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STAKEHOLDER CONSULTATION ON THE PROPOSED REGULATORY FRAMEWORK FOR BLOOD AND BLOOD COMPONENTS

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CONSULTATION REPORT

Policy and Promotion Division
Centre for Policy and Regulatory Affairs
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1.0 OVERVIEW

Health Canada's blood regulatory framework under the *Food and Drugs Act* is being revised as one element of a renewed Canadian blood system. This initiative will address the safety of whole blood and blood components in Canada by developing updated and/or new specific regulatory requirements that reflect current technology and practices by referencing commonly accepted safety standards.

The standards-based approach of the proposed new regulations aims to strike an appropriate balance between prescriptive requirements and the need for performance-based regulations that can adapt to innovation and emerging hazards. This novel approach to regulating will bring significant change and affect most stakeholders.

While updates on this ongoing regulatory initiative have been provided via email and posted on the Health Canada Web site over time, a focussed consultation was necessary to better understand stakeholder interests, the environment they work in, and their thoughts on the development of the proposed Blood Regulations.

2.0 CONSULTATION GOALS

The objectives of the consultation were to:

- share information with stakeholders about the proposed regulations and what upcoming changes may mean to their organizations,
- gather stakeholder input into specific areas of the proposed regulations, and
- identify and address potential challenges to implementation of and compliance with the proposed regulations.

3.0 CONSULTATION APPROACH

Under the new Blood Regulations, hospital blood banks will be federally regulated for the first time. This reality heightened the need for adequate consultation and information sharing and gathering. In recognizing the complexity of Canada's blood system, a three tiered approach to consulting with the broad blood stakeholder population was developed.

The first tier of the consultation involved face to face meetings between the Health Canada policy team working on development of the new regulations and representatives of each province's and territory's blood system to discuss existing provincial regulatory oversight of the blood system, the proposed regulatory framework, and compliance and enforcement approaches.

Tier two of the consultation involved a workbook for broad stakeholder involvement, based on existing analysis and information gathered during the Phase I meetings. Materials included background information on development of the regulatory framework, an overview of the

proposed regulations and targeted questions for input. The broad stakeholder population was invited to complete the Regulatory Workbook.

Tier three of the consultation was a hospital blood bank survey intended to lead to a greater understanding of blood related activities undertaken within a hospital blood bank setting as well as provincial and territorial blood safety initiatives that are currently in place. Stakeholders working in a hospital blood bank were invited to complete the Hospital Blood Bank Survey, with one submission per blood bank.

Based on advice given from a variety of stakeholders and due to the number and distribution of blood banks across Canada, online consultation was felt to be the most efficient and effective way to gather information. Although the consultation itself has closed, the documents can be viewed on the Health Canada Web site at http://www.hc-sc.gc.ca/dhp-mps/consultation/blood-sang/index_e.html/.

While updates on this regulatory initiative have been sent periodically throughout the framework's development, general notice of an upcoming consultation was included more recently. Two weeks prior to the launch of the online consultation, an advance notice email was sent to all blood stakeholders. An additional reminder was sent to all stakeholders the day the online consultation was launched.

From the Health Canada Web site and via emails, stakeholders were informed that they could complete the Regulatory Workbook and/or Hospital Blood Bank Survey online or via fax or email. While all stakeholders were invited to respond to the regulatory workbook, only hospital blood banks were invited to respond to the blood bank survey. Online submissions were captured in a database that was hosted on an external secure server until the six week consultation period was over. Upon conclusion of the consultation period, the data were migrated into a spreadsheet for analysis. Simple counts and percentages form the basis of this analysis.

4.0 MEETINGS WITH PROVINCIAL AND TERRITORIAL REPRESENTATIVES

Throughout March and April, Health Canada's policy team, which includes representatives from Biologics and Genetic Therapies Directorate (BGTD) and Health Products and Food Branch Inspectorate (Inspectorate), met with their provincial regulatory counterparts and experts working within each province's blood system to discuss topics of mutual interest related to the upcoming regulations. Representatives from Health Products and Food Branch's (HPFB) regional offices also attended, as did representatives of the blood operators (Canadian Blood Services (CBS) and Héma-Québec (HQ)). The BGTD policy team, along with regional representatives, met with territorial blood program and government representatives in October and November 2007.

Toronto	March 9
Edmonton	March 13
Regina	March 22
Winnipeg	March 23
Québec City	April 4
Halifax (Atlantic Provinces)	April 19
Vancouver	April 27
Whitehorse	October 24
Yellowknife	October 26
Iqaluit	November

The goals of these meetings were to facilitate common understanding of the blood regulatory environment, learn about blood systems at a hospital blood bank level, and build bridges for longer term working relationships.

4.1 METHOD

Meetings were arranged via contacts identified through the National Blood Portfolio, a committee comprised of representatives from all provinces and territories that work with Canadian Blood Services in the management of their blood systems. Contacts within Québec, which works with Héma-Québec in management of its blood system, were identified via the Health Canada Québec regional office. Health Canada officers from all of the regions played a key role in logistical, outreach and communication aspects of these meetings.

The Health Canada policy team presented overviews of the development of the blood regulations and Health Canada's approach to compliance and enforcement, while the provincial representatives presented information on their blood systems. In recognizing that each province may have different interests and concerns, broad discussion items were not rigidly structured and instead evolved out of the presentation topics.

4.2 FINDINGS

4.2.1 Blood Safety Environment

Canada's blood system is safe and well managed, due in part to safety activities implemented by

provincial and territorial Ministries of Health. All provinces and territories are knowledgeable about *CAN/CSA-Z902 Blood and Blood Components* (CSA Blood Standard) and are in various stages of implementing the standard in their hospital laboratories and blood banks. There was some concern raised in YT that accessibility of the CSA Blood Standard may be a problem as they must be purchased. Some provinces have undertaken a comparison between the CSA Blood Standard and other standards used in their laboratory accreditation systems. Findings from these comparisons will inform Health Canada's approach to laboratory licensing.

Most provinces have laboratory accreditation programs in place with their Colleges of Physicians and Surgeons or provincial Medical Associations that require periodic site visits. YT and NT hospitals have Canadian Council on Health Services Accreditation (CCHSA), which will focus more on laboratories for 2008. Many of the existing provincial accreditation programs include regular self-evaluation throughout their renewal cycles. The four Atlantic Provinces and NU are in discussions with CCHSA about hospital accreditation. By 2008 all Québec hospital laboratories will require CCHSA accreditation.

All provinces and territories are apprehensive about the duplication of effort that may come from the addition of a new licensing process to their current accreditation activities. They would like Health Canada to accept their existing accreditation as part of the blood bank licensing process.

Blood related activities within the provinces and territories vary from hospital to hospital, and are driven by several considerations. Increasing demand for blood and blood components that comes from an aging population and the development of new medical interventions has meant there is a need for conservation within the allogeneic blood supply, with some areas more affected than others. High-risk patients, such as those who test positive for transmissible diseases and/or with compromised health status, have a right to access medical services but may require programs that are outside the mainstream. Geography can also affect blood program decision making in that rural or remote hospitals may not have access to a blood operator or patients may wish to do preoperative donation close to home. While storage and transportation have been considered by Health Canada to be low risk activities, the provinces and territories tend to consider them to be of higher potential risk depending in particular on mode and distance of transport.

The considerations listed above are just a few of the many that provincial and territorial blood program administrators are concerned with. In part they have led to the creation of autologous collection programs in many provinces, and concerns around the regulation of these programs have been raised. If regulatory requirements are more onerous than blood safety and quality require, autologous programs within hospitals may be dropped. As a result, certain high risk patients that CBS/HQ will not or cannot collect from due to geographical or health considerations may face potential difficulties accessing medical treatment when they also cannot be accommodated at their local hospital or the hospital where their surgery will take place. Loss of autologous programs within hospitals may also lead to greater use of the allogeneic system. Some hospitals may not currently meet the voluntary CSA standards for autologous blood collection. Within the territories, only YT has an autologous program; its feasibility will be reviewed in the near future.

4.2.2 Regulatory Approach

Most provinces found the use of risk level as a way of categorising activities to be problematic as all blood related activities present some form of potential risk. Instead, they have proposed the use of priority levels, based on the need for enforcement and oversight that is required of the activity. This suggestion was accepted and used in the online Regulatory Workbook. Some provinces did not see the usefulness of three categories for activities, preferring instead only two.

The territories raised concerns about regulatory requirements for SOPs and QA systems. While they feel that in practice they meet the QA requirements, as they do not have the manpower to document their procedures. To address this potential gap, the territories are looking to adopt the SOPs of large hospitals in the provinces.

