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CAN/CSA-Z900.1-17
National Standard of Canada

Cells, tissues, and organs for transplantation: General requirements

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National Standard of Canada

CAN/CSA-Z900.1-17

Cells, tissues, and organs for transplantation: General requirements

Prepared by

CSA Group

Approved by

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Contents

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Preface

This is the third edition of CAN/CSA-Z900.1, *Cells, tissues, and organs for transplantation: General requirements*. It supersedes the previous editions published in 2012 and 2003.

This Standard and its subset standards (which contain requirements for specific types of cells, tissues, and organs) are part of a series of management system standards and were developed from the work initiated by Health Canada's Expert Working Group on Safety of Organs and Tissues for Transplantation. See Annex A. The subset standards include the following:

- CAN/CSA-Z900.2.2, *Tissues for transplantation*;
- CAN/CSA-Z900.2.3, *Perfusable organs for transplantation*;
- CAN/CSA-Z900.2.4, *Ocular tissues for transplantation*; and
- CAN/CSA-Z900.2.5, *Lymphohematopoietic cells for transplantation*.

CAN/CSA-Z900.2.1, *Tissues for assisted reproduction*, although a part of the CAN/CSA-Z900 series, is a stand-alone standard and does not refer to the requirements in CAN/CSA-Z900.1.

Major changes to this edition include the following:

- The requirement for SOP review and approvals in Clause 6 has been changed from every year to every two years.
- Guidance on specific emerging diseases and pathogens has been introduced to help ensure users of this Standard refer to the most current information available at any given time.
- Annex E has been updated to include assessment on intranasal cocaine use.
- In Annex E, the deferral period for men having sex with men has been updated from 5 years to 12 months
- Additional clarification regarding the contraindications for HBV and HCV has been provided.

CSA Group gratefully acknowledges that the development of this Standard was made possible, in part, by the financial support of Health Canada.

This Standard was prepared by the Technical Committee on Safety of Cells, Tissues, and Organs for Transplantation and Assisted Reproduction under the jurisdiction of the Strategic Steering Committee on Health Care Technology & Systems, and has been formally approved by the Technical Committee. This Standard has been approved as a National Standard of Canada.

Notes:

1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*
2) *Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.*
3) *This Standard was developed by consensus, which is defined by* CSA Policy governing standardization — Code of good practice for standardization *as "substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity". It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this Standard.*
4) *To submit a request for interpretation of this Standard, please send the following information to inquiries@csagroup.org and include "Request for interpretation" in the subject line:*
   a) *define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;*
   b) *provide an explanation of circumstances surrounding the actual field condition; and*
   c) *where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.*

   Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are available on the* Current Standards Activities *page at* ***standardsactivities.csa.ca****.*

5) *This Standard is subject to review within five years from the date of publication. Suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to inquiries@csagroup.org and include "Proposal for change" in the subject line:*
   a) *Standard designation (number);*
   b) *relevant clause, table, and/or figure number;*
   c) *wording of the proposed change; and*
   d) *rationale for the change.*

CAN/CSA-Z900.1-17
Cells, tissues, and organs for transplantation: General requirements

0 Introduction

The principle of equal consideration of cells, tissues, and organs used for transplantation has been fundamental to the development of this Standard and its specific subsets, i.e., members of the Technical Committee with expertise in tissues, perfusable organs, ocular tissues, and lymphohematopoietic cells have an equal say in the development of the Standards.

This Standard is a dynamic document, and while it is intended to reflect current scientific knowledge, it does not obviate the need for users to be aware of state-of-the-art developments. Establishments are encouraged to submit suggestions for changes to this Standard during its lifetime as needed, e.g., to reflect scientific advances or to respond to emerging diseases.

Ethical considerations associated with the transplantation of cells, tissues, and organs are outlined in Annex B. It is acknowledged that donated cells, tissues, and organs are made available by individuals as an altruistic contribution to society.

1 Scope

1.1

This Standard specifies general requirements related to the safety of human cells, tissues, and organs used for transplantation, and includes quality system requirements. It includes aspects of safety for potential and actual donors and recipients, personnel, and others who might be exposed to or affected by the transplantation of cells, tissues, or organs.

1.2

This Standard applies to establishments and individuals involved in the following activities related to cells, tissues, and organs intended for transplantation:

a) processing;
b) evaluation of the safety of cells, tissues, and organs prior to transplantation;
c) transplantation procedures;
d) recordkeeping;
e) error, accident, and adverse reaction reporting;
f) distribution;
g) importation or exportation; and
h) complaints and recalls.

1.3

This Standard is intended to serve as a benchmark and provide minimum requirements for the verification of safe practices in each of the activities listed in Items a) to h) in Clause 1.2.

Note: *Examples of establishments or individuals include the following:*

a) *organ donation organizations;*

b) *tissue retrieval organizations;*
c) *tissue banks;*
d) *eye banks;*
e) *cell or tissue processing facilities;*
f) *cell culture laboratories;*
g) *histocompatibility laboratories;*
h) *transplant programs and facilities (e.g., hospitals and special clinics);*
i) *programs for lymphohematopoietic cells, including clinical programs, collection and processing facilities;*
j) *health care professionals;*
k) *designated importers and exporters;*
l) *distributors; and*
m) *other cell-, tissue-, and organ-dispensing services.*

1.4

This Standard and its subset Standards (i.e., the CAN/CSA-Z900 series) are not intended to replace detailed specifications and standard operating procedures, but are intended to be used in their preparation.

1.5

This Standard applies to human cells, tissues, and organs retrieved from a living or deceased human body and intended for transplantation into humans. The requirements for cells and tissues in this Standard are intended for minimally manipulated cells and tissues intended for homologous use (i.e., the cells or tissues perform the same basic function after transplantation).

Notes:

1) *Although the scope of this Standard refers to minimally manipulated cells and tissues, some of its requirements can also be relevant to other human cellular and tissue-based products.*
2) *It is recognized that the topics covered by this Standard can fall within more than one regulatory jurisdiction. Two specific topics covered by this Standard that are not within the current scope of Health Canada's* Safety of Human Cells, Tissues and Organs for Transplantation Regulations *are*
   a) *tissues such as heart valves and dura mater, which are classified by Health Canada as a medical device and are subject to the requirements of the Medical Devices Regulations. Users seeking to market heart valves will require a medical device license; and*
   b) *autologous tissue banking.*

1.6

This Standard does not apply to

a) tissues for assisted reproduction (see CAN/CSA-Z900.2.1);
b) human milk and other excreted or secreted substances;
c) whole blood (except for cord blood), blood components, or blood products; and
d) fecal transplantation.

Notes:

1) *For blood components (i.e., red blood cells, granulocytes, platelets, plasma, and cryoprecipitate) and blood products (i.e., therapeutic products derived from plasma), see CAN/CSA-Z902.).*
2) *CAN/CSA-Z900.2.5 includes specific requirements for cord blood.*

1.7

Subset standards have been developed for cells, tissues, and organs (see Clause 2). Where an applicable subset standard exists, this Standard is to be used in conjunction with that subset standard.

Note: *Where a subset standard exists and its requirements differ from this Standard's requirements, the subset standard's requirements apply.*

1.8

In this Standard, "shall" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the Standard; "should" is used to express a recommendation or that which is advised but not required; and "may" is used to express an option or that which is permissible within the limits of the Standard.

Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material.

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

Annexes are designated normative (mandatory) or informative (non-mandatory) to define their application.

2 Reference publications

This Standard refers to the following publications, and where such reference is made, it shall be to the edition listed below.

Note: *New or amended editions of these referenced publications can exist. The user might also wish to refer to such editions. Additional reference information and resources not directly referenced in this Standard can be found in Annex F.*

CSA Group

Z317.10-15
Handling of health care waste materials

CAN/CSA-Z900.2.1-17
Tissues for assisted reproduction

CAN/CSA-Z900.2.2-17
Tissues for transplantation

CAN/CSA-Z900.2.3-17
Perfusable organs for transplantation

CAN/CSA-Z900.2.4-17
Ocular tissues for transplantation

CAN/CSA-Z900.2.5-17
Lymphohematopoietic cells for transplantation

CAN/CSA-Z902-15
Blood and blood components

Health Canada

Canada Health Act, 1984

Food and Drugs Act and *Regulations*, SOR/2007-118
Safety of Human Cells, Tissues and Organs for Transplantation Regulations

Guidance Document for Cell, Tissue and Organ Establishments — Safety of Human Cells, Tissues and Organs for Transplantation. Health Products and Food Branch. June 18, 2013, revised August 26, 2013.

Hazardous Products Regulations, SOR/2015-17

IATA (International Air Transport Association)

Dangerous Goods Regulations, 2002

Transport Canada

Transportation of Dangerous Goods Act and Regulations SOR/85-77

Other publications

Cameron, J.S. and R. Hoffenberg. 1999. The ethics of organ transplantation reconsidered: Paid organ donation and the use of executed prisoners as donors. *Kidney International*, vol. 55:724–732.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. 1998 (2001). *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans.*

The Declaration of Istanbul on Organ Trafficking and Transplant Tourism. http://www.asn-online.org/policy/webdocs/the%20declaration%20of%20istanbul%20on%20organ%20trafficking.pdf

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.*

Ratcliffe-Richards, J.; A.S. Daar; R.D. Guttmann; R. Hoffenberg; I. Kennedy; M. Lock; R.A. Sells; and N. Tilney. 1998. The case for allowing kidney sales. Lancet, vol. 351:1950–1952.

Report of the Standing Committee on Health, House of Commons, Ottawa, April 1999: *Organ and Tissue Donation and Transplantation: A Canadian Approach.* Available at http://www.parl.gc.ca/Infocomdoc/36/1/HEAL/Studies/Reports/healrp05-e.hum#TOC

World Medical Association. *Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects.* Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 (fifth revision, amended by 52nd WMA General Assembly, Edinburgh, Scotland, October 2000).

World Health Organization. 2009. *Human organ and tissue transplantation*. Sixty-Second World Health Assembly, Provisional agenda item 12.10, March 26, 2009. http://apps.who.int/gb/ebwha/pdf_files/A62/A62_15-en.pdf

3 Definitions and abbreviations

3.1 Definitions

The following definitions shall apply in this Standard:

Accident — an unexpected event, not attributable to a deviation from standard operating procedures or applicable laws, that could adversely affect the safety of a transplant recipient or the safety, efficacy, or quality of cells, tissues, or organs.

Adverse reaction — an undesirable response in the recipient to transplanted cells, tissues, or organs, including the transmission of a disease or disease agent, for which there is a reasonable possibility that the response might have been caused by the cells, tissues, or organs (i.e., the relationship cannot be ruled out).

Notes:

1) *This definition aligns with Health Canada regulations for cells, tissues, and organs as therapeutic products, and therefore relates to recipient safety. Establishments dealing with living donors should also make provision for the investigation of potential and actual adverse events involving donors.*
2) *It is understood that transplantation of cells, tissues, or organs can have a number of effects on the recipient that could be seen as undesirable. In this definition, an "undesirable response" would be one that is either more severe than, or substantially different from, the expected response.*

Audit — a documented review of personnel functions, facilities, procedures, records, equipment, materials, and contract service facilities or suppliers to evaluate adherence to written standard operating procedures, this Standard, and applicable laws and regulations.

Autologous — describing cells or tissues from one human being, which are intended for transplantation into that same human being.

Banked — processed cells and tissues that have been determined safe for transplantation and that are stored by the source establishment in its inventory and available for distribution or transplantation.

Cadaveric blood — blood drawn following the cessation of cardiac function.

Cell — the fundamental biological unit of a human organism that is for use in transplantation.

Complaint — any written, oral, or electronic communication concerning a perceived problem with the quality, safety, identification, or performance of the cells, tissues, or organs, the establishment, or an individual.

Consent — a documented process whereby an individual receives the information he or she requires for making a decision on a proposed action, is given an opportunity to ask questions, and then decides whether or not to agree to the proposed action.

Note: *See Clause 10.*

Disinfection — a process, directed to a product (i.e., tissue), which reduces the number of viable cellular micro-organisms, but does not necessarily destroy all microbial forms, such as spores and viruses.

Note: *The use of antibiotics, while not normally described as disinfection, is included as a means of disinfection.*

Distribution — the transfer or shipment of cells, tissues, or organs from one establishment to another establishment or individual.

Note: *Distribution does not include transplantation.*

Distributor — an establishment or individual that transfers cells, tissues, or organs to another establishment or individual.

Note: *Distributors include cell, tissue, and organ processors and importers, as well as cell, tissue, and organ distributor intermediaries. The term does not include transplant establishments.*

Donor — a living or deceased person from whom cells, tissues, or organs are retrieved for use in a recipient.

Notes:

1) *This term also applies to autologous transplantation, in which the living donor is also the recipient.*
2) *In the case of cord blood, the infant is considered the donor. Any testing that is to be done on the birth mother is referred to as surrogate testing.*

Donor identification code — a unique numeric or alphanumeric designation assigned to a donor and that associates each cell, tissue, or organ donation, or part of one, to that donor.

Note: *The unique donor identification code is distinctly associated with each source establishment responsible for processing the cells, tissues, or organs.*

Donor screening — an evaluation based on the donor's medical and social history and physical examination, the results of any diagnostic procedures performed, and, if applicable, the autopsy.

Donor suitability assessment — an evaluation to determine the suitability of a specific individual for cell, tissue, or organ donation based on donor screening and donor testing.

Donor testing — the laboratory tests and measurements done on a donor or donor specimen to determine

a) whether the donor has or ever had a transmissible disease or is or ever was infected with a transmissible disease agent;
b) donor compatibility; and
c) the degree of functionality of the cell, tissue, or organ that is to be retrieved.

