CSA Group

CAN/CSA-Z900.2.3-17
National Standard of Canada

Perfusable organs for transplantation

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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 to judge its suitability for their particular purpose.

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

Prepared by

CSA Group

Approved by

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Preface

This is the third edition of CAN/CSA-Z900.2.3, *Perfusable organs for transplantation*. It supersedes the previous editions published in 2003 and 2012.

This Standard is part of a series of management system standards related to the safety of cells, tissues, and organs for transplantation and assisted reproduction. It was developed from work initiated by Health Canada's Expert Working Group on Safety of Organs and Tissues for Transplantation.

Major changes to this edition include the following:

a) donor history related to West Nile virus has been updated;
b) donor advocate has been clarified in Clause 12.2.3;
c) exclusion of islet cells haven been updated in Clause 15.4; and
d) a new informative Annex summarizing exceptional distribution criteria has been added.

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 Subcommittee on Perfusable Organs, under the jurisdiction of the Technical Committee on Safety of Cells, Tissues, and Organs for Transplantation and Assisted Reproduction and 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.*

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

1 Scope

1.1
This Standard addresses issues related to the safety of human perfusable organs used for transplantation. It includes quality system requirements and aspects of safety for potential and actual donors and recipients, personnel, and others who might be exposed to, or affected by, the transplantation of perfusable organs.

1.2
This Standard applies to establishments (or facilities) and individuals involved in the following activities related to perfusable organs intended for transplantation:

a) processing;
b) evaluation of the safety of perfusable organs prior to transplantation;
c) recordkeeping;
d) error, accident, and adverse reaction reporting;
e) distribution;
f) importation or exportation; and
g) recall of human organs intended for transplantation.

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 g) in Clause 1.2.

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

a) *organ donation organizations (ODOs);*
b) *transplant programs and facilities (hospitals and special clinics); and*
c) *histocompatibility laboratories.*

1.4
This Standard is not intended to replace detailed specifications and standard operating procedures but is intended to be used in their preparation.

1.5
This Standard contains particular requirements for perfusable organs for transplantation and is intended to be used with CAN/CSA-Z900.1. Where differences exist, the requirements of this Standard apply.

1.6
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.

CSA Group

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

ASHI (American Society for Histocompatibility and Immunogenetics)

ASHI Laboratory Manual, 4th edition (2000)

CCDT (Canadian Council on Donation and Transplantation)

Medical management to optimize donor organ potential: A Canadian Forum (2004)

Health Canada

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.

Other publications

Shemie, S.D., *et al*. 2006a. Severe brain injury to neurological determination of death; Canadian Forum recommendations. *CMAJ* 174 (6): S1–S12.

Shemie, S.D., *et al*. 2006b. National recommendations for donation after cardiocirculatory death in Canada. *CMAJ* 175 (6) S1–S24.

3 Definitions and abbreviations

3.1 Definitions

In addition to the definitions in CAN/CSA-Z900.1, the following definitions shall apply in this Standard:

Adjunct vessels — blood vessels retrieved from a deceased donor to assist organ transplantation.

Notes:

1) *Adjunct vessels, such as iliac vessels, that are retrieved with an organ and not used immediately in the organ transplantation are subject to the same regulatory requirements as organs under Health Canada,*

SOR/2007-118 (see Section 1, "Definitions," Section 35, "Storage," and Section 67, "Requirements for Storage").

2) *Establishment requirements for adjunct vessels are included in Clause 15.6.8.*

Histocompatibility laboratory (or **HLA laboratory** or **tissue typing laboratory)** — a laboratory affiliated with one or more ODOs, and one or more transplant centres, that has the responsibility for the histocompatibility typing of donors and recipients and for performing immunologic suitability (including histocompatibility testing) for the clinical purpose of determining the suitability of an organ for a recipient.

Note: *Immunologic suitability is a state where, unique to the organ and patient being transplanted, the HLA laboratory and clinical care team have determined that transplant may proceed with acceptable and manageable immunologic risk.*

3.2 Abbreviations

The following abbreviations shall apply in this Standard:

ABG — arterial blood gases

AIDS — acquired immunodeficiency syndrome

ALP — alkaline phosphatase

ALT — alanine aminotransferase

AST — aspartate aminotransferase

CBC — complete blood count

CJD — Creutzfeldt-Jakob disease

CK MB — creatine kinase

CMV — cytomegalovirus

CORR — Canadian Organ Replacement Registry

CPK — creatine phosphokinase

EBV — Epstein-Barr virus

ECG — electrocardiogram

FRCP(C) — Fellow of the Royal College of Physicians of Canada

FRCS(C) — Fellow of the Royal College of Surgeons of Canada

GGT — gamma glutamyltransferase

HBC — hepatitis B core

HBsAg — hepatitis B virus surface antigen

HBV — hepatitis B virus

HCV — hepatitis C virus

HIV — human immunodeficiency virus

HLA — human leukocyte antigen

HTLV — human T-cell lymphotropic virus

INR — International Normalized Ratio

LDH — lactate dehydrogenase

NAT — nucleic acid test
ODO — organ donation organization
PEEP — positive end-expiry pressure
PT — prothrombin time
SOP — standard operating procedures

4 Establishment requirements

4.1 Establishment identity

4.1.1 General

In addition to the requirements specified in Clause 4.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 4.1.2 to 4.1.4 of this Standard shall apply.

4.1.2 Organ donation organization

The documentation for each organ donation organization (ODO) shall include
a) a record of the hospital(s) and regions that it serves;
b) the transplant centre(s) and transplant program(s) with which it is affiliated;
c) the other institutions (e.g., hospitals, universities) with which it is affiliated; and
d) the histocompatibility laboratory or laboratories with which it is affiliated.

4.1.3 Transplant programs

The documentation for each transplant program shall include
a) specification of the organ(s) transplanted;
b) the transplant centre(s) in which it operates;
c) the ODO(s) and the histocompatibility laboratory (or laboratories) with which it is affiliated; and
d) where applicable, the university and other institutions with which it is affiliated.

4.1.4 Histocompatibility laboratory

The documentation for each histocompatibility laboratory shall include
a) a record of the ODO(s) it serves;
b) the transplant centre(s) and program(s) with which it is affiliated; and
c) other institutions (e.g., hospitals, universities) with which it is affiliated.

4.2 Personnel

4.2.1 General

The requirements specified in Clause 4.2.1 of CAN/CSA-Z900.1 shall apply in this Standard.

4.2.2 Training

The requirements specified in Clause 4.2.2 of CAN/CSA-Z900.1 shall apply in this Standard.

4.2.3 Medical and scientific director

4.2.3.1 General

The requirements specified in Clause 4.2.3 of CAN/CSA-Z900.1 shall apply in this Standard, except where indicated in Clause 4.2.3.5 of this Standard. In addition, the requirements specified in Clauses 4.2.3.2 to 4.2.3.4 of this Standard shall apply.

4.2.3.2 Training

The medical director or scientific director shall ensure that all staff members have adequate training to perform their duties safely and competently and shall be responsible for ensuring that staff members maintain their competency by participating in training courses and technical meetings or other educational programs.

4.2.3.3 Organ donation organization

The medical director of an ODO shall be a physician or surgeon with expertise in organ donation, transplantation, or critical care.