Concerns were raised about Health Canada's terminology, with some terms being unclear to provincial stakeholders. Clarification was requested for the following terms: appropriate storage, exceptional distribution, emergency distribution, high and medium risk activities, deviation, labelling. The importance of using terminology consistent with laboratory practice was noted. The question was raised whether Adverse Event Reporting is the same as Critical Incident Reporting, and if so, would the Public Health Agency of Canada's Transfusion Transmitted Injury Surveillance System (TTISS) collect data that will be required under the new regulations, and could it be used? Some provinces have taken part in a pilot phase of TTISS and would like it to be considered for use under the regulations.

4.2.3 Compliance and Enforcement

All provinces have stated a preference for recognition of third party accreditation within the new regulations. They would like evaluation against both provincial and federal requirements to be undertaken during a single visit. Many have suggested that either paper review, report of provincial accreditation/inspection, or attestation be part of Health Canada's licensing approach.

While storage and transportation requirements have been identified as low enforcement priority (low risk) activities by Health Canada, all provinces and territories have indicated that small, remote hospitals may have difficulty meeting storage and transportation requirements, particularly those more than an hour away from a major centre.

The territories expressed some concern with potential enforcement actions associated with the proposed Blood Regulations. It is important that enforcement activities be consistent with those already established within the provinces and territories. For example, we were told that in Manitoba accreditation can be revoked by inspectors from the College of Physicians and Surgeons, however only the Minister of Health can shut down a blood bank.

4.3 CHALLENGES

Apart from the expected challenges to implementing the new Blood Regulations, including the

need for new funding, staffing and employee training, others may come from geography and hospital size. Rural hospitals may not have the resources required to implement the new Blood Regulations, and may also bear an increased burden for storage and transportation of blood and the purchase of any new equipment required. Along with other small hospitals, the size of these hospitals may also present a challenge for similar reasons. While improvements to blood distribution systems may address some of these problems, the improvements themselves may be a challenge. There were also concerns that there may be a lack of quality experts required to make any necessary changes and/or there may be inconsistency in Standard Operating Procedure design across blood bank laboratories within each province.

4.4 COLLABORATION

Several opportunities for collaborating around implementation of the new regulations were identified. Involvement of provincial and territorial leads in the development and dissemination of communication and education materials may help to identify and appropriately address critical learning and information gap areas.

Some provinces have also offered to work with Health Canada to develop a document that outlines whom hospitals are responsible to and for what. This may help to clarify for people working in the blood safety and transfusion field to better understand the regulatory differences between product safety and transfusion safety. Identification of provincial and territorial contact points both within the health care systems and the Ministries of Health would be beneficial to Health Canada.

All provinces have suggested collaboration on an evaluation of provincial accreditation audits for compatibility with federal requirements.

4.5 CRITICAL ELEMENTS FOR SUCCESS

Two critical elements for success were identified.

Education and awareness of all relevant staff (laboratory and nursing) at all levels is essential for successful implementation of and compliance with the new Blood Regulations. Adequate and appropriate educational materials and communication planning are central to this.

The provincial and territorial blood leads must continue to be involved on a meaningful level. This can begin with reporting back to the provinces with consultation findings, and continue with implementing appropriate areas for collaboration.

4.6 SUMMARY

Provincial representatives understand the need for national Blood Regulations, but want to

ensure that they are developed and implemented in a manner that builds on existing blood safety activities and that avoids duplication. They also want to see a set of effective and equitable regulations that does not interfere with patient access to treatment. They wish to be involved in development and implementation of the new Blood Regulations where possible. The working relationships that began with these meetings can be further strengthened through regular communication and collaboration where possible.

5.0 REGULATORY WORKBOOK

Feedback on various aspects of federal regulation of blood in Canada is important in the development of the proposed Blood Regulations. To this end, the Regulatory Workbook was posted on the Health Canada Web site for stakeholder feedback in May/June 2007. The Regulatory Workbook is limited to activities that may impact the safety of blood and blood components and does not consider blood transfusion itself, which is practice of medicine and falls under provincial and territorial jurisdiction.

This section of the Consultation Report presents the opinions of those blood stakeholders who completed and submitted the Regulatory Workbook. Feedback and input received through the workbook will be combined with that from meetings with provincial and territorial representatives and findings from the Hospital Blood Bank Survey.

5.1 METHOD

The Regulatory Workbook provided a comprehensive description of the blood system in Canada and Health Canada's proposed approach to regulating blood. Topics ranged from principles and objectives for developing the proposed Blood Regulations, to specific regulatory requirements and Health Canada's approach to compliance and enforcement. Each section of the workbook was followed by long answer questions where stakeholders could provide feedback and suggestions. A glossary and overview of the proposed regulations were provided as reference documents, and are included here as Appendices A and B. Stakeholders were also given the opportunity to present their questions and asked to evaluate the consultation approach.

Anyone interested in or working within Canada's blood system was invited to read and complete the workbook, particularly those who would have to comply with the new regulations, including hospitals, health institutions and commercial enterprises that undertake federally regulated activities related to whole blood and blood components for transfusion. The workbook could be completed online through a secure server, or stakeholders could print the documents and either fax or email their input to Health Canada.

5.2 FINDINGS

5.2.1 Responses

1700 individual Canadian blood stakeholders were invited to complete the regulatory workbook. Twenty-eight completed workbooks were received by email, fax and through the Health Canada Web site. Hamilton area hospitals and the British Columbia Blood Coordinating Office submitted one response each on behalf of their city or provincial hospitals, respectively, for a total of 110 stakeholders represented. No stakeholders from Québec, Saskatchewan, Yukon, Northwest Territories or Nunavut submitted a completed workbook.

5.2.2 Challenges Facing Canada's Blood System

The regulatory workbook began by describing the blood system in Canada and defining the roles and responsibilities of both federal and provincial/territorial jurisdictions. Blood stakeholders were then asked:

- What are the three biggest challenges that you and your organization face with regard to the blood system?
- Why are they challenges?
- How can these challenges be addressed?

Responses to these questions can be grouped into five key areas, as shown in the table below, and reflect issues under both federal and provincial/territorial jurisdiction.

Access to Adequate Supply
Why? Access to platelets is affected by their short shelf-life and relatively low rates of donation. Access to blood is affected by the waste that occurs due to a lack of transportation standards. Small hospitals have greater access challenges than do large hospitals. Although the Special Access Program (SAP) provides access in some cases, the process is thought to be cumbersome. Blood conservation programs may be a solution to some access challenges, but they are not consistently funded across the country. ***How to address*** While research into the shelf life of platelets was suggested as a place to begin in improving access to platelets, suggested solutions to blood and blood component access challenges were largely administrative and included: shortening mandatory testing time, arranging donor collection times differently, facilitating blood exchanges to limit blood product wastage, and allowing alternatives to SAP. A comprehensive national blood conservation strategy developed by provincial, territorial and federal regulators and that includes adequate financial funding would be useful.
Storage, Transportation and Distribution
Why? This challenge is greater for rural locations. Blood is often needed in locations other than where it is supplied, however modes of transportation are not always reliable due to infrastructure or weather issues. The absence of regulation for moving blood to or between remote sites is seen as unsafe. In addition, rural hospitals often lack appropriate fridges to store blood. ***How to address***

Suggested solutions to this challenge were both administrative and regulatory. Alternative and backup modes of transport could be required. Regulations that dictate who can transport blood may ensure product safety. A national blood conservation strategy was also thought to help address this challenge.

Adequate Human Resources

Why?

Country wide, there is a shortage of healthcare professionals. The difficulty in staffing that comes from this is compounded by staff rotating through sites. Hospitals and labs are already seen to be under-funded and under-staffed.

How to address

Hospitals need to be involved in the development of strategies to address human resource issues and their implementation. Training of new staff begins with reviving those programs of study that were cancelled in past years and increasing the number of seats in existing programs. Scholarships and bursaries may attract more students. Succession planning is important within hospital labs; mentoring opportunities for retiring staff may be useful. It is important that requirements under the new regulations do not over burden the staff currently working in hospital blood banks.

Compliance with Standards and/or Regulations

Why?

There is confusion within the blood system as to what are standards, what are regulations, which takes precedence, and what specifically will be mandatory. Where requirements are clear, such as in the case of requirements for quality management systems, resources simply aren't available. Small hospitals with limited staff and low volume usage will have greater difficulty achieving compliance. There are concerns around the requirement for process changes without regard for a hospital's capacity to accommodate the changes.

How to address

The development and provision of templates for Standard Operating Procedures may enable compliance with minimal burden. The creation of a transfusion medical officer at every institution with sufficient authority to enforce the regulations was suggested, as was the hiring of provincial facilitators and coordinators who would support the implementation of quality programs. Communication between transfusion labs and blood operators as well as within hospitals was thought to help to achieve and maintain compliance.