Note: *The specific measurements or tests used to establish the level of functionality, if any, will depend on the type of cells, tissues, or organs being processed.*

Error — a deviation from the standard operating procedures or applicable laws that could adversely affect the safety of a transplant recipient or the safety, efficacy, or quality of cells, tissues, or organs.

Establishment — a person, a partnership, or an unincorporated entity, or a part of any of them, that carries out any of the following activities in respect of cells, tissues, or organs:

a) importation;
b) processing;
c) distribution; and
d) transplantation.

Exceptional distribution — the distribution to a transplant establishment of cells, tissues, or organs that do not meet the release criteria specified in SOPs, including but not limited to those obtained from a donor for whom the donor suitability assessment identified an increased risk for disease transmission.

Expiration date — the date after which cells or tissues are no longer suitable for use.

Exterior label — the label that is affixed to the exterior package.

Exterior package — the outermost package in which a cell, tissue, or organ is delivered, transported, or shipped.

Note: *Delivery, transportation, or shipping can take place between facilities or within a single facility or complex.*

Graft — cells, tissues, or organs prepared for use in transplantation.

Interior label — the label that is affixed to the interior package.
Note: *The interior label is usually affixed to a non-sterile surface on the innermost package.*

Licensed — with regards to test kits, meeting the requirements of the authority having jurisdiction.
Note: *In Canada, test kits are licensed by Health Canada. Test kits licensed by the US Food and Drug Administration are currently recognized by Health Canada as acceptable for use in Canada.*

Lymphohematopoietic cells — cells of lymphematopoietic origin, independent of their original source.

Medical director — a physician or dentist who meets applicable requirements for the practice of medicine or dentistry and who is responsible for the application of the standard operating procedures and for all medical or dental procedures.
Note: *Applicable requirements are defined in provincial/territorial regulations.*

Next of kin — a person authorized to consent to medical treatment or donation on behalf of another, as determined by applicable requirements.
Note: *Federal or provincial/territorial laws and regulations can apply.*

Ocular tissue — human cornea, sclera, or whole globe used or intended for use in transplantation.

Organ — see **Perfusable organ**.

Organ donation organization (ODO) — the source establishment with the responsibility for the facilitation of organ donation, retrieval, and distribution.
Notes:
1) *The term "organ donation organization (ODO)" is used in this Standard in place of the term "organ procurement organization (OPO)".*
2) *The activities of an ODO include, but are not limited to,*
   a) *receiving referrals of organs for donation;*
   b) *collecting the information necessary to determine the suitability of the donor and his or her organ(s);*
   c) *offering the organ(s) to the appropriate transplant program;*
   d) *coordinating the retrieval of the organs;*
   e) *preserving, storing, transporting, releasing, and delivering the organs to the transplant program; and*
   f) *documenting this process.*
3) *ODO services can include research activities.*
4) *Tissue donation organizations can fulfill the same responsibilities as ODOs.*

Package insert — the document that is prepared by the source establishment to accompany a cell, tissue, or organ.

Perfusable organ — a human organ for use in transplantation, whether whole or in parts, and whose specific function is intended to return after revascularization and reperfusion. It includes any adjunct vessels that are retrieved with the organ for use in organ transplantation.
Note: *Examples of perfusable organs include, but are not limited to,*
a) *the whole heart (as distinct from heart valves);*
b) *kidneys;*
c) *liver;*
d) *lungs;*
e) *the pancreas and islet cells;*
f) *stomach; and*
g) *small intestine, including the duodenum.*

Plasma dilution — the dilution of the donor's plasma volume by infusion of blood products, colloids, or crystalloids.

Preservation — the use of chemical agents, alterations in environmental conditions, or other means during processing to prevent or retard biological or physical deterioration of cells, tissues, or organs.

Processing — in respect of cells, tissues, and organs, any of the following activities:
a) donor screening;
b) donor testing;
c) donor suitability assessment;
d) retrieval;
e) testing and measurements performed on the cells, tissues, or organs after they are retrieved;
f) preparation for use in transplantation;
g) preservation;
h) quarantine;
i) storage (including banking); and
j) packaging and labelling.

Qualification — a documented process using tests, observations, and challenges to confirm that equipment and systems are properly installed and configured, and are operating in accordance with specifications.

Notes:
1) *As opposed to validation, which is generally part of a design process, qualification applies to actual systems and equipment used in the establishment and is used to confirm they are working as they were designed to do.*
2) *See also **Validation**.*

Qualified — as applied to equipment or systems, documented as being properly installed and configured, and operating in accordance with specifications.

Quality assurance (QA) — the actions that are planned and performed to provide confidence that all systems and elements that influence the quality of the facility's products and services are working as expected, individually and collectively.

Quality control (QC) — the routine testing of materials, equipment, and cells, tissues, and organs to ensure their specifications are met.

Note: *Quality control can also be applied to systems and processes.*

Quality management — coordinated activities to direct and control an organization with regard to quality.

Quality system — the organizational structure, responsibilities, procedures, instructions, processes, and resources involved in the implementation of quality management.

Quarantine — the identification and removal from usable inventory of cells, tissues, and organs that are not suitable for use or that have not yet been determined safe for use.

Note: *Quarantine includes storage in an area clearly identified for controlled sequestration and other procedures that prevent the release of such cells, tissues, and organs.*

Recipient — any individual who receives a cell, tissue, or organ transplantation.

Retrieval — collection or dissection and surgical removal of cells, tissues, or organs.

Scientific director — an individual who is responsible for the application of the standard operating procedures and for all technical procedures.

Source establishment —

a) in the case of an organ from a deceased donor, the relevant organ donation organization;
b) in the case of adjunct vessels that are retrieved with an organ and not used immediately in the organ transplantation, the relevant tissue bank, organ donation organization, or transplant establishment;
c) in the case of an organ from a living donor or lymphohematopoietic cells that are not banked, the relevant transplant establishment;
d) in the case of tissues or banked lymphohematopoietic cells, the relevant cell or tissue bank; and
e) in the case of islet cells, the establishment that prepares the cells for use in transplantation.

Note: *The source establishment is responsible for the processing of cells, tissues, and organs, and ultimately responsible for determining the safety of the cells, tissues, and organs for transplantation.*

Standard operating procedures (SOPs) — the component of the quality assurance system that comprises instructions that set out the processes and procedures to follow in carrying out the activities of an establishment.

Test result — the outcome of a screening test or diagnostic test on a specimen as interpreted using the testing algorithms provided by the manufacturer's package insert.

Confirmed positive test result — the outcome of a confirmatory or supplemental test in which the tested specimen is determined to be reactive for the disease or condition being tested for.

Note: *Some manufacturers use the terms "positive" and "negative" rather than "reactive" and "nonreactive" in their package inserts.*

Indeterminate test result — the outcome in which the tested specimen produces a result that is neither reactive nor nonreactive.

Negative test result — the outcome in which the tested specimen is determined to be nonreactive.

Positive test result — the outcome in which the tested specimen is determined to be reactive to the test.

Tissue — a functional group of cells for use in transplantation. Tissues can be transplanted as viable cells or otherwise preserved or fixed.

Notes:

1) *Tissues currently used for transplantation in Canada include the following:*
   a) *skin: full, partial, and split-thickness skin grafts;*
   b) *pericardium;*
   c) *adipose tissue;*
   d) *cardiovascular tissues: veins, aortic and pulmonic conduits, arteries;*
   e) *connective tissues (e.g., fascia);*
   f) *amniotic tissues;*
   g) *[placeholder — deleted item];*
   h) *musculoskeletal tissues: bone and bone parts, cartilage structures, tendons, joints and joint surfaces, ligaments, morselized bone, demineralized bone, freeze-dried bone, and muscle flaps;*
   i) *[placeholder — deleted item];*
   j) *ocular tissues: cornea and sclera, limbal tissues;*
   k) *[placeholder — deleted item]; and*
   l) *[placeholder — deleted item].*
2) *Tissue does not include perfusable organs for transplantation.*

3) *Cells and tissues that are altered or extensively manipulated, or are intended for non-homologous use, can be subject to laws and regulations other than the* Safety of Human Cells, Tissues, and Organs for Transplantation Regulations*.*

Tissue bank — an establishment that provides or engages in one or more services involving cells or tissues from living or deceased individuals for transplantation.

Note: *Tissue bank services can include research activities.*

Transplantation — the transfer of cells, tissues, and/or organs to a recipient.

Transplant establishment — the establishment responsible for the transplantation of cells, tissues, and/or organs.

Validation — the documented act of demonstrating that a procedure, process, analytical method, or piece of equipment will consistently produce the expected result.

Notes:

1) *Validation is generally used during the design of systems, processes, methods, or equipment to confirm that they will consistently do what they are intended to do.*
2) *See also* ***Qualification****.*

Verification — the confirmation by examination and provision of objective evidence that specific requirements have been fulfilled.

3.2 Abbreviations

The following abbreviations shall apply in this Standard:

CGS — Canadian General Standard

CJD — Creutzfeldt-Jakob disease

EWG — Expert Working Group

HBV — hepatitis B virus

HCV — hepatitis C virus

HIV — human immunodeficiency virus

HTLV — human T-cell lymphotropic virus

NAT — nucleic acid test

ODO — organ donation organization

QA — quality assurance

QC — quality control

SOP — standard operating procedure

4 Establishment requirements

4.1 Establishment identity

4.1.1

Each establishment shall have a unique identifier (e.g., establishment name and address) to enhance tracking capability as well as communication.

Note: *For a source establishment or distributor, this unique identifier may be the Health Canada registration number.*

4.1.2

The purpose of the establishment shall be clearly described and documented.

4.1.3

The establishment shall have a clear organizational structure and clear delegation of authority and responsibility.

4.1.4

The organizational, reporting, and accountability structure shall be documented. The documentation shall include the technical, quality, and medical structures.

4.1.5

The affiliations, governing board, and policy-making authority of the establishment shall be clearly described and documented. Documentation should include the names and addresses of all affiliations of the establishment, the agreements and contracts defining activities to be performed, and the personnel responsible for compliance with this Standard and for performing audits or using other means to verify that these entities are in compliance with this Standard.

4.2 Personnel

4.2.1 General

4.2.1.1

Qualified and experienced personnel, as defined in the standard operating procedures (SOPs), shall be available to carry out required procedures. They shall have the skills, experience, educational background, training, and necessary authority to perform their duties properly and safely, and to ensure that quality assurance (QA) activities are carried out.

4.2.1.2

Documentation of personnel qualifications shall be maintained as part of the personnel record.

4.2.1.3

Each establishment shall be capable of providing the necessary resources to support its administrative staff, technical staff, quality staff, health care professionals, and medical directors, including the following:

a) infrastructure;
b) fiscal resources; and

c) continuing education.

4.2.2 Training

4.2.2.1

There shall be a training file for technical staff, quality staff, and medical directors. All training activities shall be documented in this file, and the file shall be retained for at least ten years after the termination of employment or as specified in applicable requirements, whichever is longer.

Note: *Federal and provincial/territorial regulations can apply.*

4.2.2.2

There shall be a documented orientation and training program for new personnel to ensure that they understand, and can properly and safely perform, their assigned duties.

4.2.2.3

Personnel orientation and ongoing training shall be described in the SOPs. Ongoing training shall be provided to all technical staff, quality staff, and medical directors to

a) ensure familiarity with this Standard and applicable laws and regulations;
b) maintain competency in the activities they perform pertaining to cells, tissues, and organs for transplantation; and
c) ensure familiarity with safety precautions and procedures.

4.2.2.4

The competency of personnel in the performance of their assigned duties shall be assessed following training and documented at regular and routine intervals thereafter, as established by the SOPs. Assessment of the competency of personnel regarding the procedures they perform and the corrective actions to be implemented for poor performance shall be documented in the SOPs.

A competency assessment program should evaluate the theoretical and practical knowledge of the procedures, and should include, but not be limited to,

a) direct observation of performance;
b) monitoring of recording and reporting;
c) written tests to assess problem-solving skills; and
d) assessment of knowledge of operating procedures and theory.

4.2.3 Medical and scientific directors

4.2.3.1

Establishments that provide health care or dental care, or are involved in processing cells, tissues, or organs, shall have a medical director and scientific director.

Note: *The medical director may be the same person as the scientific director.*

Establishments that do not provide health care or dental care and are not directly involved in processing cells, tissues, or organs (e.g., importers or distributors) shall have either a medical director or a scientific director. If the establishment does not have a medical director, it shall have an arrangement in place whereby it can obtain medical advice when needed from a licensed physician meeting the requirements of Clause 4.2.3.3).

4.2.3.2

The medical director or scientific director shall have full authority and responsibility for the application and audit of this Standard and the applicable subset Standards, and for compliance with applicable laws and regulations.

4.2.3.3

The medical director shall be a licensed physician, qualified by training and experience relevant to the activities of the establishment. The medical director shall pursue continuing education relevant to those activities.

Documentation of the licensing, training, qualifications, and education of the medical director shall be maintained as part of the establishment personnel records.

4.2.3.4

The scientific director shall be a person qualified by training and experience relevant to the activities of the establishment. The scientific director shall pursue continuing education relevant to those activities.

Documentation of the training, qualifications, and education of the scientific director shall be maintained as part of the establishment personnel records.

4.2.3.5

The medical director shall be ultimately responsible for the following:

a) all medical or dental procedures performed by the establishment;
b) the acceptance of cells, tissues, or organs, including exceptional distribution where appropriate (see Clause 18.4); and
c) the investigation, with appropriate notification and reporting, of adverse reactions (see Clause 19); and
d) the processing of cells, tissues, and organs in compliance with this Standard.

