsibility for all activities that the establishment conducts.

Separation of functions

(3) The organizational structure must separate the quality management function from all other activities of the establishment.

Requirements

97. (1) A licensed or registered establishment must have a quality management system in place that includes all of the following elements:

(*a*) a quality control program;

(*b*) a change control system;

(*c*) a process control program, within the meaning of section 3.1 of the standard;

(*d*) a system for process improvement through complaint monitoring and the implementation of corrective and preventive actions;

(*e*) 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;

(*f*) a program for the training and competency-evaluation of personnel;

(*g*) a proficiency testing program for the evaluation of the accuracy and reliability of test results;

(*h*) a document control and records management system;

(*i*) an internal audit system;

(*j*) emergency contingency plans;

(*k*) a system that uniquely identifies all critical equipment and supplies;

(*l*) written specifications for all critical equipment, software, supplies and services;

(*m*) a program for the preventive maintenance of critical equipment; and

(*n*) a program for the validation of computer systems that are used in determining the safety, quality and efficacy of blood.

Periodic review

(2) A licensed or registered establishment must review the quality management system at regular intervals that are specified in the operating procedures, to ensure its continuing suitability and effectiveness.

OPERATING PROCEDURES

Operating procedures required

98. An establishment must have operating procedures for all of the activities that it conducts with respect to the safety of donors and recipients and the safety, quality and efficacy of blood.

Requirements

99. The operating procedures must

(*a*) be in a standardized format;

(*b*) be approved by the medical director, scientific director or executive manager, as appropriate;

(*c*) be readily accessible at all locations where the relevant activities are conducted;

(*d*) have any changes to the procedures approved by the medical director, scientific director or executive manager, as appropriate, before being implemented; and

(*e*) be kept up to date.

Documented evidence

100. 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.

PERSONNEL, FACILITIES, EQUIPMENT AND SUPPLIES

Personnel

101. (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.

Facilities

102. 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 appropriate to all areas where its activities are conducted;

(*e*) controlled access to all areas where its activities are conducted; and

(*f*) visual and auditory privacy for donor screening.

Equipment

103. (1) A licensed or registered establishment must use critical equipment that is cleaned and maintained and, as appropriate, qualified 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, requalify and recalibrate the equipment, as appropriate.

Computer systems

(3) Despite subsections (1) and (2), an establishment that uses a critical computer system must

(*a*) validate it for its intended purpose; and

(*b*) revalidate it after any repair or change is made to it that could compromise the safety, quality or efficacy of the blood.

Storage equipment

104. An establishment must use equipment to store blood that enables the establishment to meet the requirements of sections 70 to 72.

Supplies

105. A licensed or registered establishment must use critical supplies that are qualified for their intended use and store them under appropriate environmental conditions.

ERROR AND ACCIDENT INVESTIGATION AND REPORTING

Errors and Accidents

Error or accident of another establishment

106. (1) An establishment that has reasonable grounds to believe that the safety, quality or efficacy 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 reason for the establishment's belief that the safety, quality or efficacy of the blood may have been compromised; and

(*b*) the donation codes of the implicated blood.

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.

Establishment's own error or accident

107. (1) An establishment that receives a notice under subparagraph 106(1)(*c*)(i) or (ii) or suspects that an error or accident that occurred during an activity that it conducted may have compromised the safety, quality or efficacy 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.

Notice of investigation

(2) If the establishment determines that an investigation is warranted, it must 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, quality or efficacy of the implicated blood may have been compromised.

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 and quarantine all implicated blood in its possession.

When no investigation — notice

(4) If the establishment determines that an investigation is not warranted, it must notify the establishment that sent it the notice under subparagraph 106(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

(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.

Written notice

(6) If a notice under this section is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

Investigation and Reporting

Requirement to cooperate

108. (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.

Investigation results

109. (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.

Reports to Minister

110. (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*) within 24 hours after the start of the investigation, a preliminary report that includes all relevant information that is available at that time; and

(*b*) within 15 days after the start of the investigation and every 15 days after that until the final report is made, a written update on any new information about the suspected error or accident, on the progress made in the investigation during those 15 days and on the steps taken to mitigate further risks.

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 or other changes that are recommended to be made to processes or procedures.

Annual report

111. (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 and 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, quality or efficacy 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.

ADVERSE REACTION INVESTIGATION AND REPORTING

Adverse Donor Reactions

Notice to Minister

112. (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 taken to address the adverse reaction; and

(*c*) the outcome.

Written notice

(3) If the notice is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

Adverse Recipient Reactions

Required action

113. (1) Subject to section 114, 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; 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 contain all of the following information:

(*a*) a description of the adverse reaction;

(*b*) an explanation of how the safety, quality or efficacy of the implicated blood may have been compromised, if known;

(*c*) the donation codes of all implicated blood; and

(*d*) the name of any suspected transmissible disease or disease agent, if known.