Education

Why?

There is a general lack of knowledge amongst physician and nursing staff with regard to blood safety procedures, informed consent, regulations and accreditation. There are also challenges to filling out paperwork correctly. These problems may be the result of a lack of training opportunities.

How to address

A uniform set of regulations that is well communicated may help raise the level of knowledge amongst all hospital staff involved in transfusion. Documentation of appropriate nursing procedures and practices may also help. Any education initiatives must be broad, and include all staff involved in transfusion. It is essential that Health Canada communicate the new regulations to lab directors and hospital Chief Executive Officers.

General observations can be made from the responses to this set of questions.

1. Communication between all players in the blood system, from transfusion officers to nurses and physicians, hospital administrators, Health Canada, provincial and territorial Ministries of Health and Canada's blood operators is fundamental to a smooth operating and safe blood system. Health Canada is expected to play a leadership role in communication about the new regulations.
2. Transportation and distribution of blood are seen as a big challenge, or *the* big challenge outside urban centres. Stakeholders want clear standards and regulations for transportation and distribution of blood between sites.
3. Many respondents feel that more resources are needed to achieve compliance with the regulations.
4. Many of the challenges noted are unrelated to federal regulation of blood and blood components, with suggested solutions requiring administrative changes at the provincial/territorial or hospital level.

5.2.3 Proposed Approach to the Blood Regulations

Stakeholders were given detailed information about Health Canada's approach to regulating blood and blood components. This approach is based on the incorporation of the CSA Blood Standard, which is familiar in Canada's blood system, regulatory requirements based on the potential risk to health posed by an activity, and a balance of prescriptive and performance requirements, also based on risk, that allows for flexibility and scientific advancement.

The following questions were presented as follow up to the information presented:

- What do you like about the proposed approach that incorporates the three elements of Standards Based, Risk Based and a Balance of Performance/Prescriptive Requirements, and why?
- What are your concerns about this approach, and how could these be addressed?
- Are there other approaches that we should be considering? Please describe.

Most respondents support the standards and risk based approach because it represents country-wide harmonization within the blood system. Many blood stakeholders are aware of the CSA Blood Standard and feel they will be on familiar ground with the blood regulations. The risk based approach gives peace of mind to stakeholders because higher risk activities will be given a greater level of regulatory oversight.

Several respondents feel all activities are equally important to patient safety and as such should be regulated with the same degree of oversight. There is some fear, however, that some facilities may opt out of certain activities or services either to avoid licensing requirements or because they lack the resources required to achieve compliance. This may lead to broad restructuring of blood program delivery within a region.

While generally speaking respondents like the flexibility seen in a mix of performance and prescriptive requirements and believe this approach will be less disruptive, they wanted to know more about how the approach will work and which activities will be defined by prescriptive requirements. One respondent was concerned that performance requirements would provide too much flexibility, while respondents from rural locations would prefer this flexibility. Another respondent cautioned against the over-use of performance requirements because of a belief that prescriptive requirements better ensure safety.

Respondents are concerned that the compliance and enforcement strategy for the new Blood Regulations may duplicate existing audit and accreditation activities, thereby increasing stakeholder burden.

Most of the respondents did not suggest alternative approaches to the proposed Blood Regulations that Health Canada could consider. One respondent suggested that Health Canada consider referencing the Canadian Society for Transfusion Medicine or American Association of Blood Banks standards instead of the CSA Blood Standard. Another suggested the creation of a national computer information network that provides the status of all blood products available nation wide and that can be accessed across Canada and includes a standardized method to document and record workload units.

5.2.4 Specific Requirements

The proposed blood regulations will contain specific safety requirements for activities that fall under Health Canada's legislative authority. Depending on the type of activities undertaken by an establishment, a license or registration that includes terms and conditions may be required. Stakeholders were asked to review a list of blood activities that Health Canada may regulate and answer several questions.

While most respondents did not suggest any additional activities be included in the list, two respondents suggested adding a Quality Management System for activities with minimal impact. Throughout the responses, however, suggestions that the new regulations should be "vein to vein" were made.

There is some concern around what the detailed requirements for transportation and storage will be as they are not viewed by stakeholders to be minimal impact activities. Instead, some respondents feel they should be considered critical core activities and regulated as such. One respondent suggested that all activities should be critical core activities, and feels compliance monitoring for all activities is important. Greater requirements for and oversight of health care

institutions that transfuse blood was suggested, although this would be largely outside federal jurisdiction.

The need for clear and detailed guidance documents developed by Health Canada that address specific requirements was raised, along with the suggestion that they be circulated for comment as part of the consultative process.

5.2.5 Compliance and Enforcement

Although the strategy for the new blood regulations had yet to be determined, the regulatory workbook gave a description of Health Canada's approach to compliance and enforcement activities. Rather than being invited to comment on a specific strategy, stakeholders were asked about their concerns around the general approach and how they felt these concerns might be addressed.

Respondents are concerned that Health Canada's compliance and enforcement activities will duplicate existing audit and accreditation requirements, such as those under Ontario's Laboratory Licencing Act. Some respondents feel that accreditation and/or audits should be done by an established accreditation body, such as the Canadian Council on Health Services Accreditation that could be authorized by the federal government and Colleges of Physicians and Surgeons to act on their behalf.

Another major concern is that the necessary funds and personnel to achieve and maintain compliance are not available at this time for most blood facilities. Respondents feel that there should be some insurance that all facilities have the resources to be able to comply with the regulations. No suggestion was made how this concern might be addressed.

Stakeholders want to know specifically which parts of the regulations will apply to them, and what the compliance and enforcement approach for them will be. They want to know whether Health Canada or a designate will be responsible for inspections and/or enforcement activities. Essentially they want to minimize surprises and confusion, know what will occur and when, what they are responsible for, and the possible impacts of noncompliance. An escalated process of enforcement was also suggested.

5.2.6 Reporting Requirements

Three different types of reporting were described in the regulatory workbook: Serious Adverse Transfusion Reaction, Serious Adverse Donor Reaction and Error/Accident Reporting. The reporting pathway, who reports, when to report and what to report were described for each type. Blood stakeholders were asked what the impact of the proposed reporting approach might be for each reporting type and how the impact might be addressed.

Most respondents felt that there would be little or no impact from the proposed reporting approach for serious adverse transfusion reaction and error/accident reporting. It was believed that no impact would be felt from the approach to serious adverse donor reaction reporting because most respondents do not collect donor blood. It was suggested that any impact from

these reporting requirements could be alleviated through clear and concise forms and instructions and proper education and training prior to implementation. Error/accident reporting would require additional resources for organizations new to this type of reporting, however a reduction in the number of error/accident reports made by blood operators could be expected if they were limited to recalls of distributed blood.

While it was explained that reporting in the Transfusion Transmitted Injury Surveillance System and the Transfusion Error Surveillance System will not meet reporting requirements under the proposed Blood Regulations, several respondents felt that an alternative reporting system would entail a duplication of effort. Some respondents noted that facilities lack sufficient time to repeatedly report the same information to different government or regulatory bodies and that small facilities do not have the resources to meet labour intensive reporting requirements to multiple bodies. Because not all facilities have access to internet, an electronic reporting model may not be suitable.

5.3 SUMMARY

Challenges:
The challenges presented by stakeholders were generally balanced between provincial/territorial or hospital jurisdiction and federal jurisdiction. Funding, human resources and blood donor scheduling issues cannot be addressed via the new Blood Regulations. Requirements for storage and transportation are in the new Blood Regulations, but they are considered low enforcement priority. Stakeholder concerns in this area will be considered in further refinement of the new Blood Regulations. Stakeholders also asked for clear and concise information about regulatory requirements to address knowledge gaps and assist implementation. As with any regulatory initiative, guidance documents will be developed. Health Canada does not expect to develop SOP templates.

Proposed Approach to the Blood Regulations:
Most respondents support the Standards Based and Risk Based approach to the Blood Regulations and are a divided in their support for a Balance of Performance/Prescriptive Requirements.

Specific Requirements:
While most respondents did not suggest any additional blood activities could be added to the list, some felt that a Quality Management System should be required for activities in the minimal impact list.

Compliance and Enforcement:
Many of the respondents are very concerned about the increased burden for compliance and enforcement and the duplication of existing audit/accreditation systems that may result from the new Blood Regulations.

Reporting Requirements:

Most respondents felt that there would be little or no impact on the proposed reporting approach for serious adverse transfusion reaction and error/accident reporting. Many respondents do not collect blood and therefore are not concerned about reporting for serious adverse donor reactions.