4.2.3.6

The medical director or scientific director shall be ultimately responsible for the following:

a) the formulation and implementation of the SOPs in accordance with Clause 6;
b) adequate staffing of the establishment with personnel qualified for the functions they perform;
c) the investigation, with appropriate notification and reporting, of errors, accidents, complaints, and recalls (see Clause 19);
d) the performance and documentation of audits; and
e) compliance with the SOPs.

4.2.3.7

The medical director or scientific director may delegate responsibilities to qualified persons within the establishment, in accordance with the SOPs.

4.2.3.8

An establishment with multiple locations may centralize the role of a medical director or scientific director, provided that

a) the medical director or scientific director retains responsibility for the functions listed in this Clause, even if he or she does not necessarily perform them; and

b) this person can be reached from any of the locations if a medical or scientific decision is needed.

Note: *This requirement is meant to ensure an unbroken chain of responsibility for all aspects of cell tissue and organ processing and use. It is understood that for some establishments, such as distribution facilities, it would be impractical to expect a medical director or scientific director onsite at each location.*

4.3 Quality management

4.3.1 Quality assurance system

4.3.1.1

The establishment shall have a quality assurance (QA) system to ensure that all policies, procedures, processes, products, and services of the establishment conform to the SOPs, this Standard, and applicable requirements. The QA system shall include quality control (QC) functions and ongoing monitoring of all aspects of the operation.

Notes:

1) *The QA system may be maintained by the establishment, its parent organization (e.g., the hospital where a transplantation unit is located), or another supporting organization.*
2) *Federal and provincial/territorial regulations can apply.*

4.3.1.2

All aspects of the QA system shall be documented. Documentation shall include the measures taken, the deficiencies identified, and any corrective or remedial action implemented.

4.3.1.3

The records of the QA activities shall be maintained by the establishment for a minimum of ten years or as specified in applicable requirements. These records shall be available to authorized individuals for inspection on request.

Note: *Federal and provincial/territorial regulations can apply.*

4.3.1.4

Cells, tissues, and organs shall be processed, preserved, and distributed in accordance with the SOPs.

4.3.2 Quality control

4.3.2.1

The QC functions shall be documented in the SOPs and should include, but not be limited to,

a) environmental monitoring (e.g., work surfaces, air sampling) at intervals specified in the SOPs;
b) reviewing of equipment-monitoring records (e.g., storage units) and records of processing functions (e.g., test results) with specified tolerance limits to ensure tolerance limits are maintained;
c) periodic inspection and/or monitoring of equipment, facilities, in-process control test results, and laboratory performance, and documentation of the inspection;
d) periodic calibration of equipment;
e) monitoring to verify that products and services provided by contract suppliers meet specifications and all other requirements in the SOPs, this Standard, and applicable requirements;

   Note: *Federal and provincial/territorial regulations can apply.*

f) monitoring the storage conditions and/or expiration dates of reagents and supplies;

g) periodic QC testing of culture media prepared by the establishment to ensure sterility and ability to support the growth of bacteria and fungi; and
h) when appropriate and applicable,
    i) testing of representative samples for bacterial contamination; and
    ii) evaluating representative samples to ensure that they meet specifications.

4.3.2.2

The SOPs shall describe the elements to be monitored or tested, the tests and procedures to be employed, the personnel responsible for performing the procedure, the tolerance limits, and the corrective actions to be taken when results and measurements fall outside acceptable limits.

4.3.2.3

The results of all tests or procedures, together with the evaluations based on the results, shall become part of the permanent record of all cells, tissues, or organs processed.

4.3.3 Process control

4.3.3.1

All establishments shall develop and maintain quality assurance protocols to
a) ensure that technical procedures, processes, analytical methods, and equipment are validated, unless the results can be systematically verified by subsequent inspections or tests, or both, either by
    i) evaluating existing validation reports from suppliers; or
    ii) validating these elements in-house using established validation procedures; and
b) qualify essential equipment and systems within their operation.

These procedures shall be documented.

Note: *Validation tests and procedures may be developed by the establishment. Alternatively, they may be*
a) *adopted from standards developed by recognized professional organizations; or*
b) *based on established practice and supported by information available in the scientific literature.*

4.3.3.2

Protocols shall be developed for validation of processing activities, including shipping. Procedures shall also be developed for the qualification of the establishment and equipment and for the validation of labels, reagents, supplies (e.g., packaging material), and computer systems.

4.3.3.3

All processes shall be validated prior to implementation. The processes shall be revalidated whenever significant changes are made in the method or material being analyzed and when deviations from a validated process occur. These activities shall be documented.

4.3.3.4

The establishment shall ensure that computer systems are designed to prevent errors in data entry and retrieval. Backup files should be maintained of all data entered into a computer. Access to computer systems shall be limited to authorized personnel.

4.3.3.5
There shall be ongoing monitoring and evaluation of activities, identification of quality incidents, and the development of plans for corrective action.

4.3.4 Audits

4.3.4.1
The establishment shall establish policies and procedures for audits. Audits shall be conducted at least every two years. The scope and frequency of the audits shall be documented in the SOPs and shall include all major components of the establishment's operation (e.g., processing, evaluation, recordkeeping, error, accident, and adverse reaction reporting, distribution, importation or exportation, complaints, and recalls of cells, tissues, and organs).

4.3.4.2
Audits shall be performed by an independent QA unit or trained personnel who do not have direct responsibility for the processes being audited. The QA unit or trained personnel shall have the appropriate qualifications and the necessary authority to ensure that quality measures are employed by the establishment and that the requirements of the SOPs, this Standard, and applicable laws and regulations are implemented. The QA unit or trained personnel shall be authorized to evaluate quality problems, initiate or recommend corrective actions, accept or reject cells, tissues, or organs, and discontinue processing of cells, tissues, or organs.

4.3.5 Investigations

4.3.5.1
Designated personnel shall investigate and document all errors, accidents, and adverse reactions, complaints, and recalls. The documentation shall include the nature of the event, the corrective actions recommended and implemented, the date, and the personnel involved.

4.3.5.2
The medical director shall review all serious error, accident, and adverse reaction reports, and shall ensure that any necessary corrective actions are taken and documented. The QA unit, in conjunction with the medical director, shall approve corrective actions prior to implementation.

4.3.5.3
Files on error, accident, and adverse reaction reporting shall be available for review by site inspectors at the time of inspection and shall be kept for a minimum of ten years or in accordance with applicable requirements.

Note: *Federal and provincial/territorial requirements can apply.*

4.3.5.4
All positive test results for transmissible diseases in the recipient, where the positive test result is attributed to cell, tissue, or organ transplantation, shall be reported in writing in a timely fashion to all the establishments and physicians involved in any manner with the cells, tissues, or organs retrieved from the same donor, and to public authorities in accordance with applicable requirements. Notification shall be documented in the donor's records.

Note: *Federal and provincial/territorial requirements can apply.*

4.3.6 Personnel training

The QA unit or trained personnel shall evaluate the training of personnel to ensure that all staff are trained to perform their duties properly and re-trained when the SOPs, this Standard, and applicable laws and regulations are amended.

5 Facilities

5.1 General

5.1.1

Each establishment shall have sufficient space to handle its workload with optimal accuracy, efficiency, sterility, timeliness, and safety as required by this Standard.

5.1.2

Each establishment shall be designed to accommodate and adequately support the procedure(s) to be performed and shall provide the necessary space for recordkeeping and secure storage of documents and samples.

5.1.3

The physical design and construction of the establishment shall

a) be of materials that permit efficient cleaning and maintenance of the premises;
b) have all work areas organized in a manner that ensures safe and logical workflow;
c) provide adequate, clean, and easily accessible hand hygiene facilities for personnel and, where applicable, the donor;
d) dedicate an area for interviews (where applicable) to ensure privacy; and
e) include adequate space for critical procedures to prevent errors and cross-contamination.

5.1.4

Each establishment shall be maintained in a clean and sanitary manner. Each establishment shall establish cleaning and disinfection procedures that detail the areas to be cleaned and/or disinfected, the frequency of cleaning and/or disinfection, and the chemicals to be used for facility cleaning and/or disinfection.

5.2 Security

5.2.1

Establishments should be secure against entry of unauthorized personnel.

A source establishment, importer, or distributor of cells, tissues, or organs shall control access to all areas where its activities are carried out.

5.2.2

The SOPs shall describe the special precautions to be taken to monitor and restrict the activities of unauthorized personnel.

5.2.3
Each establishment shall ensure that its document storage space is secure and that procedures are in place to safeguard records and electronic data against theft, fire, and flood. Electronic records shall be backed up on a regular basis and the backup files stored at a separate location.

5.2.4
Procedures shall be established to ensure access to electronic records is in accordance with applicable requirements and to prevent unintended or unauthorized disclosure.

Note: *In Canada, privacy issues are addressed by the* Personal Information Protection and Electronic Documents Act *(PIPEDA).*

5.2.5
Procedures shall be established to safeguard the integrity of electronic records in the event of equipment failure.

5.2.6
Procedures shall be in place at each establishment to ensure the security and safety of the cells, tissues, and organs inventory in the event of equipment or power failure (e.g., emergency power supply).

5.3 Equipment

5.3.1
Each establishment shall have sufficient equipment to enable it to conduct its activities related to the scope of this Standard, under the anticipated workload, with optimal accuracy and efficiency.

5.3.2
Equipment used in the processing of cells, tissues, and organs shall be designed, manufactured, and validated for appropriate cleaning, sterilization, and usage. Equipment shall be constructed with materials that do not react with or absorb reagents, cells, tissues, or organs with which they come in contact. Installed equipment shall be qualified before use on cells, tissues, or organs.

5.3.3
Designated personnel shall maintain appropriate maintenance, certification, and calibration records for each piece of equipment. These records shall show dates of inspection, performance evaluations, and any maintenance procedures or repairs performed.

5.3.4
Equipment records shall be retained in accordance with the establishment's recordkeeping requirements, or for at least ten years, whichever is longer, or as specified by applicable requirements.

Note: *Federal and provincial/territorial regulations can apply.*

5.3.5
Designated personnel shall routinely clean, disinfect, and/or sterilize equipment.

5.3.6
Equipment utilized to sterilize materials used in the processing of cells, tissues, and organs shall be designed, qualified, maintained, and used in a way that ensures the sterility of the materials.

5.3.7
The monitoring, inspection, maintenance, calibration, and cleaning procedures and schedules for each piece of equipment shall be described in the SOPs (see Clause 6).

5.3.8
Refrigerators and freezers shall be inspected on a regularly scheduled basis as described in the SOPs and shall be equipped with verifiable methods for proper temperature monitoring. Temperatures shall be recorded at defined intervals (as defined by the SOPs).

5.3.9
Designated personnel shall requalify and recalibrate equipment after repairs or system upgrades that could affect the performance of the equipment.

6 Standard operating procedures

6.1 General

6.1.1
Each establishment shall maintain SOPs that deal with all aspects of the following as they apply to its activities and scope of responsibility:
a) processing;
b) evaluation;
c) recordkeeping;
d) error, accident, and adverse reaction reporting;
e) distribution, importation, or exportation; and
f) complaints and recalls of cells, tissues, and organs.

6.1.2
The SOPs shall be prepared by a knowledgeable person(s) and shall be dated and signed by an authorized person.

6.2 Format
The SOPs should indicate or include the following:
a) the name and unique identifier of the establishment;
b) the title and purpose of the procedure;
c) the unique code identifying the document and indicating revision(s);
d) the date that the SOPs became effective and the date(s) that they were revised;
e) the signature of the authorizing person(s) and the date of authorization;
f) on each page, the page number (of the total number of pages);
g) a clear outline of steps and instructions to be followed in the described procedure [which shall match the details in the processing records (e.g., worksheets, forms, or computer screens)]; and
h) staff categories responsible for performing all or part of the steps in the SOPs.

Note: *Electronic signatures and dates are acceptable for SOPs that are approved and maintained electronically.*

6.3 Content

6.3.1 Facilities, equipment, and personnel

The SOPs shall include policies or standard procedures, or both, where relevant and appropriate, in the areas of

a) facilities, equipment, and personnel, including
   i) training programs for technical and QA staff;
   ii) facility maintenance, cleaning, and medical and hazardous waste disposal;
   Note: *See CSA Z317.10.*
   iii) emergency safety procedures; and
   iv) equipment maintenance, calibration, and qualification;
b) infection prevention and control, including
   i) verification of the effectiveness of sterilization/disinfection of reusable medical devices; and
   Note: *In medical device reprocessing, verification is performed to ensure that the sterilization or disinfection process used in the health care facility is consistent with the manufacturer's instructions for reprocessing, and by extension, with the sterilization or disinfection process that has been validated by the manufacturer.*
   ii) monitoring of environmental and microbiological conditions, such as the QC procedures used for controlling, testing, and verifying environmental and microbiological conditions;
c) laboratory processes and materials, including
   i) specifications for materials used, including reagents, storage media, and packaging materials;
   ii) retrieval and storage of blood specimens for laboratory tests; and
   iii) transfer of samples to contract facilities for laboratory testing and the receipt, review, and interpretation of test results; and
d) administrative and organization responsibilities, including
   i) recordkeeping (including electronic and manual data), retrieval, and analysis;
   ii) handling requests for cells, tissues, and organs for research;
   iii) a description of manual methods for establishment activities in the event of computer failure or equipment malfunction; and
   iv) maintenance of copies of publications cited in support of the policies and procedures.

6.3.2 Donor selection

The SOPs shall include policies or standard procedures, or both, where relevant and appropriate, for donor selection processes, including

a) donor suitability assessment (including documents related to donor screening, donor acceptability, and ineligibility criteria);
b) donor consent; and
c) notification of positive test results.