4.2.3.4 Transplant program

The medical director of a transplant program shall

a) be a transplant physician or transplant surgeon;
b) be responsible for authorization of the transplant surgeons;
c) indicate to the medical director of the ODO the name, position, and qualifications of the surgeons who are to have donor operation privileges;
d) be responsible for the authorization of the donor surgeons but not for their professional or surgical activities;
e) indicate to the medical director of the ODO the individuals who are authorized to accept an organ; and
f) indicate to the medical director of the ODO the individuals who are authorized to list or change the listing of a potential recipient.

4.2.3.5 Histocompatibility laboratory

For histocompatibility laboratories, the requirements specified in Clause 4.2.3.1 of CAN/CSA-Z900.1 shall not apply. Histocompatibility laboratories shall have a director. The director shall be a physician (i.e., medical doctor), PhD, or equivalent. If the director is not a physician, the laboratory shall have an affiliated medical consultant.

4.2.4 Transplant physicians and surgeons

4.2.4.1

Each transplant program shall have at least one transplant physician and one transplant surgeon.

4.2.4.2

Transplant physicians and surgeons shall

a) be physicians with
   i) an MD (medical doctor) degree or equivalent; and
   ii) be qualified to practise medicine in the jurisdiction of their transplant centre;
b) have an FRCP(C) or FRCS(C) certificate from the Royal College of Physicians and Surgeons of Canada, or equivalent; and

c) have an appointment as medical staff of the transplant centre and, where applicable, an appointment at an affiliated university.

Note: *In Canada, physicians are qualified to practice under provincial/territorial licensing regulations.*

4.2.4.3

In addition to the requirements specified in Clause 4.2.4.2, transplant physicians shall also have at least one year of specialized formal training in transplant medicine or a minimum of two years of experience in transplant medicine in an established transplant program, and during the course of that training have been involved in and had responsibility for all aspects of transplantation, including

a) donor assessment and match-up with potential recipient;
b) recipient management, assessment, and selection;
c) post-operative care, including immunosuppressive management; and
d) outpatient and follow-up care.

4.2.4.4

If the transplant physician's training meets all of the requirements of Clause 4.2.4.3, with the exception of Item b), a minimum of three years of experience with an established transplant program, during which all other requirements are met, shall be considered equivalent.

4.2.4.5

In addition to the requirements specified in Clause 4.2.4.2, kidney, liver, pancreas, and intestinal transplant surgeons shall also

a) have operating room privileges at the transplant centre with which they are affiliated; and
b) have completed formal transplant training, and during the course of that training have been involved in, and had responsibility for, all aspects of transplantation, including
    i) donor management, assessment, and selection;
    ii) recipient management, assessment, and selection;
    iii) post-operative care, including immunosuppressive management;
    iv) outpatient and follow-up care; and
    v) a minimum of 10 organ retrieval and 12 recipient operations as the primary surgeon or first assistant.

4.2.4.6

In addition to the requirements specified in Clause 4.2.4.2, transplant surgeons involved with heart and lung transplantation shall

a) have operating room privileges at the transplant centre with which they are affiliated;
b) have training in heart and/or lung transplantation; and
c) have performed, as primary surgeon or first assistant, at least 10 donor procedures and at least 20 heart or lung transplant recipient procedures during cardiothoracic residency or fellowship, or as an attending staff surgeon.

4.2.5 Donor coordinator

Note: *Donor coordinators can also be referred to as retrieval coordinators, clinical coordinator-advisors, or organ donor specialists.*

4.2.5.1

Each ODO shall have one or more donor coordinators. The description and responsibilities of the donor coordinator shall be documented in the SOPs.

4.2.5.2

The following shall be outlined in the SOPs:

a) the donor coordinator's responsibilities for notification of the office of the medical examiner or coroner (see Clause 10.4);
b) the criteria for organ donation (both general and organ specific), which shall be part of the working knowledge of the coordinator; and
c) the waiting list for organ allocation, to which the coordinator shall have immediate access.

4.2.5.3

A donor coordinator shall be available 24 h a day, 365 days a year, for donor referral and all the procedures required for the process of organ donation.

4.2.5.4

A donor coordinator shall have one of the following qualifications:

a) an MD (medical doctor) degree or a licensed, registered nurse degree and qualified to practice in the jurisdiction where the establishment is located;
b) a baccalaureate degree (e.g., BA, BSc), with 24 months of organ donation/retrieval or clinical health care experience; or
c) other health care professional qualification (e.g., physiotherapy, respiratory technology), with 24 months of organ retrieval or clinical health care experience.

Note: *In Canada, qualification of health care professionals is covered under provincial/territorial licensing regulations.*

4.2.5.5

An individual who is newly recruited to the ODO as a donor coordinator shall undergo a period of orientation and supervised practical training. The period of supervised practical training should be not less than three months. At the conclusion of this period, he or she shall demonstrate a theoretical and practical knowledge of the standard operating procedures (SOP), as determined by the medical director and/or designate.

The procedures for orientation and training of a new donor coordinator shall be outlined in the SOPs of the ODO. The training shall be documented in the personnel file.

4.2.5.6

Donor coordinators shall be responsible for identifying and fulfilling their own ongoing educational requirements in order to meet the requirements of the authority having jurisdiction.

ODOs shall facilitate the identification and fulfillment of the ongoing educational requirements of donor coordinators.

Note: *In Canada, qualification of health care professionals is covered under provincial/territorial licensing regulations.*

4.2.6 Recipient coordinator

Note: *Recipient coordinators can also be referred to as transplant coordinators.*

4.2.6.1

Each transplant program shall have one or more recipient coordinators. The description and responsibilities of the recipient coordinator shall be documented in the SOPs and may include activities such as pre- and/or post-operative patient assessment and management.

4.2.6.2

A recipient coordinator shall have one of the following qualifications:

a) a doctor of medicine (MD) degree or a registered nurse degree and qualified to practice in the jurisdiction where the establishment is located; or
b) a baccalaureate degree (e.g., BA, BSc), with 12 months of organ retrieval or clinical transplantation work experience.

Note: *In Canada, qualification of health care professionals is covered under provincial/territorial licensing regulations.*

4.2.6.3

An individual who is newly recruited to the transplant centre or program as a recipient coordinator should undergo an appropriate period of orientation and practical training. At the conclusion of the training period, he or she shall demonstrate a theoretical and practical knowledge of the standard operating procedures, as determined by the medical director of the transplant program.

The procedures for orientation and training of a new recipient coordinator shall be outlined in the SOPs of the transplant program. This training shall be documented in the personnel file.

4.2.6.4

Recipient coordinators shall be responsible for identifying and fulfilling their own ongoing educational requirements in order to meet the requirements of the authority having jurisdiction.

Transplant programs shall facilitate the identification and fulfillment of the ongoing educational requirements of recipient coordinators.

Note: *In Canada, qualification of health care professionals is covered under provincial/territorial licensing regulations.*

4.3 Quality management

The requirements specified in Clause 4.3 of CAN/CSA-Z900.1 shall apply in this Standard.

5 Facilities

5.1 General

5.1.1 Application

In addition to the requirements specified in Clause 5.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 5.1.2 and 5.1.3 of this Standard shall apply.

5.1.2 Organ donation organization

ODOs shall have sufficient resources for clerical and secretarial activities, such as

a) communicating with donor families and participants in the organ retrieval process;
b) documenting each donor or potential donor;

c) communicating transplant information to other ODOs or transplant centres;
d) accessing waitlist(s);
e) administrative support for maintaining the SOPs and the quality assurance program; and
f) arranging space for the storage of documentation.