6.0 HOSPITAL BLOOD BANK SURVEY

Ongoing analysis related to development of the new Blood Regulations identified a need to gather more information about blood related activities carried out within hospital blood banks, and provincial and territorial blood safety initiatives currently in place. This information would complement that gathered during face to face discussions with provincial and territorial blood system representatives and feedback gathered through an online workbook on the regulatory framework itself. The survey is limited to activities that may impact the safety of blood and blood components and does not consider blood transfusion itself, which is practice of medicine and falls under provincial and territorial jurisdiction.

Within this section of the Consultation Report, the term "hospital" refers to any Canadian hospital that has a functioning blood bank. Hospitals or health centres for long term or psychiatric care are not included in the analysis.

6.1 METHOD

Based on a clear understanding of Health Canada's regulatory responsibilities and the proposed approach and scope of the blood regulations, four categories of inquiry where blood safety may be affected were identified:

- accreditation, standards and quality systems
- blood collection programs
- blood distribution and recall
- blood modification activities

6.2 FINDINGS

6.2.1 Responses

It was assumed that only hospitals that provide acute care and perform surgery and/or transplantation have a blood bank (long term and psychiatric care facilities do not). Based on Canadian Institute of Health Information data, 626 Canadian hospitals are believed to have a hospital blood bank.

Eighty-nine surveys were received via email, fax and through the Health Canada Web site. Of these, some responses were duplicates and others incomplete; these responses were discarded for a total of 80 completed surveys received and a response rate of 12.8%.

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
n	5	12	3	4	39	1	5	4	1	3	1	0	1
% of prov. hospitals	6.17	12	4.6	5.4	28.9	1.4	19.2	11.8	14.3	10.7	50	0	100

All of the findings outlined below are presented as a reflection of respondents. The absence of a random sampling method for this survey strictly means we cannot generalize, however the number and distribution of respondents do allow for general national observations regarding the status of hospital blood banks across Canada. The report does not generalize to individual provinces, however provincial responses are summarized in Appendix C tables. The survey findings will be verified as the new regulations are implemented and licensing activities take place. As the table illustrates, Québec and Northwest Territories are significantly under-represented in this survey.

6.2.2 Accreditation, Standards and Quality Systems

This group of questions intended to find out which hospital blood banks have accreditation from or based on organizations and/or standards accepted in the blood processing and/or transfusion fields.

More than 75% of respondents have accreditation based on the CSA Blood Standard (45%) , the American Association of Blood Banks standard (21%), or the Canadian Society of Transfusion Medicine standard (65%). Forty-six percent of respondents have accreditation based on more than one of these industry standards, while approximately 24% have no accreditation.

The vast majority (89%) of respondents have implemented the CSA Blood Standard in whole or in part. Thirty-one percent have achieved full implementation of the CSA Blood Standard, while 58% have achieved partial implementation. There were insufficient responses to determine the time frame for full implementation amongst those who have not yet achieved it. Four percent of respondents did not answer the questions on implementation of the CSA Blood Standard.

Ninety percent of respondents have an overall quality system in place, while 7.5% do not. Less than 3% of respondents did not answer this question.

6.2.3 Blood Collection Programs

This group of questions aimed to determine the type of blood collection activities underway in Canada's hospital blood banks.

Preoperative autologous blood collection, not including perioperative collection, for transfusion is carried out in 21% of responding hospitals. The majority, or 71%, of respondents that do autologous blood collection have a quality system in place for this activity, while 29% do not.

Of responding hospitals that do autologous blood collection, 18% do their own testing of autologous units for transmissible diseases. Eighty-two percent rely on Canadian Blood Services or Héma Québec for transmissible disease testing of autologous units collected in their hospital.

Approximately 65% of those responding hospitals who collect autologous units for transfusion collect fewer than 50 units in a year, with 35% collecting more than 50 units per year. All responding hospitals that collect autologous units dispose of some of those units, with the majority (65%) disposing of more than 50% of those units. The remaining hospitals dispose of 26-50% of autologous units collected.

Only 1% of responding hospitals have a designated blood donation program. These programs are seldom used, with fewer than six patients going through each program per year. There is not likely to be a quality system associated with designated donation programs in Canada.

Based on survey responses, it is unlikely that there are any directed donation programs within Canadian hospitals. It is likely that there are also currently no walking donor programs within Canadian hospitals. According to survey responses, the last of Canada's walking donor programs (in 9% of responding hospitals) were cancelled within the past five years. Reasons given for cancellation include lack of need and/or funding for the program, introduction of the CSA Standard making it difficult to sustain the program, and the idea that such programs are not best for blood recipients.

6.2.4 Blood Distribution and Recall

This group of questions intended to explore the distribution or circulation by hospital blood banks of blood units that have been received from CBS or HQ. Distribution of blood and blood components between hospital blood banks is an important part of Canada's blood system given the vastness of our geography and population distribution. Well managed emergency release and recall programs play a significant role in maintaining the relatively low risk of Canada's blood system.

Approximately 26% of responding hospitals have an emergency release program in place. Of these programs, 77% are used by fewer than ten people each year. Seventy-six percent of emergency release programs have a quality system in place.

Fifty-eight percent of responding hospitals distribute blood to other hospitals. The remaining hospitals do not distribute blood.

A recall system is in place for distributed blood in 68% of responding hospitals. Sixty percent of these hospitals can recall distributed blood and blood components in under one hour (40% require fewer than 30 minutes). Only 6% of responding hospitals require more than 12 hours to recall distributed blood and blood components, with the remainder requiring 1-4 hours. Twenty-five percent of respondents did not answer this question.

6.2.5 Blood Modification Activities

Respondents were asked a series of questions about blood modification activities undertaken within their hospital blood banks. Modification activities are those activities that alter the state of blood or its components. The survey asked specifically whether hospital blood banks irradiate, wash or pool blood received from CBS or HQ. An opportunity to mention other activities was also provided.

Approximately 9% of responding hospitals irradiate blood units received from CBS or HQ, with 100% of these hospitals irradiating more than 500 units per year.

Thirty percent of responding hospitals wash blood units that have been received from CBS or HQ. Of these hospitals, close to 70% wash 50 or fewer units per year. More than 50 units per year are washed by 29% of responding hospitals that undertake this activity.

Almost 60% of responding hospitals pool blood that is received from CBS or HQ. Just over 35% of hospitals that pool blood do so for fewer than 50 units per year. Close to 2/3 of Canadian hospitals that pool blood do so for more than 50 units per year.

Several activities were incorrectly noted by respondents as other blood modification activities undertaken within their hospital blood banks. These activities include: aliquoting, splitting, dividing, neonatal small volume, sterile docking and thawing. Because these activities do not alter the state of blood or its component, they will not be assessed in this consultation report.

The following additional activities noted by respondents are considered to be blood modification. Because these activities were self-disclosed, it is possible that more responding hospitals undertake them but did not note them. It is also possible that additional blood modification activities are undertaken in Canada's hospitals but were not mentioned.

Ten percent of responding hospital blood banks do volume reduction, volume depletion or concentrating of blood units received from CBS or HQ. The majority of these hospitals (63%) perform this modification on fewer than 50 units per year. Twenty-nine percent of responding hospitals modify more than 200 units of blood in this manner per year.

Due to the small number of responses that included the following activities, it is difficult to make assumptions for Canada as a whole.

Just over 1% of respondents remove additives from blood units, while the same percentage reconstitute blood units received from CBS and HQ. While only a few respondents transform blood units in these ways, large numbers of units are processed. Additives are removed from more than 200 units in a small number of Canadian hospitals, while more than 500 units are reconstituted.

6.2.6 Quality Improvement Processes

Systematic monitoring and response related to errors, accidents and adverse reactions is essential to a safe and reliable health care system, and will form part of the new Blood Regulations. This group of questions intended to determine the extent to which Canada's hospital blood banks

systematically monitor processes, identify the need for change, and make changes where required.

More than 75% of responding hospitals have deficiency monitoring processes in place, while more than 80% have processes in place for implementing changes to blood activities.

Almost 100% of responding hospitals have a process in place for investigating transfusion related errors and accidents, with slightly over 1% having no process in place. However, 100% of responding hospitals have a process in place for reporting transfusion related errors and accidents.

Processes for adverse transfusion reaction investigation are in place for just over 96% of responding hospitals, while almost 99% have adverse reaction reporting processes in place. Just over half (56%) of responding hospitals have processes in place for investigating serious donor events. Because this percentage exceeds the number of hospitals that have autologous donation programs in place, it likely represents investigation processes for serious donor events associated with autologous and perioperative donation as well as notification to CBS when a serious event is suspected to be blood donor related.

Slightly more than 96% of responding hospitals have a system for blood and blood components to ensure that errors and accidents are identified, investigated and evaluated, and corrective action taken when required.