6.3.3 Activities related to cells, tissues, and organs

The SOPs shall include policies or standard procedures, or both, where relevant and appropriate, for

a) processing, release, and distribution/shipment of cells, tissues, and organs, including
   i) physiological, histological, and physical test specifications for cells, tissues, and organs;
   ii) determination of the optimal storage temperature of cells, tissues, and organs, and shipping conditions;
   iii) assigning expiration dates;
   iv) determination of package insert and/or interior and exterior label text;
   v) QA/QC for supplies, equipment, reagents, and processes; and
   vi) defining criteria for exceptional distribution of cells, tissues, and organs; and

b) reporting, investigation, and recall, including
   i) error, accident, and adverse reaction reporting and establishing where to report these events;
   ii) investigation of complaints and notification and documentation of follow-up to noncompliance with the SOPs;
   iii) complaints and recall of unacceptable cells, tissues, and organs; and
   iv) donor-recipient tracking.

6.4 Approvals and reviews

6.4.1

Every two years, procedures in the SOPs shall be reviewed by a knowledgeable person(s), revised as appropriate by a knowledgeable person(s), and approved by an authorized person.

6.4.2

Approvals and reviews of the SOPs shall be indicated by the dated signatures of authorized personnel. Personnel affected by new or revised SOPs shall indicate that they have read, understood, and signed off on the SOPs prior to performing its procedures.

Note: *Electronic signatures and dates are acceptable for SOPs that are approved and maintained electronically (e.g., quality management).*

6.4.3

All SOPs of a medical nature shall be reviewed every two years reviewed by the medical director and this review shall be documented.

6.4.4

Handwritten changes may be made temporarily when needed for immediate clarification or correction. The changes shall be initialled and dated by an authorized person. The SOPs should be revised within 30 days of the date of change.

6.4.5

The issuance of the SOPs and any changes shall be controlled by a documentation system that ensures that the SOPs are current and authorized.

6.5 Extra copies

Copies of the SOPs shall be available to all personnel and to authorized individuals for inspection on request.

6.6 Archives

Obsolete SOPs shall be archived for at least ten years.

7 Records and tracking

7.1 General

7.1.1
Records shall be confidential, accurate, complete, legible, and indelible.

Note: *Federal and provincial/territorial regulations on privacy and confidentiality of information can apply.*

7.1.2
Records may be maintained in paper or electronic form.

Note: *See Clause 5.2 regarding the maintenance and security of records and record systems.*

7.1.3
All entries shall be signed and dated by the person performing the activity documented in the records.

7.1.4
The establishment's records shall contain copies of any agreements between the establishment and its affiliates.

7.1.5
The records shall contain documentation of personnel qualifications, training, and competency.

7.1.6
The records of a source establishment shall be able to provide a complete history of each donated cell, tissue, or organ and shall cover all activities from consent and donor suitability assessment to the final disposition of the cells, tissues, or organs.

7.1.7
The records shall be held in an area that is secure against the entry of unauthorized persons.

7.1.8
Designated personnel, as defined in the SOPs, shall be responsible for all activities pertaining to records and tracking described in this Standard.

7.2 Donor identification

7.2.1
A source establishment shall assign a unique donor identification code to each donor of a cell, tissue, or organ for which it has responsibility. This code shall be linked to all donor tests, records, archived samples, and QC specimens (if applicable).

7.2.2
Each establishment shall ensure that the donor identification code is a component of their traceability system, which will allow the tracking of all cells, tissues, and organs from donor to recipient and back to the donor again.

7.2.3

The unique donor identification code and type of cell, tissue, or organ shall be recorded in the recipient's transplant/medical/dental record.

7.2.4

Prior to initiation of cell, tissue, or organ retrieval, staff shall verify the identity of the donor with the name stated on the consent or donation authorization form. This verification shall be documented in the donor record prior to retrieval.

7.3 Recordkeeping

7.3.1

The source establishment shall maintain records with respect to cells, tissues, and organs that it processes that contain at least all of the following information:

a) the donor identification code;
b) documentation showing completion of the donor suitability assessment;
c) a description of the cells, tissues, and organs retrieved from the donor;
d) documentation of donor testing for infectious disease;
e) documentation of notification of referrals, processing, and distribution;
f) the test results and interpretation of the test results;
g) a complete history of the work performed to enable tracking of records to the particular cells, tissues, and organs involved;
h) the reagents that came into contact with the cells, tissues, or organs during preparation, the concentrations used, and the acceptable residual amount of reagent, where applicable;
i) for each phase of the process, the date and the name of personnel involved;
j) documentation of the destruction or other disposition of unsuitable or unused cells, tissues, or organs;
k) if applicable, the name of any source establishment from which it received a donor referral or to which it made a donor referral;
l) the name of the retrieval establishment;
m) documentation of all processing activities;
n) the notice of exceptional distribution, if any; and
o) documentation of any reported errors, accidents, and adverse reactions and their investigation, if any, in connection with cells, tissues, or organs retrieved from the donor that it banked or distributed and any corrective action taken.

7.3.2

The transplant establishment shall keep records with respect to cells, tissues, and organs that it transplants that contain at least all of the following information:

a) a description of the transplanted cells, tissues, or organs;
b) the donor identification code;
c) the registration number of the source establishment;
d) the notice of exceptional distribution, if any, and confirmation that the donor suitability assessment was completed;
e) information that allows the identification of the recipient; and
f) documentation of any errors, accidents, and adverse reactions and their investigation in connection with those cells, tissues, or organs and any corrective action taken.

7.3.3
All manual transcription of test results shall be independently verified.

7.3.4
Any correction, entry of information, or notation made after the original date that a manual or electronic record was completed shall be initialled or signed and dated in such a way as to permit the reading of the original information. When significant changes are made (i.e., other than editorial corrections), the reason for the change shall also be recorded.

7.3.5
All donor records, as described in Clause 7.3.1, shall be maintained for a minimum of ten years or in accordance with applicable requirements. Provisions shall be made for collecting updated living donor information and for the maintenance of records when an establishment is closed or merged. The record of destruction shall be traceable.

Note: *Federal and provincial/territorial requirements can apply.*

7.4 Tracking

7.4.1
Records shall be

a) accessible for inspection by authorized personnel from accreditation programs, regulatory authorities, and programs involved with the facility; and
b) maintained in a manner to preserve their integrity.

7.4.2
Each establishment involved in the processing or distribution of cells, tissues, or organs shall have a unique identifier that allows for the tracking of cells, tissues, or organs from the donor source to the recipient and vice versa, and, if applicable, the tracking of archived serum samples and QC specimens to the donor. All establishments handling the cells, tissues, or organs shall ensure that their donor identification code can be linked to the donor identification code of the establishment from which it acquired the cells, tissues, or organs.

7.4.3
Each establishment involved in transferring or distributing cells, tissues, or organs to other establishments shall have mechanisms in place to ensure communication between itself and those establishments for the purpose of tracking cell, tissue, or organ donations from the donor to the next establishment in the chain of distribution, as well as notification of referrals and recall. Establishments shall have mechanisms in place to permit the tracking of all recipients of cells, tissues, and organs retrieved from a single donor.

7.4.4
Each establishment involved in the transplantation of cells, tissues, and organs shall

a) keep records of the date of transplant and outcomes; and
b) be able to identify the link to the recipient by a unique identification code.

7.4.5
Establishments where patients are treated shall keep accurate records of

a) the distribution of all cells, tissues, and organs, in accordance with the donor identification code;

b) the type of cells, tissues, or organs;
c) the personnel involved in procedures; and
d) the identification of the recipient.

8 Infection control and safety

8.1 Safety procedures

8.1.1

Safety precautions and procedures for maintaining a safe work environment shall be included in the SOPs and these shall conform to applicable requirements.

Note: *Federal and provincial/territorial occupational health and safety regulations can apply.*

8.1.2

Procedures shall be developed for biological, chemical, and radiation safety. Hazardous material training shall be offered to personnel to familiarize them with procedures for handling, using, and storing hazardous materials and for cleaning biohazard spills. Personnel training shall also include management of worker injury and the use of personal protection devices.

8.2 Routine practices and additional precautions

8.2.1

Routine practices and additional precautions shall be implemented and enforced to reduce the potential exposure of personnel to communicable diseases.

8.2.2

The establishment shall take measures to minimize the risk of injury and infection due to sharps and needle sticks. These shall include the following, appropriate to the activities and risks present in the establishment:

a) use of devices intended to protect staff from injury (e.g., self-retracting syringes);
b) provision of appropriate sharps containers at the point of use; and
c) training.

8.3 Immunization and post-exposure management

Policies shall be in place to protect personnel with job-related responsibilities that might involve the potential for exposure to blood borne pathogens.

Appropriate vaccination (e.g., hepatitis B vaccination) shall be offered. Potentially exposed personnel should be referred for appropriate medical care.

9 Disposal of cells, tissues, and organs

9.1 General

Cells, tissues, and organs shall be disposed of in such a manner as to minimize any hazard to personnel, the public, and the environment, in accordance with applicable requirements.

Note: *Federal and provincial/territorial requirements can apply.*

9.2 Human remains

Dignified and proper disposal procedures shall be applied to human remains, where applicable, and in accordance with applicable requirements.

Note: *Federal and provincial/territorial requirements can apply.*

9.3 Documentation

Destruction of cells, tissues, and organs shall be dated and recorded. Records of destruction shall be kept for ten years, or in accordance with applicable requirements.

Note: *Federal and provincial/territorial requirements can apply.*

10 Consent

10.1 General

Consent procedures shall conform to medical standards of practice and applicable requirements. A copy of the consent for donation shall be included as part of the donor record.

Note: *Federal and provincial/territorial laws and regulations and medical standards of practice can apply to different situations requiring consent, including*

a) *donor consent (for living donors);*
b) *donor consent prior to their death (e.g., will, registry); or*
c) *authorization by a person who can make this decision in accordance with local provincial/territorial requirements.*

10.2 Predonation counselling

Predonation counselling should include an explanation of

a) the donation process;
b) the risks of donation;
c) the requirement to access the deceased donor's medical records;
d) requirements for a thorough medical history and questions about behavioural risks (i.e., social history);
e) requirements for a physical examination;
f) requirements for further blood samples; and
g) the potential notification of the donor and public health authorities of positive test results.

10.3 Basis of consent

10.3.1 General

Consent shall include, but not be limited to, notification of all reasonable risks and potential harm, and of tests to be performed. A health care professional familiar with the donation process shall explain the request for donation in understandable terms.

10.3.2 Information

Persons undergoing the medical procedures for donation (or their substitute decision maker), and persons undergoing the medical procedures for transplantation shall be informed of the following:

a) all possible risks to the recipient and donor (if applicable);
b) the specific types of cells, tissues, and organs to be recovered;
c) the general purpose for which the retrieved cells, tissues, and organs are intended to be used;
d) the screening tests to be performed; and
e) the consequences of possible positive test results (e.g., potential notification of public health authorities of positive infectious disease test results).

The consenting party shall be given the opportunity to ask questions and voice concerns.

Note: *Federal and provincial/territorial requirements for consent can apply.*

10.3.3 Documentation

10.3.3.1

Documentation of the steps taken shall include

a) the name, date, and signature of the health care professional who performed the interview and reviewed the medical records; and

   Note: *An electronic signature is acceptable.*

b) the name and address of the donor or person who authorized the donation.

10.3.3.2

Documented consent for donor testing shall comply with applicable requirements for consent.

Note: *Federal and provincial/territorial requirements can apply.*

10.4 Medical examiner and coroner cases

In cases involving the medical examiner or coroner, the establishment shall adhere to the requirements for consent in accordance with applicable requirements.

Note: *Federal and provincial/territorial requirements can apply.*

11 Compensation

In Canada, no monetary inducement, goods, or services of value shall be offered to a living donor, a deceased donor's next of kin, the donor's estate, or any other third party in exchange for cells, tissues, or organs.

Notes:

1) *Reimbursement of reasonable costs directly associated with the donation is permitted under appropriate predetermined circumstances, when authorized by the authority having jurisdiction.*
2) *See Clause B.8 for information on ethical dilemmas regarding commerce in tissues and organs.*

12 Donor suitability assessment

12.1 General

Donor selection procedures shall be clearly defined in the SOPs and shall be consistent with applicable requirements for donation.

Note: *Federal and provincial/territorial regulations can apply.*

12.2 Suitability of donors

12.2.1

The donor suitability assessment shall be documented and shall be based on donor screening and testing.

Notes:

1) *A professional interpreter that is not related to the donor should be used in instances where language differences could inhibit full understanding of the screening questions and answers.*
2) *See Clause 13 for donor screening requirements.*

12.2.2

A structured questionnaire shall be administered to obtain the donor's medical history and identify any behavioural risk factors that could present contraindications to donation.

12.2.3

For living donors, the questionnaire shall be completed by the donor.

12.2.4

For donors who are deceased or otherwise incapable to provide firsthand information, the questionnaire shall be administered to a person or persons who knows the donor well enough to provide the relevant information.

12.2.5

For donors less than 11 years old, the information shall be collected in a manner that is appropriate to the age of the donor as described in the establishment's SOPs.

12.3 Documentation

Documentation of the donor suitability assessment shall include the following:

a) donor's unique identification code;
b) donor's date of birth;
c) date(s) of the interview;
d) name of the health care professional who reviewed the questionnaire(s) and medical records;
e) donor's medical records, if available;
f) date and results of physical examination;
g) completed medical and social history questionnaire, and date of completion;
h) dates and results of laboratory tests and, if applicable, the interpretation of the results; and
i) plasma dilution assessment, if required.

12.4 Documentation of donor consent

Documentation of the donor suitability assessment shall also include completed donor consent form(s).