5.1.3 Transplant program

The transplant program shall have sufficient resources for clerical and secretarial activities, such as
a) communicating transplant information to ODOs and relevant registries [e.g., the Canadian Organ Replacement Registry (CORR)]; and
b) maintaining accurate waiting lists.

5.2 Security

The requirements specified in Clause 5.2 of CAN/CSA-Z900.1 shall apply in this Standard.

5.3 Equipment

5.3.1 General

In addition to the requirements specified in Clause 5.3 of CAN/CSA-Z900.1, the requirements specified in Clause 5.3.2 of this Standard shall apply.

5.3.2 Refrigerators and freezers

Refrigerators and freezers
a) may be located in the ODO's facilities or pharmacy, or the operating room of the transplant centre;
b) shall be maintained at temperatures optimal for storage of each type of preservation solution;
c) shall have sufficient space to store preservation solution and sterile ice or saline; and
d) shall be electronically monitored and connected to an alarm system 24 h per day, seven days a week.

Note: *Recording thermometers should be used for mechanical refrigerators or freezers.*

5.4 Communication

ODOs shall have communication resources (e.g., pagers and paging systems, telephones, cellular telephones, fax machines, and, where appropriate, portable computers) sufficient for expediting communication among the personnel of the regional hospitals, the transplant programs, the ODOs, the laboratories, the office of the medical examiner or coroner, and the histocompatibility laboratory.

Note: *Time is critical in organ donation and retrieval, and fast reliable communication is an essential factor in providing timely service.*

5.5 Inpatient facilities

5.5.1

In-patient facilities shall be within a transplant centre. Sufficient clinical resources shall be available to the transplant program. These may include, but not be limited to,
a) operating rooms;
b) critical care facilities;
c) laboratory facilities meeting the requirements of the authority having jurisdiction (e.g., blood transfusion, biochemistry, hematology, microbiology, and immunoassay); and

d) nursing, pharmacy, and allied health care professional personnel skilled in the management of transplant patients.

Note: *In Canada, the authority having jurisdiction over medical laboratories is usually the province/territory in which the laboratory is located.*

5.5.2

The SOPs of the transplant program shall specify the standard patient care protocols, including those regarding cytotoxic and/or immunosuppressive medications, and infection control relevant to the transplant patient.

5.6 Outpatient facilities

Outpatient facilities (including those required for emergency medical conditions) shall be sufficient for the volume of patients being managed by the transplant program. Twenty-four hour assistance for transplant patients shall be available through either the transplant program or an affiliated hospital. These requirements shall apply to facilities for outpatient clinic visits, minor operative procedures, and counselling.

6 Standard operating procedures

The requirements specified in Clause 6 of CAN/CSA-Z900.1 shall apply in this Standard.

7 Records and tracking

7.1 General

7.1.1

In addition to the requirements specified in Clause 7.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 7.1.2 and 7.1.3 of this Standard shall apply.

7.1.2

The applicable requirements concerning confidentiality and the transmission of information shall be strictly adhered to and enforced.

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

7.1.3

Medical records shall be available to members of the patient care team.

7.2 Donor identification

7.2.1 General

In addition to the requirements specified in Clause 7.2 of CAN/CSA-Z900.1, the requirements specified in Clause 7.2.2 of this Standard shall apply.

7.2.2 Donor information

The following minimum information regarding the donor shall be obtained by the source establishment:

a) name;

b) date of birth;
c) sex;
d) address;
e) for deceased donors, cause of death, and next of kin and their relationship; and
f) the unique identifier of the establishment (see Clause 4.1.1 of CAN/CSA-Z900.1).

Strict confidentiality shall be respected at all times.

7.3 Recordkeeping

7.3.1 General

In addition to the requirements specified in Clause 7.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 7.3.2 to 7.3.5 of this Standard shall apply.

7.3.2 Documentation

Each inquiry regarding a potential donor shall be documented. Documentation of every inquiry regarding the suitability of a potential donor shall include the date and time the inquiry was conducted, the name of the inquiring centre, the status of the inquirer (nurse, physician, relative, etc.), a brief description of the inquiry, and the coordinator's response. If the inquiry leads to organ donation, the inquiry documentation shall be included in the donor log.

7.3.3 Mandatory information

The mandatory information outlined in Table 1 shall be collected and maintained by the ODO.

7.3.4 Donor chart

7.3.4.1

The donor chart shall include the following logs:
a) the transport log;
b) the follow-up log; and
c) the donor coordinator's process log (or "donor log").

7.3.4.2

The transport log shall include
a) the type of storage system and mode of transport;
b) the organ retrieved;
c) identification of the retrieval team; and
d) the date and time of the request and of the departure and arrival of the organ.

7.3.4.3

The follow-up log shall include
a) documentation of all significant laboratory results and transmissions received post-operatively (e.g., cultures and sensitivities, serology, biopsy, autopsy); and
b) all follow-up activities as determined by the SOPs.

7.3.4.4

The donor coordinator's process log (or donor log) shall include

a) complete and detailed documentation of all steps and activities performed by the donor coordinator(s) from referral to long-term follow-up;
b) the identity of the donor coordinator(s) performing the work; and
c) the date and times that the steps and activities were accomplished.

7.3.5 Recipient records

7.3.5.1 General

7.3.5.1.1

Recipient information shall be maintained in accordance with the transplant program's SOPs.

7.3.5.1.2

Information pertaining to errors, accidents, and adverse events, complaints, and recalls identified on receipt of the organ, including packaging, storage, and distribution, shall be documented.

7.3.5.1.3

Information pertaining to adverse events or outcomes shall be documented in the patient's chart.

7.3.5.2 Mandatory information

The mandatory information outlined in Table 2 shall be collected and maintained by the transplant program.

7.4 Tracking

7.4.1 General

In addition to the requirements specified in Clause 7.4 of CAN/CSA-Z900.1, the requirements specified in Clauses 7.4.2 and 7.4.3 of this Standard shall apply.

7.4.2 Registration of transplantation information

ODOs and transplant establishments shall provide the relevant registries with the information they request within the time specified by the registries.

Note: *The intent of this Clause is to*

a) *provide baseline information;*
b) *facilitate and ensure tracking and notification of all recipients; and*
c) *if necessary, allow the recall of all untransplanted organs.*

7.4.3 Transmission

The transmission of information shall be made in a manner that ensures confidentiality and does not affect accuracy, completeness, or legibility.

8 Infection control and safety

The requirements specified in Clause 8 of CAN/CSA-Z900.1 shall apply in this Standard.

9 Disposal of organs

9.1 General

The requirements specified in Clause 9.1 of CAN/CSA-Z900.1 shall apply in this Standard.

9.2 Human remains

9.2.1

In addition to the requirements specified in Clause 9.2 of CAN/CSA-Z900.1, the requirements specified in Clause 9.2.2 of this Standard shall apply.

9.2.2

The SOPs shall describe the procedure for the disposal of organs from the medical examiner's and coroner's cases.

9.3 Documentation

9.3.1

In addition to the requirements specified in Clause 9.3 of CAN/CSA-Z900.1, the requirements specified in Clause 9.3.2 of this Standard shall apply.

9.3.2

Information concerning the disposal of non-transplantable organs shall be documented in the ODO's donor chart.

10 Consent

10.1 General

10.1.1

In addition to the requirements specified in Clause 10.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 10.1.2 to 10.1.4 of this Standard shall apply.

