Cells, tissues, and organs for transplantation: General requirements
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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.
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   a) Standard designation (number);
   b) relevant clause, table, and/or figure number; 
   c) wording of the proposed change; and
   d) rationale for the change.
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

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


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