13 Donor screening

13.1 Contraindications or exclusion criteria

13.1.1

Contraindication criteria for donation are specific to each type of cell, tissue, and organ. It is recognized that contraindication criteria will vary between cells, tissues, and organs as defined in the specific subset Standards.

13.1.2

Each establishment shall establish guidelines for the evaluation of general or specific contraindication criteria.

13.1.3

A donor shall be excluded if any of the following contraindications apply:

a) persons whose probable cause of death cannot be adequately determined by the medical director of the source establishment and there is likelihood of other exclusionary criteria;
b) persons who died from neurological disease of an unestablished etiology;
c) persons with prion-related disease;
d) recipients of human growth hormone within the following time frames:
   i) prior to 1986, if the treatment took place in Canada or the US; or
   ii) if the treatment took place in a country other than Canada or the US, anytime that human-derived pituitary growth hormone was available for therapeutic use in that country;

   Note: *This Item refers to growth hormone extracted from human pituitary glands, used for therapeutic purposes prior to 1986. The human-derived product was removed from the market in Canada and the US and replaced with a recombinant manufactured product, due to a possible link between the human-derived product and Creutzfeldt-Jacob disease.*
e) recipients of dura mater;
f) persons with active encephalitis or meningitis of infectious or unknown etiology;
g) persons with a history of dementia or degenerative neurologic disorders of viral or unknown etiology;
h) persons with rabies or persons who, within the past six months, were bitten by an animal and treated as if the animal was rabid;
i) persons with a history of infection with HIV, clinically active HCV, or clinically active HBV;
j) persons at higher risk for HIV, HBV, or HCV infections as specified in Annex E; and
k) persons with infections that would pose a significant risk to the recipient if transmitted.

Notes:

1) *Regarding Item k), it is a matter of clinical judgement to determine the significance/level of risk depending on the clinical history, type of transplant, etc.*
2) *Items a) and b) do not apply to living donors.*

13.1.4

Exceptional distribution of cells, tissues, or organs from donors to whom any of the contraindication criteria in Clause 13.1.3 or Annex E apply shall be in accordance with Clause 18.4.

13.1.5

The risk of emerging diseases/pathogens shall be assessed to determine if additional contraindication criteria or screening criteria, or both, are necessary.

Notes:

1) *This includes an infectious disease that has newly appeared in a population or that has been known for some time but is rapidly increasing in incidence or geographic range.*
2) *Governmental health ministries, departments, and other agencies issue alerts/notices for guidance, as applicable.*
3) *Establishments may establish/update/modify SOPs so that donor screening criteria is more stringent than current federal regulation or the CSA Group standards.*

13.2 Physical examination

13.2.1

A physical examination on all potential donors shall be performed by a qualified person in accordance with the establishment's SOPs.

13.2.2

The physical examination of all deceased potential donors shall include an assessment of any physical evidence that could indicate higher-risk behaviour associated with the presence of a transmissible disease.

13.2.3

If the social or medical history contains evidence that could indicate high-risk behaviour, or if a risk factor is identified in the living potential donor, a new physical exam shall be performed. The exam shall assess any physical evidence that could indicate high-risk behaviour associated with the presence of a transmissible disease.

Note: *If an examination of a living potential donor was recently performed for other reasons, findings of the examination may be reviewed and documented in the donor's records in lieu of a new physical examination.*

14 Testing

14.1 General

The SOPs shall describe the tests and procedures required for measuring, assaying, or monitoring properties of cells, tissues, and organs essential to the evaluation of their safety for transplantation. These tests and procedures shall be in accordance with applicable requirements.

Note: *Federal and provincial/territorial requirements apply to laboratory testing.*

14.2 Laboratory testing

14.2.1 Infectious disease testing

14.2.1.1

Donors of cells, tissues, and organs intended for transplant into another individual shall be tested for all the infectious diseases specified in Clause 14.2.6.1. Autologous donors should also be tested for the infectious diseases specified in Clause 14.2.6.1.

14.2.1.2

The SOPs shall describe all infectious disease tests to be performed. Testing shall be performed by a laboratory that meets the applicable requirements, or in the case of imported cells, tissues, and organs, by a laboratory that meets the current requirements of the donor centre of origin.

Notes:

1) *Federal and provincial/territorial requirements can apply to the licensing of laboratories.*
2) *For more information about packaging and transportation of blood samples for testing, see the* Transportation of Dangerous Goods Act and Regulations*.*

14.2.1.3

Mandatory testing of donor blood for specified infectious agents shall be performed with test kits that meet applicable requirements. The manufacturer's instructions for the performance and interpretation of its test shall be followed.

If additional tests are performed to evaluate the safety of cells, tissues, and organs, and these are not licensed by the authority having jurisdiction, the laboratory shall either

a) ensure that such tests are validated to support the use of the method for the intended application; or
b) include a notice in its test report that the results were obtained using a kit unapproved for its intended use.

Note: *Federal and provincial/territorial requirements can apply to the licensing of laboratory test kits.*

14.2.1.4

For samples of cadaveric blood, tests that meet applicable requirements of the authority having jurisdiction shall be used.

Note: *In Canada, Health Canada is the authority having jurisdiction over the licensing and approval of test kits.*

14.2.2 Blood tests

Blood tests shall be performed in accordance with the manufacturer's instructions. Unless otherwise specified in this Standard or the subset standards, cells, tissues, and organs shall not be released for transplantation if the tests for infectious diseases or disease agents specified in Clause 14.2.6.1 produce positive or indeterminate test results.

Note: *Examples of such exceptions include*

a) *exceptional distribution of cells, tissues, or organs as specified in Clause 18; and*
b) *distribution as permitted in certain subset standards in the case of false positive non-treponemal test results for syphilis.*

14.2.3 Confirmatory or supplemental tests

14.2.3.1

Additional testing may be performed to confirm positive test result(s). Unless otherwise specified in this Standard or the subset standards (e.g., to allow for exceptional distribution), cells, tissues, and organs shall not be released for transplantation even if confirmatory or supplemental tests for HIV-1, HIV-2, HBV, or HCV produce a negative test result. Additionally, leukocyte-rich cells or tissues shall not be released for transplantation even if confirmatory or supplemental tests for HTLV-I or HTLV-II produce a negative test result.

14.2.3.2

Where exceptional distribution or donor re-entry (see Clause 14.2.4) is based on the results of confirmatory or supplemental tests, the tests shall be acceptable to the authority having jurisdiction.

Note: *In Canada, Health Canada is the authority having jurisdiction over the acceptance and use of test kits. At present, the following applies:*

a) *If testing is performed in Canada, Health Canada requires the use of test kits licensed in Canada.*
b) *If the testing is performed outside of Canada, Health Canada accepts the use of test kits licensed in Canada or in the United States.*

14.2.4 Donor re-entry

Living donors of cells, tissues, or organs who have been deferred from donating because of a positive test result may be re-entered into the donation program if

a) the donor's confirmatory or supplemental test produces negative test results; and
b) subsequent testing is performed using a documented re-entry protocol in accordance with the establishment's SOPs.

14.2.5 Notification

14.2.5.1

Standard operating procedures for handling confirmed positive test results and indeterminate test results from confirmatory or supplemental testing, and the notification of the living donor shall be established and documented in the SOPs, when required and appropriate.

14.2.5.2

Positive test results obtained from either a living or a deceased donor shall be reported in accordance with protocols established by the authority having jurisdiction. Positive test results shall be immediately reported to all organ donation organizations (ODOs), tissue and cell banks, and transplantation programs involved with the donor.

14.2.6 Minimum testing for infectious diseases

14.2.6.1 General

Minimum donor testing shall include testing for the following diseases or disease agents:

a) HIV-1 and HIV-2;
b) HBV;
c) HCV; and
d) any additional diseases or disease agents as specified in the infectious disease testing requirements of the applicable subset standards.

The test results shall be documented in the donor record.

Note: *Refer to the most current version of Health Canada's* Guidance Document for Cell, Tissue, and Organ Establishments — Safety of Human Cells, Tissues and Organs for Transplantation.

14.2.6.2 Blood testing of infant donor, including surrogate testing

To address possible vertical transmission of infectious agents in donors 18 months of age or less, or in

those who were breastfed within the 12 months preceding the donation, both the donor and the birth mother shall be tested as specified in Clause 14.2.6.1, with the following exceptions:

a) In the case of donated cord blood, surrogate testing of the birth mother need only be performed as specified in Clause 14.2.6.1.
b) For donors who are 28 days old or younger and who had no obvious potential exposure to a blood-born pathogen after birth, surrogate testing of the birth mother need only be performed, as specified in Clause 14.2.6.1.
c) To address possible vertical transmission of infectious agents in donors who are 29 days old or older and who
   i) are less than 18 months old, or
   ii) were breastfed within 12 months* preceding the donation,

   in addition to testing the donor as specified in Clause 14.2.6.1, the birth mother shall also be tested as specified in Clause 14.2.6.1 a) and c), unless the donor was tested using nucleic acid testing (NAT) for the detection of HIV-1 and HCV.

   * *To inform the decision making process under this Clause, it is only deemed necessary to obtain history information regarding breastfeeding within the past 12 months for donors less than five years of age.*

14.2.7 Blood typing

Donor blood shall be tested for the following, where clinically indicated for donation of applicable cells, tissues, and organs:

a) blood type (A, B, AB, O);
b) Rh factor; and
c) histocompatibility, i.e., human leukocyte antigen (HLA) typing.

14.2.8 Plasma dilution

Note: *Plasma dilution can be a concern in cases where a deceased donor received a transfusion or infusion before death.*

14.2.8.1

For all prospective donors, a blood sample should be collected before any transfusions or infusions have been administered to avoid possible distortion of test results by dilution in the sample.

14.2.8.2

The time between the collection of the test sample and the retrieval of cells, tissues, or organs should be within the timeframes required by Table 1 and Table 2 of Health Canada's *Guidance Document for Cell, Tissue and Organ Establishments – Safety of Human Cells, Tissues and Organs for Transplantation*. The tests should be performed on the most recent sample for which donor identity and sample quality can be ensured.

14.2.8.3

The suitability of samples collected after a prospective donor has received a transfusion or infusion shall be determined in accordance with the SOPs.

14.2.9 Archived samples

Refer to the subset standards for requirements regarding archived samples.

Note: *CAN/CSA-Z900.2.3 and CAN/CSA-Z900.2.5 currently include requirements for archived samples.*

14.3 Other testing

Other tests specific to cells, tissues, and organs might apply and, where they exist, are described in the appropriate subset standard.

15 Retrieval, preparation, preservation, and storage

15.1 General

15.1.1

Procedures for retrieval, preparation, preservation, and storage of cells, tissues, and organs for transplantation shall be outlined in the SOPs.

15.1.2

All nondisposable surgical instruments, devices, and supplies used for processing shall be cleaned, disinfected, and, where indicated by manufacturers, sterilized between donations to prevent contamination and cross-contamination.

15.2 Reagents and supplies

15.2.1

Reagents and supplies used in the processing of cells, tissues, and organs shall be described in the SOPs.

15.2.2

The SOPs shall describe methods to record receipt of reagents and supplies, as well as the reagent name, manufacturer, lot number, date of receipt, and expiration date. It shall also detail appropriate methods of storage and of inventory rotation of reagents and supplies.

15.3 Retrieval

15.3.1

Cells, tissues, and organs shall be retrieved using aseptic techniques and preserved within time intervals for the retention of biological functions in a way that is compatible with the intended use of the cells, tissues, and organs.

15.3.2

The SOPs shall describe the maximum recommended storage periods for all cells and tissues.

15.3.3

The SOPs shall describe the time limits and environmental conditions for retrieval, preservation, and transportation to the processing establishment (if applicable). All conditions with tolerance limits (e.g., temperatures, retrieval time) shall be validated. The SOPs shall also describe the assignment of expiration dates to all cells and tissues, and the proper documentation.

15.3.4

The SOPs shall include descriptions of techniques for retrieval. These techniques shall include any procedures to determine the acceptability of the cells and tissues.

15.3.5

Each donation shall be documented and a record retained by the donor retrieval establishment. The records shall include the following:

a) identifier of the retrieving establishment;
b) documentation of consent;
c) the donor's name, age, sex, and identification code;
d) the reagent name, lot number, expiration date, and manufacturer of reagents and supplies used;
e) a description of and identification code for all cells, tissues, or organs retrieved;
f) the date and time of retrieval; and
g) the names of staff involved in retrieving the cells, tissues, or organs.

15.4 Preparation and preservation

15.4.1

Each establishment shall have data to support methods, time limits, and environmental conditions to maintain the integrity of cells, tissues, and organs and to prevent contamination. Such data may be obtained through industry standard practices, scientific literature, or validation studies.

15.4.2

Controls shall be implemented to ensure that the process conforms to the requirements specified in the SOPs.

15.4.3

Cells, tissues, and organs shall be evaluated when processing is completed to determine whether they meet the criteria specified in the SOPs. The transplanting physician or dentist shall be notified of any defects identified in the cells, tissues, or organs and the notification shall be documented.

15.4.4

Each establishment that handles cells, tissues, and organs for use in transplantation shall maintain records of preparation or preservation, or both.

Note: *See the subset standards for applicable additional requirements.*

15.5 Pooling

15.5.1

An establishment shall not pool cells or tissues from different donors during preparation except when this is necessary to create a therapeutic dose for a single recipient.

15.5.2

The SOPs shall describe methods to prevent contamination of the cells or tissues when pooling is done.

15.6 Packaging and storage

15.6.1

All materials that come into direct contact with the cells, tissues, or organs shall be sterile. The establishment shall determine that packaging materials used in the retrieval, preparation, preservation, and storage of cells, tissues, and organs are for the intended purpose, as defined in the SOPs.