10.1.2

The SOPs shall outline the process for obtaining consent for organ donation. The donor coordinator shall ensure that consent for organ donation has been obtained.

10.1.3

The SOPs shall outline the process for obtaining consent for organ transplantation. The process shall include a discussion of the risks and benefits of transplantation by a transplant physician or surgeon, and consent shall be obtained prior to transplantation.

10.1.4

The determination of the appropriate individual to grant consent shall conform to applicable requirements and shall be documented in the SOPs.

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

10.2 Predonation counselling

10.2.1
In addition to the requirements specified in Clause 10.2 of CAN/CSA-Z900.1, the requirements specified in Clause 10.2.2 of this Standard shall apply.

10.2.2
The consenting person(s) shall be fully informed of the process of organ donation, including the requirement for further screening for the presence of communicable diseases, including viral hepatitis, acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), and cancer.

10.3 Basis of consent

10.3.1
In addition to the requirements specified in Clause 10.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 10.3.2 and 10.3.3 of this Standard shall apply.

10.3.2
In addition to the requirements specified in Clause 10.3.3.1 of CAN/CSA-Z900.1, documentation of the steps taken shall include
a) the establishment (or facility) identifier;
b) the organ(s) to be donated;
c) the name, address, and relationship/position of the person giving consent; and
d) the name of the person acting as a witness, if used.

10.3.3
A copy or photocopy of the consent shall be kept by the source establishment as part of the documentation for that donor.

10.4 Medical examiner and coroner cases
The requirements specified in Clause 10.4 of CSA Z900.1 shall apply in this Standard.

10.5 Living donors

10.5.1
The SOPs of the transplant program shall describe the mandatory living donor assessment procedures that are used to determine the suitability of the potential donor.

10.5.2
In transplant programs that use a two-consent process (i.e., the first expressing intent and consent for investigation and the second consent for the operative procedure), the process shall be documented.

10.5.3
The SOPs shall describe the methods used to minimize the potential for coercion in the living donor selection and consent process, as well as the methods used to determine that no material reward (financial or otherwise) is given to the donor.

10.5.4
The potential donor shall be fully informed of the process of living donor organ donation, including the testing for his or her suitability for organ donation, and testing for the presence of notifiable communicable diseases as well as the risks of the procedure.

11 Compensation
The requirements specified in Clause 11 of CAN/CSA-Z900.1 shall apply in this Standard.

12 Donor suitability assessment

12.1 General
The requirements specified in Clause 12.1 of CAN/CSA-Z900.1 shall apply in this Standard.

12.2 Suitability of donors

12.2.1 General
In addition to the requirements specified in Clause 12.2 of CAN/CSA-Z900.1, the requirements specified in Clauses 12.2.2 and 12.2.3 of this Standard shall apply.

12.2.2 History

12.2.2.1
For living and deceased donors, a donor history shall be obtained from all available medical sources, as well as from next of kin (if applicable), and shall include the completion of a questionnaire.

12.2.2.2
For living and deceased donors, the identity of the person(s) eliciting the donor history shall be documented.

12.2.2.3
The history for all donors, living or deceased, shall include

a) any history of tuberculosis or positive skin-testing for tuberculosis, hepatitis, HIV infection, Creutzfeldt-Jakob disease (CJD), or other communicable disease;

   Note: *Other communicable diseases that could be of concern include (but are not limited to)*

   a) *Epstein-Barr virus (EBV);*
   b) *CMV;*
   c) *syphilis;*
   d) *herpes; and*
   e) *toxoplasmosis, in the case of a heart donation.*

b) any history of malignancy, or other major illnesses, previous hospitalizations, previous surgical procedures, previous blood or blood product transfusions, current medications;
c) any history of disease or abnormality of any of the consented organs or tissues;
d) any suspected or confirmed diagnosis of West Nile virus (WNV) within the last 120 days, or travel in the preceding 56 days to areas where WNV is endemic;
e) any suspected or confirmed diagnosis of an emerging infectious disease;

f) any behaviour or history associated with higher risk of HIV, HBV, and HCV as specified in Annex E of CAN/CSA-Z900.1;
g) travel outside of the donor's province and outside of Canada in the past six months;
h) history of residence longer than one month outside of Canada;
i) history of animal bite in the past six months; and
j) any history of potential life-threatening allergy.

Notes:

1) *Information gathered in the donor history is used to evaluate the donor's risk of having a transmissible disease. An identified risk will not necessarily lead to exclusion; however, it is important information for the purpose of clinical decision making.*
2) *The information in Item j) (history of allergy) should be communicated to the recipient if it is considered to be clinically significant. For example, information on the presence of a life-threatening allergy in the donor, with potential to be transferred to the recipient, would alert the recipient to avoid the allergen(s) in question and/or seek appropriate testing.*

12.2.2.4

In addition to the requirements of Clause 12.2.2.3, the history for deceased donors shall include

a) the probable cause of death;
b) any episode of hemodynamic instability since the onset of critical illness, the treatment history, and most recent status;
c) any episode of sepsis since the onset of critical illness, its documentation (culture report), and treatment; and
d) for a donor infant less than 18 months of age or who was breast-fed within the 12 months* preceding the donation, a maternal history that includes
   i) history of tuberculosis, hepatitis, or other communicable disease; and
   ii) any high-risk behaviour for HIV, HBV, and HCV as specified in Annex E of CAN/CSA-Z900.1.

   Note: *Other communicable diseases that could be of concern include, but are not limited to,*
   a) *EBV;*
   b) *CMV;*
   c) *syphilis;*
   d) *herpes; and*
   e) *toxoplasmosis, in the case of a heart donation.*

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

12.2.3 Assessment of living donors

12.2.3.1

Potential living donors should undergo an independent assessment by

a) a physician/surgeon who is not a member of the recipient transplant team; or
b) a donor advocate (e.g., nurse or other physician) knowledgeable in the risks involved and also independent from recipient care.

12.2.3.2

The assessment described in Clause 12.2 of CAN/CSA-Z900.1 shall include a general assessment of the risk for the living donor operation, as well as a specific assessment of the organ(s) to be donated. During this process, the potential living donor should be given the opportunity to decline to donate.

12.2.3.3
The SOPs shall identify the physicians who are authorized to perform the assessment described in Clause 12.2 of CAN/CSA-Z900.1.

12.2.3.4
The preoperative assessment procedures shall include
a) history;
b) physical examination;
c) testing; and
d) psychosocial evaluation.

12.2.3.5
The process for psychosocial assessment shall be documented.

12.2.3.6
The same process for history that is used for deceased donors should be used for potential living donors.

12.2.3.7
In addition to the requirements of Clause 12.2 of CAN/CSA-Z900.1, the physical examination for living donors shall include
a) an assessment of risks by an anesthesiologist and surgeon ;
b) a determination of the health of the organ(s) to be donated; and
c) assessment of potential impact of donation on the long-term health of the donor.

12.2.3.8
The tests specified in Clause 14.2 shall be performed within one month of the surgery. The minimum testing required at the transplant centre for the anaesthetic and operative procedure shall be performed.

Note: *Living donors should be retested at the time of donation, even if the results are not available before the time of transplantation.*

12.2.3.9
The requirements for human leukocyte antigen (HLA) typing and crossmatching shall be documented in the SOPs.

12.3 Documentation
The requirements specified in Clause 12.3 of CAN/CSA-Z900.1 shall apply in this Standard.

13 Donor screening

13.1 Contraindications or exclusion criteria

13.1.1 General
In addition to the requirements specified in Clause 13.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 13.1.2 and 13.1.3 of this Standard shall apply.