Action on receipt of notice

(3) An establishment that is notified under paragraph (1)(*c*) or under this subsection must immediately notify to the same effect every establishment and other person to which it distributed implicated blood and take the following actions:

(*a*) quarantine all implicated blood in its possession; and

(*b*) in the case of the establishment that collected the blood, initiate an investigation into the blood.

Written notice

(4) If the notice is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

Autologous donations

114. An establishment that both collects and transfuses the 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 initiate an investigation into the adverse reaction and the implicated blood.

Investigation and Reporting of Adverse Recipient Reactions

Requirement to cooperate

115. 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.

Notice to Minister

116. (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 the notice is given verbally, a confirmatory written notice must be sent as soon as possible afterwards.

Results of investigation

117. (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.

Final report to Minister

118. 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 or other changes that are recommended to be made to processes or procedures.

Annual report

119. At the end of each year, an establishment must file an annual report with the Minister that summarizes all of the final reports filed in the year, including a concise and critical analysis of the investigations that were the subjects of those reports.

RECORDS

Record quality

120. Records kept by an establishment must be accurate, complete, legible, indelible and readily retrievable.

Code part of all records

121. 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.

Records required

122. (1) An establishment set out in column 1 of the table to this section must keep the records set out in column 2 for the period set out in column 3.

Exception — autologous donations

(2) Despite subsection (1), in the case of autologous donations, the retention period for records set out in column 2 is 10 years.

Calculation of record retention period

(3) The record retention period is calculated from the day on which the record is created, except for the personnel records set out in item 25, in which case the period is calculated from the day on which the employee was last employed by the establishment.

TABLE TO SECTION 122

RECORDS AND RETENTION PERIODS

Column 1	Column 2	Column 3
Item Establishment	Records	Retention period

1.	Licensed and registered establishments	Donor suitability assessment	50 years
2.	Licensed and registered establishments	Determinations of donor unsuitability	50 years
3.	Licensed and registered establishments	Collection	50 years
4.	All establishments	Donor identification code	50 years
5.	All establishments	Donation code	50 years
6.	Licensed establishments	Reconciliation of donation codes	10 years
7.	Licensed and registered establishments	Lot number of blood container for each donation and name of container manufacturer	50 years
8.	Licensed and registered establishments	Blood component preparation	10 years
9.	Licensed and registered establishments	Test results for transmissible disease testing and ABO group and Rh factor	50 years
10.	All establishments	Destruction or other disposition of blood	50 years
11.	Registered establishments	Transformation	10 years
12.	All establishments	Temperature monitoring	10 years
13.	All establishments	Distribution	50 years
14.	All establishments	Shipping documents	10 years
15.	All establishments	Exceptional distribution	50 years
16.	Licensed establishments	Importation in urgent circumstances	50 years
17.	Licensed establishments	Post-donation information	10 years

18.	Establishments that transfuse blood	Records that permit identification of the recipient	50 years
19.	Licensed and registered establishments	Complaints and their investigation	10 years
20.	Licensed and registered establishments	Internal audit reports	10 years
21.	Licensed and registered establishments	Quality control testing	10 years
22.	All establishments	Maintenance, qualification and calibration of critical equipment	10 years
23.	All establishments	Records related to critical supplies, including their qualification	10 years
24.	All establishments	Every version of the operating procedures that was implemented	50 years
25.	All establishments	Records related to personnel qualifications, training and competency evaluation	10 years
26.	Licensed establishments	Records related to proficiency testing	10 years
27.	All establishments	Investigations and reports of errors and accidents that are not serious	10 years
28.	All establishments	Investigations and reports of serious errors and accidents	50 years
29.	All establishments	Investigations and reports of serious adverse reactions	50 years
30.	All establishments	Investigations and reports of unexpected adverse reactions	50 years

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.

POWERS OF INSPECTORS

Taking photographs

124. An inspector may, in the administration of these Regulations, take photographs 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.

TRANSITIONAL PROVISIONS

Deemed authorization

125. 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.

Licence continued

126. If an establishment applies for a licence under section 17 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 19 or refused under section 20 of these Regulations.

Delayed registrations

127. (1) An establishment that, before the day on which these Regulations come into force, conducts any of the activities mentioned in section 28 may continue to do so without a registration if it submits an application for registration under section 29 within three months after that day.

Duration

(2) Subsection (1) applies until the determination of the application under section 30.

COMING INTO FORCE

One year after publication

128. (1) These Regulations — except subsections 4(3) to (5) and paragraph 65(1)(*b*) as it applies to registration numbers — come into force one year after the day on which they are published in the *Canada Gazette*, Part Ⅱ.

Subsections 4(3) to (5) and paragraph 65(1)(*b*)

(2) Subsections 4(3) to (5) and paragraph 65(1)(*b*), as it applies to registration numbers, come into force six months after the day on which these Regulations come into force.

[10-1-o]

Footnote a
S.C. 2005, c. 42, s. 2

Footnote b
R.S., c. F-27

NOTICE:
The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

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