15.6.2
Packaging materials shall maintain the integrity, quality, function, and sterility of cells, tissues, and organs for the entire shelf life. Methods and materials to prevent or indicate the occurrence of tampering should be applied.

15.6.3
The SOPs shall describe methods to inspect, test, clean, and sterilize all packaging materials, where applicable.

15.6.4
The SOPs shall set criteria for the approval and qualification of packaging materials. Packaging materials shall be validated, as defined in the SOPs, to prevent leakage and contamination under the storage conditions employed. All packaging materials shall be checked for damage prior to use.

15.6.5
The establishment shall ensure that cells, tissues, and organs are preserved and stored safely, in accordance with the requirements in the SOPs.

15.6.6
Procedures for environmental monitoring of storage devices shall be established. When used to store cells and tissues or items that have an impact on the quality and safety of these cells and tissues, refrigerators and freezers shall be equipped with verifiable methods for ensuring adequate and continual storage temperatures. Alarm systems for refrigerators and freezers shall be installed and monitored as appropriate to protect the quality and safety cells and tissues.

15.6.7
Each establishment shall set, validate, and specify in the SOPs acceptable temperature ranges for storage and the maximum storage period for cells, tissues, or organs. The SOPs shall describe

a) the storage temperatures and environmental conditions for all cells, tissues, and organs and the procedures to follow in case of power failure or other errors or accidents during storage; and
b) procedures to follow when cells, tissues, or organs are exposed to environments outside of recommended storage limits.

15.6.8
Electronic or physical segregation of donations during storage shall occur for

a) untested donations (including donations from which test results are pending); and
b) donations that have tested positive for transmissible disease markers or are from donors who have a positive test result for a transmissible disease.

Note: *See the subset standards for specific requirements regarding the type of segregation required, i.e. whether electronic segregation is acceptable or if physical segregation is required.*

16 Labels, packaging inserts, and accompanying documentation

16.1 General

Cells, tissues, and organs shall be labelled for identification and tracking during all phases of processing and distribution. The unique donor identification code (see Clause 7.2) shall be included on the identification label of the cells, tissues, or organs to facilitate donor-recipient tracking.

16.2 Documentation

16.2.1

The SOPs shall specify

a) all information to be included on the exterior and interior labels and package insert;
b) steps to follow to ensure that correct labels and packaging materials are used for cells, tissues, and organs; and
c) instructions for proper storage, special handling, and inspection on receipt.

16.2.2

The SOPs shall describe documented controls, including the review of labels to ensure accuracy and to prevent transcription and other labelling errors.

16.2.3

In regards to relabelling, the SOPs shall describe

a) conditions under which relabelling is permitted;
b) the authorized personnel; and
c) the necessary documentation.

16.2.4

A list of the labels used, as well as an example of every label used, shall be maintained.

16.2.5

When a label is removed from the inventory (i.e., retired from use), one copy shall be retained for the archives and all remaining copies shall be discarded. The SOPs shall then be updated.

16.3 Information requirements

16.3.1 General

Exterior and interior labels and package inserts applied to cells, tissues, and organs shall comply with the labelling requirements in Annex C.

16.3.2 Donor confidentiality

Each establishment that distributes cells, tissues, and organs to the end-user for use in transplantation shall ensure the labelling and packaging process protects the donor’s confidentiality.

16.3.3 Autologous donations

All autologous donations shall be clearly labelled “FOR AUTOLOGOUS USE ONLY” or bear equivalent text to prevent the release of these donations for allogeneic use.

16.3.4 Labelling for exceptional distribution

Each establishment distributing cells, tissues, or organs by exceptional distribution shall include a notice of exceptional distribution. The notice of exceptional distribution shall include

a) the name of the transplanted cell, tissue, or organ;
b) the reason why the cell, tissue, or organ did not meet the release criteria specified in SOPs at the time of its distribution;
c) the justification for the distribution that formed the basis for the decision to authorize it;
d) the name of the source establishment that distributed the cell, tissue, or organ;
e) the name of the transplant establishment and of the transplanting physician or dentist who authorized the distribution; and
f) the time and date of the written authorization of the distribution and a copy of the authorization signed by the transplanting physician or dentist.

17 Quarantine and release

17.1 General

17.1.1

The SOPs shall describe the quarantine and release criteria for cells, tissues, and organs.

17.1.2

Cells, tissues, and organs shall be quarantined until

a) donor suitability assessment has been completed and deemed acceptable by the source establishment;
b) infectious disease testing has been completed and test results are negative (see Clause 14.2.1); and
c) compliance with QC tests and procedures has been demonstrated.

17.1.3

Cells, tissues, and organs that have been quarantined as a precautionary measure following an error, accident, or adverse reaction shall be kept in quarantine until the results of the investigation have been communicated and appropriate actions taken in accordance with Clause 19.2.

17.1.4

Quarantine of cells, tissues, and organs shall be documented.

17.2 Living donor quarantine

Refer to the subset standards for living donor quarantine requirements.

Note: *CAN/CSA-Z900.2.2 currently contains requirements for living donor quarantine.*

18 Distribution

18.1 General

18.1.1

The distribution of cells, tissues, and organs for transplantation shall be restricted to transplant establishments, ODOs, tissue banks, eye banks, tissue processing facilities, cell processing facilities, physicians, dentists, and other qualified health care professionals. Distribution shall follow

a) the requirements of this Standard and the applicable subset standards;
b) the SOPs; and
c) applicable requirements.

Note: *Federal or provincial/territorial laws and regulations can apply.*

The ultimate responsibility for determining the clinical suitability of the cells, tissues, and organs for transplantation shall rest with the transplanting physician or dentist.

18.1.2

The SOPs shall describe the procedures for documentation, final verification of release, unit selection, inspection of final packaging material, and collection of tracking information for distributed cells, tissues, and organs.

18.1.3

Each establishment that distributes cells, tissues, or organs to another establishment shall provide the receiving establishment with all original labelling materials or package inserts, or both. Copies of any other information that is required to assess the suitability of the donor or the cells, tissues, or organs for transplantation, except information that compromises donor confidentiality, shall be provided to the transplanting physician on request.

18.1.4

The records maintained by the distributing establishment shall include the donor identification code for cells, tissues, or organs. In addition, the records should include, but not be limited to, the following:

a) the name and address of the receiving establishment;
b) the name of the establishment personnel who placed the request;
c) the name of the establishment personnel filling the request;
d) the date that the request was placed and filled;
e) the type and quantity of cells, tissues, or organs requested;
f) the retrieval date or expiration date, or both;
g) the type and amount of refrigerant used for shipment, if applicable;
h) the date of shipment; and
i) information for identifying the recipient, when available.

18.2 Transportation

18.2.1

Transportation and shipping arrangements by all establishments shipping cells, tissues, or organs shall not risk the safety and integrity of the cells, tissues, or organs.

18.2.2
Tamper-evident indicators shall be in place to secure the safety and integrity of cells, tissues, and organs.

18.2.3
The SOPs shall describe packaging materials for transport and shipping. The establishment shall use packaging materials that will maintain the safety and integrity of the cells, tissues, and organs during transit.

Note: *Packaging materials should be validated for their intended use.*

18.2.4
The SOPs shall describe all labelling and documentation to be included in the shipment.

18.2.5
The SOPs shall describe the extent of which temperature and environmental monitoring devices are to be included if the cells, tissues, or organs are transported or shipped. If monitoring devices are not used, shipping containers shall be validated for maintaining the appropriate environmental conditions. Use of hazardous elements, such as dry ice or liquid nitrogen, shall comply with applicable requirements.

Notes:

1) *Federal and provincial/territorial regulations can apply.*
2) *For more information about packaging and the transportation of cells, tissues, and organs that have been tested and determined to be infectious, see the* Transportation of Dangerous Goods Act and Regulations*, IATA's* Dangerous Goods Regulations*, and other applicable laws and regulations.*

18.3 Receiver of cells, tissues, and organs

18.3.1
All establishments receiving cells, tissues, and organs shall be responsible for verification of shipment and for obtaining and retaining records that allow tracking of donor cells, tissues, and organs to the recipient. The transplant centre shall retain all recipient identifying information and ensure that its records link the donor to the recipient.

18.3.2
Processes shall be in place for the sharing of information between establishments to enable donor-recipient tracking (see Clause 7). These processes shall be documented in the SOPs of the processor, distributor, and final receiver of the cells, tissues, or organs, with the exception of cells, tissues, and organs from an international source.

18.3.3
The receivers of cells, tissues, or organs shall promptly provide information to the processors and distributors of cells, tissues, or organs about complications or technical problems with the use of the cells, tissues, or organs.

18.3.4
All cells, tissues, and organs forwarded to another establishment by the receiver shall be accompanied by the original labelling material and package insert.

18.3.5
The transplanting physician or designate shall provide recipient identifying information to the source establishment or distributor.

18.4 Exceptional distribution

18.4.1
For reasons related to the interests of the recipient, cells, tissues, or organs that do not meet the release criteria specified in the SOPs (see Clause 17.1.1), including those obtained from a donor with identified contraindication criteria, may be released. The SOPs shall specify the necessary procedures, including the required signature(s), to authorize the use of cells, tissues, or organs under exceptional distribution. The authorization shall be signed by the transplanting physician or dentist at a minimum.

Note: *The medical director of the transplant establishment is ultimately responsible for authorizing the use of cells, tissues, or organs under exceptional distribution (see Clause 4.2.3.5). Depending on the type of establishment, the authorizing signature with its associated responsibility could be provided by another qualified professional who is involved with the transplantation, e.g., the transplanting physician who has obtained consent.*

18.4.2
Exceptional distribution shall be based on the clinical judgment of the transplanting physician or dentist, with the consent of the recipient.

18.4.3
The exceptional distribution of cells, tissues, or organs shall be recorded.

18.4.4
Cells, tissues, or organs released under exceptional distribution shall be subject to all other QA measures described in the SOPs, e.g., donor suitability assessment and follow-up testing.

18.4.5
Distribution of cells, tissues, or organs by exceptional distribution shall include a notice of exceptional distribution, describing the provisions of the applicable standards and regulations with which the cell, tissue, or organ are not in compliance at the time of its distribution.

18.4.6
Documentation of exceptional distribution in the donor records shall include the following:

a) the reason for exceptional distribution;
b) processing information available at the time of release;
c) a review of all relevant information and approval by the medical director and transplanting physician or dentist;
d) a statement to the transplanting physician indicating which requirements specified in the Standard and applicable laws and regulations have not been met and if/when these requirements will be met; and
e) the results of follow-up testing, donor suitability assessment, and other QA measures described in the SOPs.

Note: *See Clause 16.3.4 for exceptional distribution labelling requirements.*

18.5 Release of cells, tissues, and organs not intended for transplantation

The establishment shall develop policies and procedures for the release of cells, tissues, and organs that are not intended for transplantation.

19 Error, accident, and adverse reaction investigation and reporting

19.1 General

All errors, accidents, and adverse reactions shall be investigated and reported in accordance with the applicable requirements.

Note: *Reporting of errors, accidents and adverse reactions are addressed in Sections 43 to 54 of the* Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, as amended.*

19.2 Recall

19.2.1

The medical director shall ensure that all procedures for recall or notification of possible contamination and defects in preparation, storage, distribution, and other factors affecting the suitability of cells, tissues, and organs for clinical transplantation are followed.

19.2.2

Each source establishment, and each establishment that distributes, shall have procedures for recall and notification, as well as all documentation required. Documentation shall include the following:

a) reason for the recall;
b) steps taken to quarantine recalled cells, tissues, or organs that have not been transplanted or for the return of such cells, tissues, or organs to the establishment;
c) all communications and correspondence regarding the recall;
d) final disposition of cells, tissues, or organs;
e) corrective actions recommended and implemented, if applicable;
f) notification of recipients; and
g) packaging and shipping instructions.

20 Continuous improvement

20.1

There shall be a periodic review of establishment activities, as appropriate to its function (i.e., source, distribution, or transplant establishment) and the type of cells, tissues, or organs it processes, distributes, or transplants.

20.2

The scope and timing of the reviews at source establishments and establishments that distribute shall be in accordance with the SOPs and applicable requirements.

Note: *Federal and provincial/territorial requirements can apply.*

20.3

For a transplant establishment, the review should consider the transplant process as a whole. The number of individual cases reviewed will depend on the type of transplant, i.e., an organ transplant establishment should review every case, while an establishment that transplants tissues may review representative cases for each type of tissue transplanted. Reviews may be performed by an institutional transplant committee or by another committee that can effectively address all aspects of the establishment's activities.

20.4

The main goals of the process for a transplant establishment shall be as follows:

a) to evaluate errors, accidents, and adverse reactions for the purposes of identifying trends and adopting appropriate preventive measures to ensure continuous safety of the transplantation process;

   Note: *Federal or provincial/territorial laws and regulations can include requirements for the documentation and maintenance of such analyses, as well as requirements for making them available for review on inspection, and for submission on request by the authority having jurisdiction.*

b) to identify and address any other safety-related deficiencies;

c) to disseminate information and education related to safety and best transplantation practices to facilitate continuous improvement in transplantation at the establishment; and

d) to comply with this Standard and applicable subset standards.

Annex A (informative)
Developmental background and history of the CSA Group general requirements standard and its subsets

Notes:
1) *This Annex is not a mandatory part of this Standard.*
2) *The seed document for this Standard and the subset standards was the Canadian General Standard and its subsets, which were developed by Health Canada's* Expert Working Group on Safety of Organs and Tissues for Transplantation*. This Annex outlines the developmental background of the Canadian General Standard and its subsets. A list of the members of the Expert Working Group is also included.*

A.1 Background

A.1.1
A National Consensus Conference on Safety of Organs and Tissues for Transplantation was held on October 29 to 31, 1995. The goal of this conference was to reach an agreement on methods to reduce the risks of disease transmission by organs and tissues intended for transplantation.