13.1.2 Additional criteria

In addition to the contraindications specified in Clause 13.1.3 of CAN/CSA-Z900.1, the following additional contraindications or exclusion criteria shall apply:

a) persons with unexplained lymphadenopathy mass or mucocutaneous lesions;
b) persons with needle tracks or other signs of injection drug abuse;
c) persons with active infections of clinical significance;
d) persons with syphilis; and
e) persons with a malignancy, except for a cutaneous basal cell or squamous cell carcinoma that has been treated.

13.1.3 Exceptional distribution

13.1.3.1

Exceptional distribution of perfusable organs from donors to whom any of the contraindications or exclusion criteria apply (as specified in Clause 13.1.3 of CAN/CSA-Z900.1, and Clauses 13.1.2 and 13.2.2 of this Standard) is provided for in Clause 18.4 of CAN/CSA-Z900.1 and Clause 18.7 of this Standard.

Note: *Exceptional distribution can occur in circumstances other than emergency transplantation.*

13.1.3.2

Potential recipients of perfusable organs under exceptional distribution shall be advised and consent shall be documented in accordance with applicable requirements.

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

13.2 Physical examination

Note: *This Clause applies to both living and deceased donors.*

13.2.1 General

In addition to the requirements specified in Clause 13.2 of CAN/CSA-Z900.1, the requirements specified in Clauses 13.2.2 to 13.2.4 of this Standard shall apply.

13.2.2 Clinical procedures

Additional contraindications or exclusion criteria as specified in Clause 13.1.2 shall also apply and shall be assessed through physical examination, donor screening questions, and/or laboratory tests as appropriate. As appropriate, the physical examination shall also be used to assist in determining whether there is evidence of

a) high-risk behaviour for HBV, HCV, or HIV (see Annex E of CAN/CSA-Z900.1); or
b) the contraindications specified in Clause 13.1.3 of CAN/CSA-Z900.1.

13.2.3 Documentation

The name(s) of the individual(s) performing the physical examination, their status and affiliation, and relevant positive findings shall be documented.

13.2.4 Intraoperative assessment

13.2.4.1

For living donors, the donor's surgeon(s) shall assess the donor for the presence of an infection or malignancy.

13.2.4.2

For living and deceased donors, the presence of an unsuspected infection or malignancy shall be identified and reported. The donor's surgeon shall also assess the physical quality of the organ(s) to be donated. Any abnormality or concern shall be documented, and the transplanting program shall be immediately notified.

13.3 Release

An organ shall not be released by an ODO to another ODO or transplant program unless

a) all donor suitability assessment requirements as specified in Clause 14 have been met, including completion of the required infectious serological tests; and
b) the requirements of Clause 13.1 have been met.

Outside of these conditions, organs may be released only under exceptional distribution, as specified in Clause 18.4 of CAN/CSA-Z900.1 and Clause 18.7 of this Standard.

14 Testing

14.1 General

14.1.1

In addition to the requirements specified in Clause 14.1 of CAN/CSA-Z900.1, the requirements specified in Clause 14.1.2 of this Standard shall apply.

14.1.2

General tests and measurements shall include the following:

a) height;
b) weight;
c) ABO blood type;
d) complete blood count (CBC) to include at minimum hemoglobin, hematocrit, white blood cell (WBC), platelet counts;
e) levels of serum electrolytes, to include at minimum sodium and potassium;
f) levels of creatinine; and
g) chest X-ray.

Note: *For lung or heart-lung donors, the chest X-ray images should be available to the surgeon at the time of recovery.*

14.2 Laboratory testing

14.2.1 Infectious disease testing

The requirements specified in Clause 14.2.1 of CAN/CSA-Z900.1 shall apply in this Standard.

Note: *Testing protocols should be designed to facilitate the exceptional distribution of otherwise acceptable organs from donors who do not meet the selection requirements as specified in Clause 13.1.3 of CAN/CSA-Z900.1 and Clause 13.1.2 of this Standard. Testing recommendations for potential organ donors should take into account the urgency, geography, and other logistical issues inherent to organ donation. For example, donors should also be tested for HIV-1 and HCV using NAT, if available. In particular, NAT should be performed in circumstances where it is clinically indicated, for example, if a decision is made to use exceptional distribution for a cell, tissue, or organ (CTO) from a donor with a history of high risk behaviour and a negative serological test for HIV and HCV.*

14.2.2 Blood tests

The requirements specified in Clause 14.2.2 of CAN/CSA-Z900.1 shall apply in this Standard.

14.2.3 Confirmatory or supplemental tests

The requirements specified in Clause 14.2.3 of CAN/CSA-Z900.1 shall apply in this Standard.

14.2.4 Donor re-entry

The requirements specified in Clause 14.2.4 of CAN/CSA-Z900.1 shall apply in this Standard.

14.2.5 Notification

The requirements specified in Clause 14.2.5 of CAN/CSA-Z900.1 shall apply in this Standard.

14.2.6 Minimum testing for infectious diseases

14.2.6.1

In addition to the requirements specified in Clause 14.2.6 of CAN/CSA-Z900.1, Clauses 14.2.6.2 to 14.2.6.4 of this Standard shall apply.

14.2.6.2

Each laboratory shall have established its proficiency and accuracy of performance as part of its ongoing program of quality assurance. This shall be documented within the laboratory.

For laboratories that are not within a transplant centre or regional hospital, the ODO shall keep on file a copy of the documentation that demonstrates compliance with the applicable authority having jurisdiction.

Note: *Documentation may include a license or certificate of accreditation or inspection.*

14.2.6.3

Donor testing shall include testing for the following diseases or disease agents:

a) syphilis;
b) CMV;
c) EBV;
d) HTLV 1 and HTLV 2; and
e) if the donor is a heart donor, toxoplasmosis.

The test results shall be documented in the donor record. It is acceptable to report the results of the tests for CMV, EBV, and toxoplasmosis following organ distribution.

Note: *These tests are in addition to those specified in Clause 14.2.6 of CAN/CSA-Z900.1.*

14.2.6.4

The donor should also be tested for WNV if the donation is made during the time of year when WNV is potentially transmissible to humans in the country in which the donor resides, or if there are other circumstances that would lead to testing, e.g., if in the preceding 56 days, a donor has travelled to an area where WNV is endemic. The results of this test may be reported following organ distribution.

Note: *Donors should be tested for WNV using a test kit that has been licensed for the detection of viral nucleic acid.*

14.2.6.5

Placeholder

Note: *The requirement for toxoplasmosis testing in Clause 14.2.6.5 of the 2003 edition of this Standard has been revised and moved to Clause 14.2.6.3 of this current edition. The clause number has been retained in this edition to maintain alignment with clause references in Health Canada, SOR/2007-118.*

14.2.6.6

Placeholder

Note: *The requirement for syphilis testing in Clause 14.2.6.6 of the 2003 edition of this Standard has been revised and moved to Clause 14.2.6.3 of this current edition. The clause number has been retained in this edition to maintain alignment with clause references in Health Canada, SOR/2007-118.*

14.2.7 Blood typing

The requirements specified in Clause 14.2.7 of CAN/CSA-Z900.1 shall apply in this Standard.

14.2.8 Plasma dilution

The requirements specified in Clause 14.2.8 of CAN/CSA-Z900.1 shall apply in this Standard.