6.3 SUMMARY

This survey has enabled a better understanding of blood related activities carried out within hospital blood banks, and of provincial and territorial blood safety initiatives currently in place.

The findings suggest that no Canadian hospitals undertake allogeneic blood collection and instead use blood provided by Canadian Blood Services and Héma-Québec. Some hospitals have autologous collection programs, but very few have designated donation programs and none have directed or walking donor programs. Very few hospital blood banks modify blood units received from CBS and HQ, with the exception of pooling. All activities they undertake are considered to be medium enforcement priority (medium risk).

Most of Canada's hospital blood banks likely have blood safety programs in place, including accreditation based on an industry acceptable standard and quality systems. Various options for licensing of Canada's hospital blood banks are currently being explored, some of which make use of existing accreditation bodies.

Quality systems play an important role in the safety of blood and blood components and will form part of the new regulatory framework. Most hospitals likely have quality systems in place. The majority of Canada's hospitals have also likely made gains in implementing the CSA Blood

Standard since its publication in 2003. Those hospitals that have implemented the CSA Blood Standard in full will be best prepared for the new Blood Regulations.

Blood safety activities and modernization efforts undertaken independently by Canada's hospital blood banks suggest a significant degree of readiness for the new Blood Regulations, and the existence of blood safety systems that the new blood regulations can build upon.

The results of this survey indicate that the goals of building upon existing blood safety activities underway within the provinces and territories and having consistent blood safety regimes across the country are realistic and consistent with what hospitals have been achieving through their own initiatives.

7.0 CONCLUSIONS

Consistent messages from all three tiers of this consultation have indicated that while many blood safety activities and initiatives have been undertaken independently within Canada's hospitals, stakeholders support the need for national regulations. Implementation of the CSA Blood Standard in most hospitals puts them in a good position for receiving the new Blood Regulations upon their publication.

While stakeholders raised several challenges facing Canada's blood system today, many, such as funding and human resource pressures that may affect implementation of the regulations, are outside the scope of this regulatory initiative and instead require administrative or funding decisions to be taken elsewhere. Key concerns that hold the potential to be addressed in the regulations include storage and transportation of blood and blood components and the possibility of duplication of reporting, accreditation and inspection activities that are currently underway within hospitals.

Ongoing communication between all parties involved in blood safety across Canada, and collaboration where appropriate, is essential to ongoing development and successful implementation of the Blood Regulations. Clear knowledge of regulatory roles and responsibilities between different jurisdictions is important, as is a common understanding of the differences between standards and regulations, and which are applicable by law. By identifying and working through implementation challenges during the regulatory development phase, many of them may be avoided later on. To this end, it is important that Health Canada be clear on its requirements, and continue to communicate them to stakeholders in a timely manner.

8.0 LESSONS LEARNED

Online Consultation
Reaction was generally favourable to conducting this consultation online, in part because stakeholders felt it would reach a broad base for input. Although respondents felt the workbook

was very informative, it required a significant time commitment to complete. While stakeholders liked that they could participate at a time convenient to them, they did not appreciate having to complete each document in one sitting. A key drawback for stakeholders was the absence of an opportunity for review and discussion amongst all stakeholders.

The coordinated efforts of Hamilton and British Columbia suggest that future consultations (online and otherwise) may attain a higher cross-country representation by channelling requests for feedback through a central body.

Communication
Stakeholders want regular communication between all players in Canada's blood system. They feel the field would benefit from annual face-to-face meetings to discuss timely issues, and from getting regular updates at conferences. Existing communication structures of CBS/HQ or the provincial blood coordinating offices could be used to inform and receive feedback from all facilities in a province or territory. The publication of articles or letters in Canadian laboratory magazines, newsletters, or Web sites could inform and update, the lab community of this process.

Stakeholder Population
Value could be gained in involving professionals outside the transfusion medicine community in the consultation and communication process. General lab staff, general pathologists, and many clinical staff who perform transfusions may have meaningful input related to the new blood regulations, and may play a role in their successful implementation. Hospital administration, provincial and territorial Ministries of Health and existing accreditation bodies should also be involved.

9.0 NEXT STEPS

Summer 2008	Canada Gazette I publication, with 75 day comment period
2009	Canada Gazette II publication

Throughout the latter part of 2008 and 2009 and following the promulgation of the regulations, Health Canada will prepare to operationalise the regulations. It is expected that this will include the revision/development of guidance documents and any other tools deemed necessary to support the new regulations.

APPENDIX A
GLOSSARY

Some of the definitions contained in this glossary are taken from the Plasmapheresis Regulations, and may not appear the same in the final Blood Regulations.

accident
An unexpected event that is not attributable to a deviation from the blood establishment's operating procedures or applicable laws and that could adversely affect the safety of a donor or recipient or the safety, efficacy or quality of blood or blood components.

allogeneic
Cells or tissues from individuals belonging to the same species but genetically dissimilar (and hence immunologically incompatible), e.g. blood.

autologous donation
Blood that is collected from an individual for the purpose of transfusion back into the same individual at a later time. It does not include perioperative donations.

blood component
Blood is a fluid composed of cells and plasma that flow in the arteries and veins of the body. The cellular components of blood are red blood cells, white blood cells and platelets. Plasma is the fluid component of blood that carries red and white blood cells to the body's organs as well as the nutrients and by-products of metabolism.

blood product
A therapeutic product manufactured or processed from whole blood, blood components or blood plasma.

blood safety
Refers to the safety of whole blood and blood components.

Blood Standards (Canadian Standards Association)
The CSA Standards are consensus standards developed by Canadian experts in their respective fields. The CSA Blood Standards (Blood Standards) are identified as CAN/CSA-Z902-04, Blood and Blood Components.

The Blood Standards, developed by the CSA Technical Committee on Blood and Blood Components, outline specific requirements aimed at ensuring the safety and quality of whole blood and blood components and include requirements for the collection, processing, preservation, packaging, labelling, storage, quarantining, record keeping, distribution, adverse event reporting, and recall of whole blood and blood components. They include activities that fall under both federal and provincial/territorial jurisdiction.

compliance
The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement.

compliance monitoring
Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the *Food and Drugs Act* and its associated regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys and a product sampling program.

compliance verification
Actions taken to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the *Food and Drugs Act* and its associated regulations. This includes actions such as information gathering either off-site or by on-site visits.

deviation management system
A system that includes policies, processes and procedures to ensure the identification, assessment, investigation and monitoring of deviations from meeting, or failing to meet, specified requirements. It should also include methods and procedures to input product or quality problems into a corrective and preventive action system.

distributed products
Whole blood or blood components that have left the control of the establishment (including hospital blood banks).

enforcement
Actions that may be taken to induce, encourage or compel compliance with the *Food and Drugs Act* and its associated regulations.

error
A deviation from a blood establishment's operating procedures or applicable laws that could adversely affect the safety of a donor or recipient or the safety, efficacy or quality of blood or blood component.

establishment
A person, a partnership or an unincorporated entity, or a part of any of them, that carries out any of the following activities with respect to blood or blood components:

(a) collection;
(b) testing;
(c) processing;
(d) distribution;
(e) transformation;
(f) importation;
(g) storage; or

(h) transfusion

establishment license
A licence granted by Health Canada to undertake activities that are regulated by the department. EL must be applied for in the manner described in the regulations. In the case of blood safety, EL will be required for the following activities: allogeneic whole blood and blood component collection, testing, processing, initial distribution into the general blood supply and importation.

establishment license/registration
A licence/registration granted by Health Canada to undertake activities that are regulated by the department. ELR application involves informing the federal department, in the manner described in the regulations, of the activities being carried out.

incident
An accident or error that could lead to an adverse outcome affecting (a) the safety, or quality of whole blood or blood components; or (b) the safety of recipients.

inspection
An on-site monitoring and assessment against the applicable requirements of the *Food and Drugs Act* and its associated regulations. Inspections are routinely conducted on a predetermined cycle or as required to assess compliance.

investigation
An action taken to gather evidence to support a case referral for potential judicial determination regarding specific violations of the *Food and Drugs Act* and its associated regulations. This includes taking statements and activities carried out under the Criminal Code, i.e., executing search warrants.

jurisdiction
The geographical area over which a court or government body has the power and right to exercise authority.

lookback
A procedure in which previous donations (and related blood components) from a donor who is subsequently found to have a transfusion-transmissible infection are identified, and follow-up activities are undertaken to notify any involved organizations and affected individuals.

National Standards
National Standards must be developed through a consensus process by a balanced stakeholder committee. National Standards are consistent with existing international standards. The public has an opportunity to comment on standards. Although compliance with National Standards is voluntary, accreditation by an accrediting body is often associated with standards compliance.