A.1.2
The objectives of the conference included obtaining expert guidance on a proposed Canadian General Standard (CGS) on Safety of Organs and Tissues for Transplantation. The proposed CGS was initially produced in consultation with international experts and with a careful review of recommended standards, guidelines, and publications from Canada, the United States, Australia, the United Kingdom, and Europe.

Note: *For an updated bibliography of the standards, guidelines, and publications reviewed, see Annex F.*

A.1.3
The conference was attended by 65 invited participants, who represented a broad spectrum of Canadian expertise in fields related to organ and tissue transplantation. Organs and tissues under discussion at this conference included solid organs (kidneys, liver, heart, pancreas, lungs), ocular tissues (corneas), bone and skin grafts, heart valves, lymphohematopoietic cells, and reproductive tissues.

A.1.4
The conference recommendations included the following:
a) that the proposed CGS be revised to incorporate input from experts at the conference; and
b) that the revised CGS be accepted as a template for the development of subsets of specific standards for individual organ and tissue types.

A.1.5
The Expert Working Group (EWG) was established in March 1996 to assist in the revision of the proposed CGS and the development of subsets of specific organ and tissue standards based on the proposed CGS. Each tissue/organ grouping had an equal voice in the formulation of the CGS and its subsets.

A.1.6

The following values were identified by the EWG in relation to organ and tissue transplantation:

a) organ and tissue transplantation is a high priority in clinical practice, teaching, and research in Canada;
b) national distribution of organs and tissues should respect the principles of equity and fairness for the patient;
c) there is a need to balance relative risks and benefits within the overall framework of maximizing safety; and
d) there are emerging trends in organ and tissue transplantation, particularly in the areas of outcomes, audit, look-back, and track-back, which are considered important.

A.1.7

Transplantation of cells, tissues, and organs is a practice that can enhance the quality and duration of life, restore function, and facilitate human reproduction. Transplantation has recognizable risks, which include disease transmission, immunological damage, sepsis, and toxic transfer.

A.1.8

Transmission of disease includes potentially infectious pathogens, malignancies, genetic defects, and other aspects of the quality of cells, tissues, and organs that might have an adverse effect on the future health of the recipient or offspring. The EWG advice on safety was balanced by a need to ensure optimal access for Canadians to cells, tissues, and organs for transplantation.

A.1.9

This Standard is provided as a general overview of cell, tissue, and organ transplantation standards and as a generic standard that will serve as the template for standards specific to cells, tissues, or organs. It is a dynamic document that will respond to current scientific knowledge in a timely fashion.

A.2 Original EWG members

Dr. C. Stiller (Chair)
London, Ontario

Dr. P. Dubord
Vancouver, British Columbia

Dr. A. Eaves
Vancouver, British Columbia

Dr. P. Greig
Toronto, Ontario

Dr. M. Gross
Halifax, Nova Scotia

Dr. J. Jarrell
Calgary, Alberta

Dr. W. Keon
Ottawa, Ontario

S. McCabe
Toronto, Ontario

Dr. H. Messner
Toronto, Ontario

Dr. W. Schlech
Halifax, Nova Scotia

Corresponding members

C. Birks
Montréal, Québec

Dr. N. Kneteman
Edmonton, Alberta

E. Knight
Rockville, Maryland, USA

Consulting ethicist

J.B. Dossetor
Edmonton, Alberta

Bureau of Biologics and Radiopharmaceuticals, Health Canada
(now the Biologics and Genetic Therapies Directorate, Health Canada)

Dr. M. Smith (Executive Secretary)

Dr. K. Bailey

Dr. P. Ganz

A. La Prairie

Drugs Directorate, Health Canada
(now the Therapeutic Products Directorate and Biologics and Genetic Therapies Directorate, Health Canada)

D. Michols
Ottawa, Ontario

Annex B (informative)
Ethics: Cells, tissues, and organs for transplantation

Note: *This Annex is not a mandatory part of this Standard.*

B.1 General

B.1.1
This Annex describes the ethical principles adopted by the Expert Working Group of Health Canada and the Technical Committee on Safety of Cells, Tissues, and Organs for Transplantation and Assisted Reproduction of CSA Group.

B.1.2
In regards to ethical issues, secondary effects could be as significant as primary considerations. Thus, some of the issues in this Annex extend beyond considerations of the safety of cells, tissues, and organs to the context in which such cells, tissues, and organs are obtained and used. The Technical Committee, while in no way wishing to be seen as aiming to regulate transplantation practices, nevertheless believes that its mandate includes consideration of these wider ethical issues.

B.1.3
Where appropriate, these ethical considerations recognize the goal of prolonging life, or improving its quality, through the use of cells, tissues, and organs.

B.2 Principles

B.2.1
The principles of the *Canada Health Act* (1984) are
a) accessibility;
b) portability;
c) universality;
d) comprehensiveness; and
e) public administration.

B.2.2
The following additional principles have been suggested:
a) affordability;
b) appropriateness; and
c) accountability.

These may be implicitly accepted.

B.2.3
In all aspects of transplantation, safety is paramount and a cardinal principle. This principle is implicit in all health care but should be dominant and explicit in modalities of treatment that use materials that can harm others by either being insufficiently viable or functional or being the source of unsuspected contamination by infectious agents.

B.2.4

Other principles governing transplantation include gratuity, as described in applicable laws and regulations, and the need to balance risks and benefits in the case of inter vivos (i.e., between living persons) donations.

B.3 Basic values

B.3.1

The principles mentioned in Clause B.2 are derived from deeper values shared by people living in Canada. Although not explicitly stated, except in documents such as the *Canadian Charter of Rights and Freedoms* and the *Universal Declaration of Human Rights*, these values are based on the belief that all individuals are of equal moral worth in a mutually interdependent society that respects all cultures and communities that uphold human dignity.

B.3.2

The discipline of medical ethics (bioethics) has codified these deeper values in the concepts of

a) beneficence (i.e., the moral obligation to do good to others);
b) non-malfeasance (i.e., the moral obligation not to harm others and the obligation to balance benefits and harms);
c) autonomy (i.e., the moral obligation to promote the self-fulfilment of others while respecting their privacy and recognizing the need for consent prior to action); and
d) justice and inclusiveness (i.e., the moral obligation to share the benefits of our society with all its members primarily according to need, avoiding to the greatest extent consistent with available societal resources such considerations as social merit or the ability to pay).

B.3.3

From substantive values in Clause B.3.2 stem certain procedural values, such as

a) honesty;
b) being willing to listen to the opinions of others;
c) accountability and fiscal responsibility;
d) administrative transparency;
e) willingness to address new or emerging issues;
f) striving for consensus;
g) declaring and managing conflicts of interest; and
h) committing appropriate periods of time.

B.3.4

It is the expression of these procedural values in day-to-day operations that reflects the deeper substantive values from which they stem.

B.3.5

It is hoped that these ethical concepts, both basic and procedural, have imbued these Standards with moral value and will be observed throughout the transplantation community in Canada. This hope extends to those who need cell, tissue, or organ transplants because of the failure of a vital organ.

B.4 Issues of consent regarding the sources of tissues and organs

B.4.1

Tissues and organs are derived from

a) persons who have died;
b) persons who, while living, donate one of their paired vital internal organs or a segment of a single vital internal organ; and
c) healthy persons who donate (or, in some foreign jurisdictions, provide for commercial gain) readily renewable tissues such as bone marrow.

For each of these sources there can be special issues regarding consent.

B.4.2

For tissues and organs removed after death, it is crucially important to have consent

a) from the donor prior to death, at a time when he or she retains decision-making capacity;
b) from surrogate decision-makers such as those appointed through advance directives or as legal guardians; or
c) from appropriate family members when permission for removal is sought after death in the absence of a premortem donation request.

The option in Item a) should take precedence over the options in Items b) or c), but ethics demands that the grief of those who have lost a loved one must always be considered.

B.4.3

The need for tissues and organs from persons who have just died calls for great sensitivity to the special needs of persons who are bereaved, especially when the bereavement has been sudden and unanticipated. Also, the need for safety at all levels necessitates consent for special tests, access to previous health records, and also a crucially important but seemingly intrusive interrogation of donors, families, or their representatives. To identify the risk of disease transmission, these questions focus on the health, well-being, and social behaviours of the deceased, and can ask about sexual partners and close contacts. The process calls for those interviewing the family to have special professional training in interacting with persons in crisis — who might be distracted or have impaired perception — in order to maintain ethical sensitivity and propriety.

Unique issues of consent are connected with the following donors:

a) For living donors of whole or renewable parts of vital internal organs (single kidneys, liver segments), these issues include
    i) the need to temper compassion for a loved one or other person in need with a full understanding of the entire donation process (e.g., medical and psychological assessment, surgical procedure, perioperative complications, monetary impact of the donation, long-term medical risks for the donors, recipients' outcomes);
    ii) possible coercion or inappropriate persuasion from other family members or the recipient transplant team;
    iii) the need for professionals to be fully informed about outcomes; and
    iv) appropriate period of time for decision-making.

    In order to avoid any conflict of interest, the living donor's assessment should be done by a physician who is not involved in the recipient's care and/or include a donor advocate (e.g., nurse or physician) knowledgeable in the risks and independent from recipient care. This physician or nurse, or both, should be considered the donor's advocate during the donation process.

b) For donors of readily renewable tissues, these issues include
   i) persuasion that verges on coercion; and
   ii) issues related to the need for repeated donation.

All aspects of the safety and health of the live donor must always take priority over the concerns of the recipient.

B.5 Responsibilities and obligations pertaining to recipient selection

The ethical issues pertaining to recipient selection involve societal fairness or distributive justice. The principles used for recipient selection can be ethically acceptable, ethically questionable, or ethically flawed, as outlined below:

a) ethically acceptable though competing principles:
   i) rescue of a dying patient;
   ii) maximizing the medical outcome between potential recipients;
   iii) time spent on the waiting list, or the first-come, first-served principle (if all have equal access to the list);
   iv) random choice; and
   v) recognition of past individual discrimination;
b) ethically questionable principles:
   i) maximizing the outcome for society;
   ii) favouring those who have lived preferred lifestyles; and
   iii) social merit or position in society; and
c) ethically flawed principles:
   i) ability of recipients to pay (in Canada);
   ii) discrimination based on an irrelevant disability, e.g., denial of heart transplants for persons with Down's syndrome;
   iii) discrimination based on the recipient's age;
   iv) lobbying, e.g., by influential persons on behalf of a possible recipient, or when misplaced fiduciary duty becomes favouritism;
   v) deviation from nationally approved protocols or agreements on recipient selection; and
   vi) undeclared conflicts of interest in recipient selection, such as selection for "the good of the program" (to maintain funding, etc.).

B.6 The responsibility to treat the deceased body with dignity and respect

No one would deny the ethical imperative to treat the deceased body with dignity and respect, but in the urgency of tissue and organ retrieval it is easy to lose contact with the full reality of the situation and the need to maintain respect for the body of the deceased donor. Hospital administrators and directors of intensive care units, emergency rooms, operating rooms, and transplant units have an obligation to remind their personnel of the human values that underlie the process of tissue and organ retrieval from the dead and to consider policies that reinforce this ethical commitment.

B.7 Responsibility for sufficient tissues and organs being available to meet demand

In Canada, promoting awareness of the need for tissues and organs has largely been left to nongovernmental organizations (support groups), though several provincial governments have funded organ donation initiatives. However, falling organ donor rates in the face of growing waiting lists have created a crisis of supply that demands much greater involvement by governments, professional

organizations, institutions, and health care professionals. This is an ethical issue at the level of society itself and has evoked new responses and commitments from governments (Report of the Standing Committee on Health, 1999). See Clause B.11.

B.8 Ethical dilemmas regarding commerce in tissues and organs

The need for tissues and organs has pushed private individuals as well as the corporate world toward solutions based on monetary gain through tissue and organ buying and selling. For human vital internal organs, nearly all countries, including Canada, have legislation that forbids monetary reward for organs and forbids organ marketing. Others have questioned whether this is altogether just (Ratcliffe-Richards et al., 1998; Cameron and Hoffenberg, 1999). Some societies allow commerce in renewable tissues such as skin, semen, and ova. A full exploration of ethical issues in this area is beyond the scope of this Standard. Additional information on ethics concerning cells, tissues, and organs for transplantation can be found in

a) World Health Organization (2009); and
b) "The Declaration of Istanbul on Organ Trafficking and Transplant Tourism" (2008).

B.9 Maintaining optimal health — A shared responsibility for transplant recipients and transplant team

Organ transplantation is a stressful experience for recipients. Most transplant recipients successfully cope with this experience and adhere to their medical treatment plans; some recipients, however, have difficulties adapting following transplantation. Transplant professionals are encouraged to provide appropriate supports to help transplant recipients adopt behaviours to maintain a healthy lifestyle. Maintaining optimal health following organ transplantation is an important way for a recipient to demonstrate their appreciation for the gift of donation.

B.10 Responsibilities and obligations of persons who identify donors and counsel bereaved families

Professionals who undertake the sensitive and difficult work of identifying donors and counselling bereaved families face ethical dilemmas that are so challenging that they require special training and expertise. While acting, indirectly, for those who urgently need tissues and organs, donor coordinators must also respect the body of the deceased and be sensitive to the vulnerability of those who have recently lost a loved family member, while also rigorously searching for possible risk factors associated with donated tissues and organs. These dedicated professionals are crucial to obtaining tissues and organs for transplantation. In the field of solid organ transplantation, donor coordinators have different responsibilities from those of transplant coordinators; the former act as advocates primarily for donor families, the latter primarily for potential organ recipients. Where tissues are concerned, this role differentiation is unnecessary.