14.2.9 Archived samples

14.2.9.1

For every donor, serum samples should be collected and saved for at least five years. These may be used for retrospective testing.

14.2.9.2

The process used in the preparation, labelling, documenting, and storage of the specimen should be documented in the SOPs.

14.3 Other testing

14.3.1 Histocompatibility laboratory

The SOPs, the operations of the laboratory, and participation in proficiency testing programs of the histocompatibility laboratory shall conform to standard procedures and advanced techniques described in the *ASHI Laboratory Manual.*

The SOPs shall also describe

a) the specimens (peripheral blood, lymph nodes, spleen) and the quantities of each that are required by the histocompatibility laboratory from the potential perfusable organ donor;
b) the methods of preparation, labelling, storage, transportation, and timely delivery of the specimens; and
c) the procedures for communicating the results from the laboratory in a confidential and timely manner.

14.3.2 Additional testing for specific types of organ donation

14.3.2.1 General

Depending on the type of organ being donated, donor tests in addition to those specified in Clauses 14.1.2 and 14.2.6.3 shall be performed as specified in Clauses 14.3.2.2 to 14.3.2.6.

14.3.2.2 Kidneys

At a minimum, the following tests shall be performed for potential kidney donors:

a) urea testing; and
b) urinalysis.

14.3.2.3 Heart

At a minimum, the following tests shall be performed for potential heart donors:

a) electrocardiogram (ECG); and
b) cardiac echocardiography.

14.3.2.4 Lungs

14.3.2.4.1

At a minimum, the following tests shall be performed for deceased potential lung donors:

a) a tracheal or bronchial airway gram stain and specimen for culture, obtained prior to or at the time of organ procurement; and
b) pO_2 on 100% oxygen after being on positive end-expiratory pressure (PEEP), with the PEEP settings and timing determined through clinical judgement.

Note: *Typical settings and timing for PEEP would be 5 cm H_2O for a minimum of 10 min.*

14.3.2.4.2

Living lung donors shall be tested through a gram stain and culture of tracheal aspirate at the time of organ procurement.

14.3.2.5 Liver

At a minimum, the following tests shall be performed for potential liver donors:

a) bilirubin testing;
b) either aspartate aminotransferase (AST) or alanine aminotransferase (ALT); and
c) either prothrombin time (PT) or International Normalized Ratio (INR).

14.3.2.6 Pancreas (including donations for islet cells)

At a minimum, the following tests shall be performed for potential pancreas donors:

a) blood sugar; and
b) amylase or lipase.

15 Retrieval, preparation, preservation, and storage

15.1 General

15.1.1

In addition to the requirements specified in Clause 15.1 of CAN/CSA-Z900.1, the requirements specified in Clause 15.1.2 of this Standard shall apply.

15.1.2

The primary responsibility for the donor's medical care shall remain with the primary physician of record in the intensive care unit, or his or her designate.

15.2 Reagents and supplies

The requirements specified in Clause 15.2 of CAN/CSA-Z900.1 shall apply in this Standard.

15.3 Retrieval

15.3.1 General

In addition to the requirements specified in Clause 15.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 15.3.2 to 15.3.8 of this Standard shall apply.

15.3.2 Organ donation organization

15.3.2.1

The SOPs of the ODO shall describe the time limits and environmental conditions for retrieval, preservation, and transportation of the perfusable organ (if applicable).

Note: *See Clause 15.6.8 for the requirements relating to adjunct vessels.*

15.3.2.2

The SOPs of the ODO shall

a) describe principles of donor management that are intended to optimize the oxygenation and perfusion of the organs to be donated;
b) provide specific guidelines for the critical care management of the donor to optimize pulmonary function, cardiovascular stability, and renal function;
c) describe the time limits, environmental conditions, and appropriate records to be kept for each organ;
d) describe the assignment of expiration to each organ and the proper documentation; and
e) describe the coordination of organ retrieval and, where applicable, include strategies to ensure timeliness and coordination with recipient procedure.

Note: *These principles should be based on the CCDT* Medical Management to Optimize Donor Organ Potential: A Canadian Forum.

15.3.2.3

The organ retrieval procedure in the operating room shall be detailed in the SOPs. For each organ, the standard operating procedures shall include

a) the equipment and perfusion solutions required;
b) the procedures for set-up and operation of the perfusion solutions;
c) documentation of the operative procedure;
d) inspection and documentation of the data concerning the organ's anatomy, quality, anomalies, etc.;
e) packaging; and
f) required labelling.

15.3.2.4

The SOPs shall describe the medical consultation resources available to the coordinator for advice on specific items of donor management.

15.3.3 Donor consideration

15.3.3.1
A donor referral shall initiate the documentation of the referral and subsequent events in order to provide a complete record over time of the organ donation process for that donor. This documentation (i.e., the record, log, or chart of the donation) shall become a part of the record to be kept by the ODO on that patient.

15.3.3.2
The donor coordinator shall evaluate the suitability of the potential donor and initiate the additional tests necessary to determine suitability.

15.3.4 Neurological determination of death

15.3.4.1
The SOPs of the ODO shall set out guidelines for the neurological determination of death that conform to applicable requirements.

Notes:
1) *Federal and provincial/territorial regulations can apply.*
2) *The guidelines should be based on Shemie et al. (2006a).*

15.3.4.2
The SOPs of the ODO shall describe the process to be followed in a donor coordinator's review of a neurological determination of death.

Each donor coordinator shall have a working knowledge of the guidelines described in Clause 15.3.4.1.

15.3.4.3
The record for the donor shall include documentation of the name of the hospital, date and time of declaration, and the name of each of the two physicians who declared neurological death.

15.3.5 Cardiocirculatory death

15.3.5.1
Where applicable, the SOPs of the ODO shall set out guidelines for determination of cardiocirculatory death that conform to applicable requirements.

Notes:
1) *Federal and provincial/territorial regulations can apply.*
2) *The guidelines should be based on Shemie et al. (2006b).*

15.3.5.2
Where applicable, the SOPs of the ODO shall describe the process necessary for a donor coordinator's review of cardiocirculatory death.

Each donor coordinator shall have a working knowledge of the guidelines described in Clause 15.3.5.1.

15.3.5.3
The record for the donor shall include documentation of the name of the hospital, date and time of declaration, and the name of each of the two physicians who declare cardiocirculatory death.

15.3.6 Donor team transportation

15.3.6.1
Each ODO shall have documented procedures for facilitating transportation of a donor surgical team, including clearance from national border authorities if required. The logistics procedures shall be set out in the SOPs.

Note: *Canada's national borders are managed by the Canada Border Services Agency.*

15.3.6.2
The safety of the team members and of the transplanted organ shall be regarded as paramount, and strategies to ensure safety of travel shall be developed and documented.

The life insurance coverage provided by the ODO or transplant centre in connection with travelling personnel shall be documented in the SOPs.

15.3.7 Transplant surgeons

15.3.7.1
The ODO shall maintain a list of transplant surgeons who are authorized to perform the donor operation as the responsible operating surgeon for each type of organ.

15.3.7.2
The transplant surgeons shall be members of the affiliated transplant program(s) and have operating privileges in the affiliated transplant centre. See Clause 4.2.4.

15.3.8 Living donor operation and post-operative management
The surgeon(s) who are authorized by the medical director to perform the living donor operation shall be documented in the SOPs of the transplant program.