The Standards Council of Canada (SCC) has responsibility for co-ordination of the Standards System in Canada and has accredited the Canadian Standards Association (CSA) as a standard

development organization to develop National Standards of Canada.

non-serious error/accident (E/A)
Any E/A that does not have a direct impact on the safety of blood and blood components, and for which the associated risk may be minimal.

prescriptive regulations
Regulations specifically describe the *means* to achieve the objective. Establishments must all meet the regulatory requirement in the same way. The government verifies information from regulated establishments and conducts compliance inspections.

performance-based regulations
Describes *ends* in terms of performance that will assure meeting the objective. Establishments must meet the objective, however, the manner in which they do so can vary. This allows for advances in technological innovations and, consequently, fewer regulatory amendments.

quality system
The following are mandatory requirements for a complete quality system:

(a) change control system
(b) document control and record retention system
(c) emergency contingency plan
(d) proficiency testing program, if applicable
(e) quality control program
(f) internal audit system
(g) a system for the identification of critical elements
(h) written specifications for all critical supplies, equipment and services
(i) a system for the reconciliation of donation numbers and collection sets
(j) preventive maintenance of equipment
(k) validation of computer systems
(l) deviation management system, including recall
(m) process control
(n) process improvement through complaint monitoring, and corrective and preventive action
(o) training program

regulation
Regulations are a form of law with the same binding legal effect as Acts. Regulations are made under the authority of an enabling Act.

regulatory authority
Health Canada derives its authority to regulate the safety, quality and efficacy of health products under the *Food and Drugs Act (F&DA)*. The objective of the *F&DA* is to protect the health and safety of Canadians and to prevent fraud and deception in the manufacture and sale of food, drugs, devices, and cosmetics. Blood is defined in the *F&DA* as a Schedule D drug.

In Canada, the law states that any distribution of whole blood and blood components is prohibited unless the manufacturing premises and the processes and conditions of manufacture have been found suitable to ensure that the blood and blood components are safe and of high quality for use in Canada.

regulatory framework
Laws and regulations that outline the legal requirements to be met. They may also be complemented by policies, standards, directives and guidelines. Key elements of a regulatory framework for drugs may include: clinical trials, pre-approval requirements, licensing schemes, product safety standards, compliance and enforcement policies and post-approval surveillance requirements.

serious adverse transfusion reaction
An unexpected and undesirable response in a recipient associated with the transfusion of blood or blood components that results in any of the following consequences for the recipient:

(a) hospitalization or its prolongation;
(b) persistent or significant disability or incapacity;
(c) a medical or surgical intervention to preclude a persistent or significant disability or incapacity;
(d) a life threatening condition; or
(e) death

serious adverse donor reaction
An unexpected and undesirable response in a donor associated with the collection of blood or blood components that results in any of the following consequences for the donor:

(a) hospitalization;
(b) persistent or significant disability or incapacity;
(c) a medical or surgical intervention to preclude a persistent or significant disability or incapacity;
(d) a life threatening condition; or
(e) death

traceback
A traceback is the process of investigating a report of a suspected transfusion-associated infection in order to identify a potential implicated donor.

transform
Transform means to wash, pool or irradiate blood.

APPENDIX B
OVERVIEW OF REGULATIONS

Overview of Proposed Regulations under the *Food and Drugs Act*

Safety, Quality and Efficacy of Human Blood and Blood Components for Transfusion

Please note that this overview is meant to provide general information about possible sections of the new blood regulations. This information is subject to change based on stakeholder feedback and further analyses of the issues.

Regulatory requirements are in-line with requirements in the National Standard. Clauses and Tables from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components* for inclusion in the new Blood Regulations were carefully considered based on federal jurisdiction, technical scope and regulatory drafting conventions.

1. Interpretation

The Interpretation section of the regulations will provide definitions of terms used in the new Blood Regulations. Examples of terms are: *donor suitability assessment* and *release into inventory.*

2. Application

The Application section of the regulations will describe the scope of the new Blood Regulations.

- The proposed regulations will apply to human whole blood and blood components for transfusion and include recovered plasma for further manufacture and red blood cells for immunization. It is proposed that the regulations would apply to:
  - (i) collection (includes donor registration and donor suitability assessment) and testing of whole blood and blood components *for transfusion or recovered plasma for further manufacturing.*
  - (ii) processing, pooling, irradiation, washing, storage, importation from other countries and distribution of whole blood and blood components *for transfusion.*

- The proposed regulations will cover allogeneic designated, directed and walking donor donations as well as the collection and testing of whole blood and blood components for autologous use.

- If whole blood and blood components are imported, processed, stored or distributed for further manufacturing these regulations will not apply, since blood products are covered under Division 8 of the *Food and Drug Regulations*.

- The regulations will not apply to stem cells and cord blood, source plasma, therapeutic apheresis, peri-operative blood collection. Stem cells will be regulated under the *CTO Regulations* and source plasma will be regulated under the *Plasmapheresis Regulations*. Therapeutic apheresis and peri-operative blood collection are considered to be practice of medicine and will, therefore, not be regulated within this framework.

- No other regulations under the *Food and Drugs Act* will apply to the whole blood and blood components covered by these regulations.

3. Prohibition

The Prohibition section of the regulations will describe what is not allowed unless regulatory requirements are met.

A general prohibition will prohibit the importation or sale of whole blood and blood components unless these regulations are met, and unless establishments collect (includes donor suitability assessment), test, process, pool, irradiate, wash, store or distribute whole blood or blood components in accordance with regulatory requirements.

3A. **Establishments** responsible for whole blood and blood components activities covered in the new Blood Regulations will be subject to regulatory requirements. The amount of regulatory oversight of establishments will be based on the risk associated with the activities that they perform.

3B. **Activities** will be classified based on potential risk to the safety of whole blood and blood components, the donor and the recipient. The proposed new regulatory framework defines:

- **high risk activities** as critical core activities with maximal impact on donor and recipient safety and the safety, quality and efficacy of allogeneic whole blood and blood components. These activities include donor suitability assessment, collection, processing, labelling, testing, release and importation of allogeneic whole blood and blood components.
- **medium risk activities** as
  - (i) additional modification activities performed on allogeneic whole blood and blood components already distributed into the general blood supply, such as washing, pooling or irradiation of allogeneic blood; and/or
  - (ii) activities with moderate impact on donor and recipient safety and the safety, quality and efficacy of whole blood and blood components, including collection, testing, labelling and storage of autologous blood.
- **low risk activities** as activities with minimal impact on donor and recipient safety and the safety, quality and efficacy of whole blood and blood components. These activities include transportation or storage of allogeneic whole blood and blood components released into general inventory and transfusion-related record keeping.

4. Licensing/Registering

The Licensing/Registering section is under development and will depend on the outcome of stakeholder consultations. It will describe when and what type of regulatory obligations establishments must meet in order to carry out activities, listed in the Prohibition section, related to whole blood and blood components.

Licensing, registration and/or third party accreditation, based on the risk associated with the activities the establishment undertakes, are all considerations. Once the regulatory tools are chosen, they will be stated in the Prohibitions section as prerequisite requirements to be fulfilled before undertaking specific activities.

- Establishments undertaking high risk activities, will be required to apply for an establishment licence.

- Stakeholder input will aid in determining the regulatory approach for establishments that undertake medium risk activities.

- Whole blood or blood components *imported for transfusion* will be covered by these regulations. Establishments importing whole blood or blood components will require an establishment licence.

5. Donor Suitability Assessment

The Donor Suitability Assessment section will reference clauses from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components,* and provide requirements for allogeneic, autologous, directed, designated and walking donor donations. Requirements will include:

- informing the donor of potential risks associated with donating blood and risks to the recipient of transfusion transmission of infectious disease by blood;

- collecting donor information;

- verifying that donors are in good general health, free from evidence of diseases transmissible by blood transfusion or conditions that would adversely affect (i) the safety, quality and efficacy of blood and blood components or (ii) the health of the donor; and,

- sharing donor deferral information

The Donor Suitability Assessment section will contain donor deferral criteria in line with what is currently proposed in *Amending the Food and Drug Regulations (Human Plasma Collected by Plasmapheresis)* Deferral Criteria Tables 1 and 2.
http://canadagazette.gc.ca/partII/2006/index-e.html (Wednesday, December 27, 2006, Vol. 140)

6. Collection

The Collection section will reference clauses from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components,* and contain requirements for the collection of whole blood and blood components; including,

- methods and devices
- samples for testing
- confidential unit exclusion
- post-donation information
- autologous collection
- blood components collected by apheresis

The Maximum Volumes and Minimum Intervals section will reference clauses from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components,* and include requirements for:

- whole blood and blood components collected for allogeneic use

7. Testing

The Testing section will reference clauses from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components,* and contain requirements for allogeneic and autologous blood and blood components testing. The requirements include:

- test kits
- testing protocols
- screening tests for transmissible diseases
- ABO and RH group testing
- disposition of blood or blood components that test repeat reactive or positive
- testing for clinically significant red cell antibodies
- quality control testing
- visual inspection

8. Processing

8A. Labelling

This section will reference clauses from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components*, and include requirements for information to be provided on each container of blood or blood component and corresponding samples.