B.11 The ethics of research in transplantation

Many transplantation procedures take place in the context of clinical research. This poses unique dilemmas for professionals undertaking clinical research, especially when the researcher or principal investigator (in search of "generalizable knowledge") is also the patient's physician (with an obligation "to seek only the best interests of the patient"). In 1998, the three Canadian research councils that existed at that time — the Medical Research Council (MRC), the Social Sciences and Humanities Research Council (SSHRC), and the National Science and Engineering Research Council (NSERC) — issued a guideline known as the *Tri-Council Policy Statement (TCPS) on Ethical Conduct for Research Involving Humans* (1998). The MRC was later expanded to become the Canadian Institute of Health Research (CIHR), but the guideline retains its original title. The TCPS has been adopted by all of the institutions

receiving research funds from the CIHR, SSHRC, and NSERC, and by their research ethics boards. The CIHR policy statement supports and elaborates on such seminal research documents as the Declaration of Helsinki (2000) and the Belmont Report (1979).

B.12 Conclusion

While this Annex just touches on the difficult ethical issues surrounding transplantation, the intent of the CSA Z900 series of Standards is to address the practical aspects, creating a solid foundation for making this important interaction — where a part of one human being is used to treat illness or deprivation in another — sensitive, humane, safe, and successful.

Annex C (normative)
Labelling requirements

Notes:

1) *This Annex is a mandatory part of this Standard.*
2) *Tables C.1 to C.4 are taken from Sections 30(1), 30(2), 31 and 32 of the* Safety of Human Cells, Tissues, and Organs for Transplantation Regulations*.*

Table C.1
Labelling requirements for cells, except islet cells

Item	Column 1 Required information	Column 2 From retrieval establishment to transplant establishment			Column 3 From retrieval establishment to cell bank			Column 4 From cell bank to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
Information about donor and cell										
1.	Name of cell	X	X		X	X		X	X	
2.	Description of cell		X			X			X	
3.	Donor identification code, clearly labelled as such	X	X					X	X	
4.	Information capable of identifying the donor				X	X				
5.	Donor assessment record					X				
6.	ABO group and Rh factor of donor, if applicable	X	X		X	X		X	X	
7.	The hazard symbol entitled "Biohazardous Infectious Material" set out in Schedule III to the *Hazardous Products Regulations*, if applicable	X		X	X		X	X		X
Retrieval information										
8.	Date, time, and time zone of retrieval		X			X				
9.	Information specific to retrieval procedure		X			X				
Processing information										
10.	Name of anticoagulant and other additive, if applicable		X			X			X	

(Continued)

Table C.1 (Continued)

Item	Column 1 Required information	Column 2 From retrieval establishment to transplant establishment			Column 3 From retrieval establishment to cell bank			Column 4 From cell bank to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
11.	Statement "For Autologous Use Only", if applicable	X	X		X	X		X	X	
Information for transplant establishment										
12.	Statement that the cells have been declared safe for transplantation. [See #13 in the case of exceptional distribution]								X	
13.	Statement "For Exceptional Distribution," if applicable		X						X	
14.	If applicable, the reasons for exceptional distribution and a statement of how the cell does not meet the requirements of these Regulations		X						X	
15.	Instructions on how to report errors, accidents and adverse reactions								X	
16.	Expiry date and time, if applicable							X	X	
Establishment information										
17.	Name of retrieval establishment, its civic address, and contact information		X	X		X	X			
18.	Name of source establishment, its civic address, and contact information		X	X		X	X		X	X

(Continued)

Table C.1 (Concluded)

Item	Column 1 Required information	Column 2 From retrieval establishment to transplant establishment			Column 3 From retrieval establishment to cell bank			Column 4 From cell bank to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
19.	Registration number of source establishment, clearly labelled as such		X	X					X	X
20.	Name of transplant establishment, if known, its civic address, and contact information			X						X
Storage information										
21.	Statement “Human cells for transplant”			X			X			X
22.	Handling instructions for storage and for storage during transportation			X			X			X

Table C.2
Labelling requirements for pancreas for islet cells, and islet cells

Item	Column 1 Required information	Column 2 Pancreas for islet cells: From retrieval establishment to source establishment			Column 3 Islet cells: From source establishment to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
Information about donor and organ or islet cells							
1.	Name of organ or cells, as applicable	X	X		X	X	
2.	Description of organ or cells, as applicable		X			X	
3.	Donor identification code, clearly labelled as such				X	X	
4.	Information capable of identifying the donor	X	X				
5.	Donor assessment record		X				
6.	ABO group and Rh factor of donor, if applicable	X	X		X	X	
7.	The hazard symbol entitled "Biohazardous Infectious Material" set out in Schedule III to the *Hazardous Products Regulations*, if applicable	X		X	X		X
Retrieval information							
8.	Date, time, and time zone of asystole or aortic clamping, if applicable		X				
9.	Date, time, and time zone of retrieval		X				
10.	Information specific to retrieval procedure		X				
11.	Name of perfusion solution		X				
Processing information							
12.	Name of storage solution		X				
13.	Name of additives, if applicable					X	

(Continued)

Table C.2 (Concluded)

Item	Column 1 Required information	Column 2 Pancreas for islet cells: From retrieval establishment to source establishment			Column 3 Islet cells: From source establishment to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
Information for establishments							
14.	Statement that the cells have been declared safe for transplantation [See #15 in the case of exceptional distribution]					X	
15.	Statement “For Exceptional Distribution,” if applicable		X		X	X	
16.	If applicable, the reasons for exceptional distribution and a statement of how the organ or cells do not meet the requirements of these Regulations		X			X	
17.	Instructions on how to report errors, accidents and adverse reactions		X			X	
18.	Expiry date and time, if applicable				X	X	
Establishment information							
19.	Name of retrieval establishment, its civic address, and contact information		X	X		X	X
20.	Name of source establishment, its civic address, and contact information		X	X		X	X
21.	Registration number of source establishment, clearly labelled as such		X	X		X	X
22.	Name of other establishment, its civic address, and contact information						X
Storage information							
23.	Statement “Human organ for transplant” or “Human cells for transplant”, as applicable			X			X
24.	Handling instructions for storage and for storage during transportation			X			X

Table C.3
Labelling requirements for tissue

Item	Column 1 Required information	Column 2 From retrieval establishment to tissue bank			Column 3 From tissue bank to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
Information about donor and tissue							
1.	Name of tissue, and whether left or right side, if applicable	X	X		X	X	
2.	Description of tissue		X			X	
3.	Donor identification code, clearly labelled as such				X	X	
4.	Information capable of identifying the donor	X	X				
5.	Donor assessment record		X				
6.	The hazard symbol entitled “Biohazardous Infectious Material” set out in Schedule III to the *Hazardous Products Regulations*, if applicable	X		X	X		X
Retrieval information							
7.	Date, time, and time zone of asystole or aortic clamping, if applicable		X				
8.	Date, time, and time zone of retrieval		X				
9.	Information specific to retrieval procedure		X				
Processing information							
10.	Name of storage solution, if applicable		X			X	
11.	Name of anticoagulant and other additive, if applicable					X	
12.	Statement that the tissue has been irradiated, if applicable				X	X	

(Continued)

Table C.3 (Continued)

Item	Column 1 Required information	Column 2 From retrieval establishment to tissue bank			Column 3 From tissue bank to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
13.	Description of the disinfection and sterilization processes that were used, if applicable					X	
14.	Statement “For Autologous Use Only”, if applicable	X	X		X	X	
Information for transplant establishment							
15.	Tissue-specific instructions for preparation for use, if applicable					X	
16.	Statement that the tissue has been declared safe for transplantation if applicable					X	
17.	Statement “Tissue is not claimed to be sterile” or, in the case the tissue has been subject to sterilization, the statement “Tissue has been sterilized; the Sterility Assurance Level is [indicate level] “					X	
18.	Statement “For Exceptional Distribution”, if applicable				X	X	
19.	If applicable, the reasons for exceptional distribution and a statement of how the tissue does not meet the requirements of these Regulations					X	
20.	Instructions on how to report errors, accidents and adverse reactions					X	
21.	Expiry date and time, if applicable				X	X	
Establishment information							
22.	Name of retrieval establishment, its civic address, and contact information		X	X			
23.	Name of source establishment, its civic address, and contact information		X	X		X	X
24.	Registration number of source establishment, clearly labelled as such					X	X

(Continued)

Table C.3 (Concluded)

Item	Column 1 Required information	Column 2 From retrieval establishment to tissue bank			Column 3 From tissue bank to any other establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
25.	Name of transplant establishment, if known, its civic address and contact information						X
Storage information							
26.	Statement “Human tissue for transplant”			X			X
27.	Handling instructions for storage and for storage during transportation			X			X

Table C.4
Labelling requirements for organs

Item	Column 1 Required information	Column 2 Deceased donor: From retrieval establishment to transplant establishment			Column 3 Living donor: From retrieval establishment to transplant establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
Information about donor and organ							
1.	Name of organ, and whether left or right side, if applicable	X	X	X	X	X	
2.	Description of organ		X			X	
3.	Donor identification code, clearly labelled as such	X	X		X	X	
4.	All information in the donor assessment record that is not capable of identifying the donor		X				
5.	ABO group and Rh factor of donor	X	X		X	X	
6.	The hazard symbol entitled "Biohazardous Infectious Material" set out in Schedule III to the *Hazardous Products Regulations*, if applicable	X		X	X		X
Retrieval information							
7.	Date, time, and time zone of asystole or aortic clamping, if applicable		X				
8.	Date, time, and time zone of retrieval		X			X	
9.	Information specific to retrieval procedure		X			X	
10.	Name of perfusion solution		X			X	
Processing information							
11.	Name of storage solution		X			X	

(Continued)

Table C.4 (Concluded)

Item	Column 1 Required information	Column 2 Deceased donor: From retrieval establishment to transplant establishment			Column 3 Living donor: From retrieval establishment to transplant establishment		
		Interior label	Package insert	Exterior label	Interior label	Package insert	Exterior label
Information for transplant establishment							
12.	Statement that the organ has been declared safe for transplantation if applicable		X				
13.	Statement “For Exceptional Distribution”, if applicable	X	X		X	X	
14.	If applicable, the reasons for exceptional distribution and a statement of how the organ does not meet the requirements of these Regulations		X			X	
15.	Instructions on how to report errors, accidents, and adverse reactions		X			X	
Establishment information							
16.	Name of retrieval establishment, its civic address, and contact information		X	X		X	X
17.	Name of source establishment, its civic address, and contact information		X	X		X	X
18.	Registration number of source establishment, clearly labelled as such		X	X		X	X
19.	Name of transplant establishment, its civic address and contact information			X			X
Storage information							
20.	Statement “Human organ for transplant”			X			X
21.	Handling instructions for storage and for storage during transportation			X			X

Annex D
Placeholder

Annex E (normative)
Factors and behaviours associated with a higher risk of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV)

Notes:

1) *This Annex is a mandatory part of this Standard.*
2) *Contraindications for donation are provided in Clause 13.1.3.*
3) *Exceptional distribution may be considered for cells, tissues, or organs from donors to whom any of the contraindication criteria in Clause 13.1.3 or this Annex apply.*
4) *The term "higher risk" relates to the Canadian population in general and reflects the disproportionately greater chance that a person with an identified contraindication could have contracted one of the infectious diseases named.*
5) *Clinically active includes ongoing infections such that there is a risk of transmission through body fluids.*

E.1

The assessment of donors 11 years of age or older shall include the following risk factors and risk behaviours associated with HIV, HBV, and HCV:

a) persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding five years;
b) men who have had sex with another man in the preceding 12 months;
c) persons who have engaged in sex in exchange for money or drugs in the preceding five years;
d) persons with a history of intranasal cocaine use in the last 6 months, unless HCV NAT is performed and found to be negative;
e) persons who have had sex in the preceding 12 months with any persons described in Items a) to c) or with a person known or suspected to have HIV, or clinically active HBV or clinically active HCV;
f) persons who have been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane;
g) persons who have been in youth correctional facility, jail, or prison for more than 72 consecutive hours in the preceding 12 months;
h) persons who within 12 months* preceding donation have undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used (e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used); and
i) persons who have had close contact within 12 months preceding donation with another person having clinically active HBV or clinically active HCV infection (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly).

** The 12 month period specified in Items f) and h) may be reduced to 6 months if nucleic acid testing (NAT) is used for the detection of HIV, HBV, and HCV. See Clause 14.2.6.1.*

E.2

The assessment of donors less than 11 years of age shall include the following risk factors and risk behaviours associated with HIV, HBV, and HCV:

a) persons who have been exposed, in the preceding 12 months*, to known or suspected HIV-, HBV-, and/or HCV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane;

b) persons who within 12 months* of donation have undergone tattooing, ear piercing, or body piercing in which sterile procedures were not used (e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used);
c) persons who have had close contact within 12 months preceding donation with another person having clinically active viral hepatitis (e.g., living in the same household, where sharing of kitchen and bathroom facilities occurs regularly);
d) persons who have been breastfed within the past 12 months† of donation by women with or a risk for HIV, HBV, and/or HCV; and
e) persons less than 18 months of age who are born to women with or at risk for HIV, HBV, and/or HCV infection.

* *The 12 month period specified in Items a) and b) may be reduced to 6 months if NAT is used for the detection of HIV-1, HBV, and HCV. See Clause 14.2.6.1.*

† *It is only necessary to assess donors less than five years of age against the criteria in Item d).*

Annex F (informative)
Bibliography

Note: *This Annex is not a mandatory part of this Standard.*

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