15.4 Preparation and preservation
Note: *Islet cells are excluded from this Clause.*

15.4.1
In addition to the requirements specified in Clause 15.4 of CAN/CSA-Z900.1, the requirements specified in Clauses 15.4.2 to 15.4.5 of this Standard shall apply.

15.4.2
The SOPs of the ODO shall define the assessment process for each organ. The assessment findings shall be documented in the ODO's donor chart.

15.4.3
The donor surgeon shall be responsible for the initial evaluation of the excised organ(s). The name and hospital/institute affiliation of every donor surgeon shall be documented in the ODO's donor chart. The

ODO shall be responsible for documenting the condition and abnormalities of the organ and advising the recipient program of abnormalities.

15.4.4

The SOPs of the ODO shall describe the responsibilities of persons qualified to make a subsequent assessment of an organ. The assessment findings shall be documented in the ODO's donor chart.

15.4.5

The SOPs of the ODO shall

a) detail the procedures for facilitating a biopsy of a donor organ;
b) describe the indications for biopsy of each organ; and
c) describe the process of communicating the biopsy report to the transplant program or surgeon.

Biopsy information and the original report shall be documented in the ODO's donor chart.

15.5 Pooling

The requirements specified in Clause 15.5 of CAN/CSA-Z900.1 shall apply in this Standard.

15.6 Packaging and storage

15.6.1

In addition to the requirements specified in Clause 15.6 of CAN/CSA-Z900.1, the requirements specified in Clauses 15.6.2 to 15.6.8 of this Standard shall apply.

15.6.2

Organs shall be preserved and stored safely, in accordance with scientifically recognized methods. These procedures shall be documented in the ODO donor chart.

The SOPs shall

a) identify packaging and storage containers that are appropriate for the packaging and storage of organs, tissues, and blood samples;
b) describe the methodology for packaging each organ, tissue, or blood sample;
c) describe the responsibilities of the persons involved in the packaging and storage;
d) identify the storage location and the persons responsible for its safekeeping;
e) describe the appropriate environments for storage;
f) describe methods and materials to be used to prevent or deter tampering, along with the responsibilities of the persons authorized to place or remove these materials; and
g) describe methods to inspect, test, clean, and sterilize all containers and packaging materials.

15.6.3

The SOPs shall define the correct storage temperature and environmental conditions for each organ and accompanying tissue and blood. The SOPs shall set out procedures to follow when organs are exposed to conditions other than those defined by the recommended storage limits.

15.6.4

Sterile supplies and packaging materials shall

a) be stored in a manner to ensure integrity and sterility;
b) indicate a sterilization and expiration date; and

c) be stored in a clean, dry, and secure area.

15.6.5
A three-barrier packaging technique shall be used for packaging all organs.

15.6.6
All organs shall be immersed in preservation solution.

15.6.7
Packaging and storage of perfusable organs (except islet cells) shall ensure a temperature of > 0 °C or ≤ 10 °C during transportation.

15.6.8
Adjunct vessels not used immediately in the transplantation of the organ from which they were retrieved shall be stored by a tissue bank and used within a scientifically-based predetermined number of days.

Note: *Adjunct vessels stored under these conditions are subject to the same regulatory requirements as organs under Health Canada Regulation and are not considered, or regulated, as tissues.*

15.7 Disposition of donor's body
The SOPs shall describe the responsibilities of the donor coordinator to ensure the prompt return of the donor's body to the family following organ retrieval and autopsy. Documentation of follow-up procedures shall be included in the ODO donor chart.

15.8 Medical examiner and coroner cases

15.8.1
Where a donor's death becomes a medical examiner's and/or coroner's case, the donor coordinator shall obtain any necessary authorization from the medical examiner or coroner's office before proceeding with organ retrieval.

15.8.2
The SOPs shall describe the procedures required for a medical examiner's or coroner's case.

15.8.3
The SOPs shall document the applicable federal and provincial/territorial laws, regulations, and guidelines for notifying the office of the medical examiner or coroner.

15.8.4
Instances in which the medical examiner or coroner is notified shall be documented.

16 Labels, packaging inserts, and accompanying documentation

16.1 General
The requirements specified in Clause 16.1 of CAN/CSA-Z900.1 shall apply in this Standard.

16.2 Documentation

The requirements specified in Clause 16.2 of CAN/CSA-Z900.1 shall apply in this Standard.

16.3 Information requirements

16.3.1 General

In addition to the requirements specified in Clause 16.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 16.3.2 to 16.3.6 of this Standard shall apply.

16.3.2 Labels

16.3.2.1

The external label shall be durable and shall include the following information in addition to the information required in Table C.4 of CAN/CSA-Z900.1:

a) name of contact person, address, and 24 h telephone numbers of the source ODO;
b) name, address, and telephone numbers of the receiving ODO or hospital and of a contact person; and
c) recommended storage temperature.

16.3.2.2

The exact placement of the interior and exterior label on the packaging material shall be described in the SOPs. The SOPs shall identify the persons authorized to complete the labels.

16.3.3 Inserts

16.3.3.1

A package insert shall accompany the organ and shall contain the following information in addition to the information required in Table C.4 of CAN/CSA-Z900.1:

a) organ classification/code;
b) description of the organ and anatomical details and other assessment and surgical information specific to each organ;
c) donor's serology results (and pathology and microbiology reports, where required);
d) name and quantity of perfusion solution used;
e) name of retrieving surgeon and primary ODO;
f) instructions for maintaining recipient tracking; and
g) the name of the donor coordinator.

The package insert shall become part of the donor log.

16.3.3.2

The exact placement of the insert in the packaging material shall be described in the SOPs. The SOPs shall identify the persons authorized to complete the insert.

16.3.4 Donor confidentiality

Information identifying the donor shall not be included on any labels or inserts.

16.3.5 Verification of packaging, labels, and package inserts

Just prior to release, the packaging shall be examined visually by the primary ODO for appropriate interior and exterior labels, package insert, content, packaging material, and seal quality, and evidence of contamination. The coordinator of the primary ODO shall ensure that interior and exterior labels and package insert are complete and accurate before releasing the organ.

16.3.6 Documentation for future tracking

The following information shall be included in the recipient's chart to permit future tracking, if necessary:

a) the name and phone number of the procuring ODO;
b) the unique donor identification number;
c) the ABO group; and
d) the date and time of aortic cross clamp.

17 Quarantine and release

17.1 General

The requirements specified in Clause 17.1 of CAN/CSA-Z900.1 shall apply in this Standard.

17.2 Living donor quarantine

In reference to the statement in Clause 17.2 of CAN/CSA-Z900.1, this Standard contains no requirements for living donor quarantine.

18 Distribution

Note: *Clauses 18.3, 18.5, and 18.6 are specific to this Standard. Because of their insertion, Clauses 18.4 and 18.7 of this Standard parallel Clauses 18.3 and 18.4 of CAN/CSA-Z900.1, respectively.*

18.1 General

18.1.1

In addition to the requirements specified in Clause 18.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 18.1.2 to 18.1.4 of this Standard shall apply.

18.1.2

The ODO shall be responsible for recordkeeping.

18.1.3

All requests for organs for research shall be submitted in writing and shall indicate the type of organs and the name, address, affiliation of the principal investigator, and the required ethics approval. The request shall be reviewed and final approval shall be determined by the medical director.

18.1.4

The release of organs for transplantation shall be restricted to ODOs, transplant programs, and other medical professionals as identified in the SOPs.