8B. Release into Inventory

This section will reference clauses from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components*, and include requirements for release of blood and blood components into general inventory.

8C. Exceptional Distribution

A blood establishment may distribute blood and blood components that have not been determined safe for transfusion, if regulatory conditions for exceptional distribution are met. In addition, a notice of exceptional distribution must be completed according to regulatory requirements and included in both the donor and recipient records. The blood establishment, following the exceptional distribution, must complete the regulatory requirements for donor assessment, any other appropriate follow-up testing and notification of the relevant transfusion establishment of the results.

8D. Walking Donor Programs

This section will reference clauses from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components*.

9. Storage and Storage During Transportation

This section will reference criteria listed in Table 2 'Storage requirements' from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components* and include requirements for:

- segregation of autologous, directed donation blood and blood components from the allogeneic blood supply
- environmental conditions for storage
- temperature requirements during transportation

10. Quality System

This section will reference the criteria set out in Table 3 'Allogeneic blood component quality control' of the blood standard and Table 4 'Record retention requirements' from the National Standard, CAN/CSA-Z902-04 *Blood and Blood Components*.

Establishments will be required to have a quality system in place that complies with the regulatory requirements for all activities. The purpose of the quality system is to maximize the safety, quality and efficacy of blood and blood components, or the safety of donors or recipients.

Other sections of the quality system include:

10A. Errors, Accidents and Serious Adverse Reaction Investigation and Reporting

Error and Accident (E/A) reporting will include requirements for:

- reporting of any serious E/A to Health Canada that may impact blood safety, quality or efficacy or the safety of the donor within a specific time frame
- steps to be taken following a suspected E/A
- contents of an E/A notice

Serious Adverse Reaction reporting will include requirements for:

- reporting of serious adverse reactions occurring in donors or recipients within a specific time frame

- steps to be taken following a suspected serious adverse reaction
- contents of a serious adverse reaction notice

Investigation will include a requirement for an establishment to cooperate by providing information relevant to an investigation of an E/A or a serious adverse reaction to the blood establishment conducting the investigation. The blood establishment will also be required to provide:

- a notice containing a preliminary report to Health Canada, within 24 hours after the start of the investigation
- notification of the investigation results to all implicated establishments
- a final report to Health Canada

The **Lookback/Traceback** section will include requirements for:

- when to conduct a lookback/traceback
- annual lookback/traceback summary reports to Health Canada
- annual written summary report of the outcomes of all closed investigations of lookbacks and tracebacks to Health Canada

10B. Records

Requirements for record-keeping include types of records, length of record retention, and record storage requirements within a records management system that achieves the following:

(i) incorporates the donor identification code;
(ii) creates a complete and traceable history of the donation for each unit of blood or blood components, from donor registration to final disposition of blood component; and
(iii) is designed to allow rapid recall of blood or blood components.

11. Other

Other possible requirements may be developed for transitional provisions and quarantine.

APPENDIX C
SURVEY TABLES

How to Interpret the Tables:
Each tables includes data received for a single survey question or similar questions that have been grouped together. The tables appear in the same order as the questions. Please refer to Appendix C when reviewing these tables as the survey question numbers are noted with the corresponding table.

Data cells indicate either the number of hospitals to which each factor applies, or N/A for "not applicable". N/A would apply when a question is a follow up to one with a zero response.

Example 1: Zero Saskatchewan respondents indicated that they do autologous collection (Table 6). Therefore N/A appears in the SK column of the following two tables (Table 7 and Table 8).

Example 2: Table 1 provides an overview of completed surveys received from hospitals across the country. According to our information, British Columbia has 81 hospitals with blood banks. Five of these hospitals, or 6.17%, completed and submitted a survey. These five responses represent 6.25% of all completed surveys received.

Example 3: Of Ontario's 39 hospitals that responded to the survey, 21 have an accreditation based on the CSA Standard (Table 2), 29 have an accreditation based on the CSTM Standard, while 11 have an accreditation based on the AABB Standard. 32 of Ontario's 39 responding hospitals have a single accreditation, while 22 have multiple accreditations. Seven Ontario respondents do not have an accreditation based on either of these three standards.

Table 1: Surveys Received

prov (n hospitals)	BC (81)	AB (100)	SK (65)	MB (74)	ON (135)	QC (70)	NB (26)	NS (34)	PE (7)	NL (28)	YT (2)	NT (4)	NU (1)
n rec'd	5	12	3	4	39	1	5	4	1	3	1	0	1
% prov	6.17	12	4.6	5.4	28.9	1.4	19.2	11.8	14.3	10.7	50	0	100
% total	6.25	15	3.75	5	48.75	1.25	6.25	5	1.25	3.75	1.25	0	1.25

Section 1: Accreditation, Standards and Quality Systems

Table 2: Accreditation (Q1 - 3)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
CSA	4	6	1	2	21	0	2	0	0	0	0	*	0
CSTM	5	12	2	2	29	0	1	0	0	1	0	*	0
AABB	0	2	1	2	11	0	1	1	0	0	0	*	0
EITHER	5	12	3	4	32	0	2	1	0	1	0	*	0

MULTI	5	8	3	2	22	0	1	0	0	0	0	*	0
NONE	0	0	0	0	7	1	3	0	1	2	1	*	1

Table 3: Implementation of CSA Standard *CAN/CSA-Z902 Blood and Blood Components* (Q4)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
PART	4	5	2	0	19	1	4	4	1	3	1	*	1
FULL	1	5	0	2	16	0	1	0	0	0	0	*	0
NONE	0	1	1	0	4	0	0	0	0	0	0	*	0
NULL	0	1	0	2	0	0	1	0	0	0	0	*	0

Table 4: Quality System (Q6)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	4	11	2	3	39	1	4	3	0	3	0	*	1
NO	1	1	1	0	0	0	1	0	1	0	1	*	0
NULL	0	0	0	1	0	0	0	1	0	0	0	*	0

Section 2: Blood Collection Programs

Table 5: Allogeneic Collection (Q7)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	0	0	0	0	0	0	0	0	0	0	0	*	0
NO	5	12	3	4	39	1	5	4	1	3	1	*	1
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 6: Preoperative Autologous Collection (Q8)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	1	5	0	0	5	0	4	1	0	0	1	*	0
NO	4	7	3	4	34	1	1	3	1	3	0	*	1
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 7: Autologous Testing (Q9-10)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES - internal	0	1	N/A	N/A	1	N/A	1	0	N/A	N/A	0	*	N/A
YES - CBS/HQ	1	5	N/A	N/A	4	N/A	4	0	N/A	N/A	1	*	N/A

NO	0	0	N/A	N/A	1	N/A	0	1	N/A	N/A	0	*	N/A
NULL	0	0	N/A	N/A	0	N/A	0	0	N/A	N/A	0	*	N/A

Table 8: Autologous Units Collected (yearly) (Q11)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
1 - 25	0	2	N/A	N/A	0	N/A	4	1	N/A	N/A	1	*	N/A
26 - 50	0	2	N/A	N/A	1	N/A	0	0	N/A	N/A	0	*	N/A
51 - 100	1	1	N/A	N/A	2	N/A	0	0	N/A	N/A	0	*	N/A
101 - 500	0	0	N/A	N/A	2	N/A	0	0	N/A	N/A	0	*	N/A
>500	0	0	N/A	N/A	0	N/A	0	0	N/A	N/A	0	*	N/A
NULL	0	0	N/A	N/A	0	N/A	0	0	N/A	N/A	0	*	N/A

Table 9: Autologous Units Discarded (yearly) (Q12)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
< 10%	0	0	N/A	N/A	0	N/A	0	0	N/A	N/A	0	*	N/A
11 - 25%	0	0	N/A	N/A	0	N/A	0	0	N/A	N/A	0	*	N/A
26 - 50%	0	2	N/A	N/A	2	N/A	1	0	N/A	N/A	0	*	N/A
51 - 75%	0	3	N/A	N/A	3	N/A	1	0	N/A	N/A	0	*	N/A
> 75%	1	0	N/A	N/A	0	N/A	2	1	N/A	N/A	0	*	N/A
NULL	0	0	0	0	0	0	0	0	0	0	1	*	0

Table 10: Autologous - Quality System (Q13)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	0	4	N/A	N/A	4	N/A	4	0	N/A	N/A	0	*	N/A
NO	1	1	N/A	N/A	1	N/A	0	1	N/A	N/A	1	*	N/A
NULL	0	0	N/A	N/A	0	N/A	0	0	N/A	N/A	0	*	N/A

Table 11: Designated Blood Donation (Q14)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	0	0	0	0	0	0	0	1	0	0	0	*	0
NO	5	12	3	4	39	1	5	0	1	3	1	*	1
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 12: Designated Donation - Patients (yearly) (Q15)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU

1 - 5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	N/A	N/A	N/A	*	N/A
6 - 10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	*	N/A
11 - 15	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	*	N/A
16 - 25	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	*	N/A
>25	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	*	N/A

Table 13: Designated - Quality System (Q16)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	*	N/A
NO	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1	N/A	N/A	N/A	*	N/A
NULL	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0	N/A	N/A	N/A	*	N/A

Table 14: Directed Blood Donation (Q17)[1]

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	0	0	0	0	0	0	0	0	0	0	0	*	0
NO	5	12	3	4	39	1	4	4	1	3	1	*	1
NULL	0	0	0	0	0	0	1	0	0	0	0	*	0

Table 15: Walking Donor Program (Q20)[2]

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	0	0	0	0	0	0	0	0	0	0	0	*	0
NO	5	12	3	4	37	1	5	4	1	2	1	*	1
NULL	0	0	0	0	2	0	0	0	0	1	0	*	0

Table 15: Walking Donor Program - Cancelled within last five years (Q21) [3]

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	0	2	0	0	1	0	0	0	0	0	1	*	1
NO	5	10	2	3	32	1	4	4	1	3	2	*	0

[1]Because no respondents have a directed blood donation program in place within their hospitals, the follow-up questions have been disregarded.

[2]Because no respondents have a walking donor program in place within their hospitals, some follow-up questions have been disregarded.

[3]Please see survey findings for reasons why walking donor programs have been cancelled in the last five years.

NULL	0	0	1	1	6	0	1	0	0	0	0	*	0

Section 3: Blood Distribution and Recall

Table 16: Emergency Release Program (Q25)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	1	2	2	0	14	0	0	0	0	1	0	*	1
NO	4	10	1	4	25	1	5	4	4	2	1	*	0
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 17: Emergency Release - Usage (yearly) (Q26)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
1 - 5	1	2	1	N/A	9	N/A	N/A	N/A	N/A	1	N/A	*	1
6 - 10	0	0	0	N/A	2	N/A	N/A	N/A	N/A	0	N/A	*	0
11 - 15	0	0	0	N/A	0	N/A	N/A	N/A	N/A	0	N/A	*	0
16 - 25	0	0	0	N/A	1	N/A	N/A	N/A	N/A	0	N/A	*	0
>25	0	0	0	N/A	0	N/A	N/A	N/A	N/A	0	N/A	*	0
NULL	0	0	1	N/A	2	N/A	N/A	N/A	N/A	0	N/A	*	0

Table 18: Emergency Release - Quality System (Q27)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	0	2	1	N/A	11	N/A	N/A	N/A	N/A	1	N/A	*	1
NO	1	0	0	N/A	1	N/A	N/A	N/A	N/A	0	N/A	*	0
NULL	0	0	1	N/A	2	N/A	N/A	N/A	N/A	0	N/A	*	0

Table 19: Blood Distribution Program (Q28)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	4	6	2	0	20	1	5	3	1	2	1	*	0
NO	1	4	1	4	19	0	0	1	0	1	0	*	1
NULL	0	2	0	0	0	0	0	0	0	0	0	*	0

Table 20: Blood Distribution - Recall System (Q29)[4]

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU

[4] Responses may reflect intra-hospital distribution.

YES	3	10	2	2	25	1	4	3	1	1	0	*	1
NO	1	2	1	1	13	0	1	1	0	1	1	*	0
NULL	1	0	0	1	1	0	0	0	0	1	0	*	0

Table 21: Blood Distribution - Recall Time(Q30)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
<30 min	2	4	2	1	15	1	2	2	1	0	1	*	0
<1 hr	2	4	0	0	8	0	1	0	0	0	0	*	1
1 - 4 hrs	0	2	0	0	2	0	0	2	0	1	0	*	0
5 - 12 hrs	0	0	0	0	0	0	0	0	0	0	0	*	0
>12 hrs	0	0	0	1	3	0	0	0	0	1	0	*	0
NULL	1	2	1	2	11	0	2	0	0	1	0	*	0

Section 4: Blood Modification Activities

Table 22: Blood Modification Activities (Q31)[5]

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
Irradiation	2	2	3	0	2	0	0	0	0	0	0	*	0
Washing	4	2	2	0	12	0	3	0	0	0	0	*	0
Pooling	5	4	3	1	29	1	4	3	1	2	0	*	0
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 22: Blood Irradiation - Frequency (Q32)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
1 - 25	0	0	0	0	0	0	0	0	0	0	0	*	0
26 - 50	0	0	0	0	0	0	0	0	0	0	0	*	0
51 - 200	0	0	0	0	0	0	0	0	0	0	0	*	0
201 - 500	0	0	0	0	0	0	0	0	0	0	0	*	0
>500	2	2	1	0	2	0	0	0	0	0	0	*	0
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 23: Blood Washing - Frequency (Q32)

[5] Other self-disclosed blood modification activities include volume reduction, reconstitution and removal of additives. Please see the Section 6.2.5 of the Consultation Report for more information.

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
1 - 25	2	1	1	0	9	0	1	0	0	0	0	*	0
26 - 50	0	0	1	0	0	0	0	0	0	0	0	*	0
51 - 200	1	0	0	0	2	0	2	0	0	0	0	*	0
201 - 500	1	1	0	0	0	0	0	0	0	0	0	*	0
>500	0	0	0	0	0	0	0	0	0	0	0	*	0
NULL	0	0	0	0	1	0	0	0	0	0	0	*	0

Table 22: Blood Pooling - Frequency (Q32)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
1 - 25	1	2	1	1	7	0	0	0	0	2	0	*	0
26 - 50	0	1	0	0	2	0	0	1	0	0	0	*	0
51 - 200	1	0	0	0	11	1	2	0	1	0	0	*	0
201 - 500	1	0	0	0	3	0	1	1	0	0	0	*	0
>500	2	1	2	0	6	0	0	1	0	0	0	*	0
NULL	0	0	1	0	0	0	1	0	0	0	0	*	0

Section 5: Quality Improvement Processes

Table 23: Process in Place for Monitoring Deficiencies in Blood Activities (Q33)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	3	10	2	2	33	1	4	4	1	1	0	*	1
NO	2	2	1	2	5	0	1	0	0	2	1	*	0
NULL	0	0	0	0	1	0	0	0	0	0	0	*	0

Table 24: Process in Place for Implementing Changes to Blood Activities (Q33)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	5	10	2	2	33	1	4	4	1	1	1	*	1
NO	0	2	1	2	5	0	1	0	0	2	0	*	0
NULL	0	0	0	0	1	0	0	0	0	0	0	*	0

Table 25: Process in Place for Investigating Transfusion Related Errors and Accidents (Q33)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	5	12	3	3	39	1	5	4	1	1	1	*	1
NO	0	0	0	1	0	0	0	0	0	0	0	*	0

NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 26: Process in Place for Reporting Transfusion Related Errors and Accidents (Q33)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	5	12	3	4	39	1	5	4	1	1	1	*	1
NO	0	0	0	0	0	0	0	0	0	0	0	*	0
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 27: Process in Place for Investigating Adverse Transfusion Reactions (Q33)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	5	12	3	3	39	1	5	4	1	1	1	*	1
NO	0	0	0	1	0	0	0	0	0	0	0	*	0
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 28: Process in Place for Reporting Adverse Transfusion Reactions (Q33)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	5	12	3	4	39	1	5	4	1	1	1	*	1
NO	0	0	0	0	0	0	0	0	0	0	0	*	0
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0

Table 29: Process in Place for Investigating Serious Donor Events (Q33)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	3	8	1	2	22	0	3	1	1	2	1	*	0
NO	2	4	2	1	15	1	1	3	0	1	1	*	1
NULL	0	0	0	1	2	0	1	0	0	0	0	*	0

Table 30: Process in Place for Identifying, Investigating, Evaluating and Correcting Blood Related Errors and Accidents (Q34)

	BC	AB	SK	MB	ON	QC	NB	NS	PE	NL	YT	NT	NU
YES	4	12	3	4	38	1	5	4	1	3	0	*	1
NO	1	0	0	0	1	0	0	0	0	0	1	*	0
NULL	0	0	0	0	0	0	0	0	0	0	0	*	0