18.2 Transportation

18.2.1

In addition to the requirements specified in Clause 18.2 of CAN/CSA-Z900.1, the requirements specified in Clauses 18.2.2 and 18.2.3 of this Standard shall apply.

18.2.2

The SOPs shall describe the procedures used in the transfer of a donor from one facility to another, specifying

a) the processes of consent;
b) the methods of safe transportation; and
c) the means of ensuring optimal medical management during transfer.

18.2.3

The ODO shall have sufficient means of transportation for travel to a donor hospital, for the transportation of organs and specimens, and for the transportation of transplant teams.

18.3 Organ allocation, offering, and acceptance

18.3.1 Organ allocation

18.3.1.1

The ODO shall retain on file a copy of the organ allocation algorithm that is used for each organ.

18.3.1.2

The SOPs shall document the procedures used to maintain the local, regional, and national waiting list (Canadian Transplant Registry) for each of the perfusable organs, according to the organ allocation algorithm and the procedure used to ensure that the lists are kept up to date and accurate.

The required documentation shall include, but not be limited to,

a) the process used to receive changes to local, regional, and national waiting lists (additions, deletions, and other changes); and
b) the ODO shall only release a perfusable organ to a transplant centre and/or Health Canada registered ODO, or the United States equivalent.

18.3.1.3

The SOPs shall describe the procedures used to access local, regional, and national waiting lists for each organ. The procedures used to offer an organ internationally shall also be documented.

18.3.2 Organ offering

18.3.2.1

The SOPs shall

a) list the individuals from the ODO who are authorized to offer an organ and those from the transplant program(s) who are authorized to decline or accept an organ offering; and
b) describe time limits that ensure timely decision making.

18.3.2.2

The offering of an organ shall

a) be documented;
b) be kept with the donor documentation; and
c) include
    i) the organ(s); and
    ii) the date and time of both the offering and the decision.

18.3.2.3

For organs that are not transplanted, the reasons for not offering the organs shall

a) be documented;
b) be kept with the donor documentation; and
c) include documentation of the name of the individual affiliated with the transplant program who makes the decision, if applicable.

18.3.2.4

An organ may be offered before all the results of the screening tests have been received.

18.3.3 Acceptance of organ offering

18.3.3.1

The SOPs of the transplant program shall contain the list of the names and positions (usually transplant physician or surgeon) of the individuals who are authorized to accept an organ that is offered to the program by an ODO; affiliated ODOs shall also keep this list. The transplant program shall inform the ODO of any changes to this list.

The SOPs shall describe the policies and procedures that ensure timely decision making regarding an organ that is offered.

18.3.3.2

Authorized personnel shall be available 24 h a day to receive organ offerings and to determine who shall receive the organ that is offered, according to the organ allocation algorithm. The SOPs of the transplant program shall document the current organ allocation algorithm.

18.4 Receiver of organs

18.4.1 General

18.4.1.1

In addition to the requirements specified in Clause 18.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 18.4.1.2 to 18.6 of this Standard shall apply.

18.4.1.2

The SOPs shall describe the procedures for the release of an organ to an authorized ODO or transplant program.

18.4.1.3
The source ODO shall be responsible for the organ until it is received by the receiving program or another ODO.

18.4.1.4
The SOPs shall describe the final verification of release, procedures, documentation, and the collection of tracking information for all organs.

18.4.2 Release to an organ donation organization

18.4.2.1
The ODO shall maintain a list of ODOs that are authorized to receive a preserved organ.

18.4.2.2
The responsibility for the preserved organ shall be transferred to the receiving ODO on receipt of the organ.

18.4.2.3
The documentation of the transfer for the originating ODO shall include the date and time of transfer and the name of the receiver.

18.4.2.4
The documentation of the transfer for the receiving ODO shall include a copy of the donor documentation (“log”) to date, as well as the date and time of transfer and the name of the receiver.

18.4.3 Release to a transplant program

18.4.3.1
The ODO shall maintain a list of transplant programs that are authorized to receive a preserved organ.

18.4.3.2
The responsibility for the preserved organ shall be considered to be transferred to the transplant program on receipt of the organ.

18.4.3.3
The documentation of the release to be maintained in the donor log shall include at a minimum the date and time of the release and the name and position of the receiver.

18.5 Recipient consideration

18.5.1 Referral of potential recipient
The SOPs shall describe the mechanism(s) for referral of a potential transplant recipient to the transplant program.

18.5.2 Assessment of potential recipient

18.5.2.1

All potential transplant recipients shall require preoperative investigation in a timely fashion, as outlined in the SOPs.

18.5.2.2

The results of the preoperative investigation shall become part of the potential recipient's chart and shall include the indication for transplantation (with the results of tests that establish the diagnosis) and the assessment of risk factors relevant to successful transplantation (e.g., medical, surgical, psychosocial, and financial).

18.5.2.3

Each recipient should undergo tests for the following infections:

a) anti-HIV-1 and anti-HIV-2;
b) HBV;
c) HCV;
d) CMV;
e) EBV;
f) tuberculosis;
g) varicella zoster; and
h) syphilis.

Note: *Serum should be stored for future testing.*

18.5.2.4

The decision-making mechanism for patient acceptance and placement on the waiting list shall be documented in the SOPs.

18.5.2.5

The individuals who have responsibility for this decision and the process by which each patient's candidacy is assessed shall be documented in the SOPs. For each potential transplant recipient referred to the program, the results of the assessment and the date of the decision shall become part of the patient's medical record.

18.5.3 Listing of future recipients

18.5.3.1

The mechanism by which a patient is placed on a transplant waiting list for deceased organ donors and the information required for that listing shall be documented in the SOPs. The documentation shall include the names of those individuals who are authorized by the medical director to list or to change the listing status of a patient.

18.5.3.2

The mechanism for the timely change in a recipient's status on the waiting list shall be documented in the SOPs. For each patient placed on the waiting list, the date and time of listing shall become part of the patient's medical record.

18.5.3.3
Strict patient confidentiality shall be maintained regarding the waiting list. The waiting list(s) shall be reviewed regularly to ensure accuracy.

18.5.3.4
Certain recipient-specific listing items are critical in the allocation and acceptance of a donor organ, e.g., ABO blood type. The transplant program shall document those data elements that are considered critical.

All critical elements shall be verified at source by a transplant physician/surgeon and a transplant coordinator. The process for verification of these critical data elements shall be documented in the SOPs.

18.5.4 Recipient notification/preparation

18.5.4.1
The transplant program, and/or affiliated ODO, shall maintain a list of the addresses and telephone numbers and, where appropriate, the pager number through which the patient can be contacted when a potential organ becomes available.

18.5.4.2
The procedure and protocol for calling a patient into the transplant centre for the transplant operation shall appear in the transplant program's SOPs.

18.5.4.3
The standard preoperative preparation of the patient, including antibiotic and immunosuppressive management, shall be documented in the SOPs.

In addition, the other patient care protocols [e.g., immediate post-operative orders, intensive care unit (ICU) discharge orders, immunosuppression protocols, protocols for the treatment of acute rejection, etc.] shall also be kept in the SOPs. These protocols shall be reviewed and updated on a regular basis.

18.6 Organ assessment and transplantation

18.6.1
On receipt of an organ and prior to transplantation, the transplant surgeon shall inspect it carefully and assess its suitability and acceptability, using a biopsy when necessary.

18.6.2
If the organ is deemed to be unacceptable, the ODO shall be notified of the reasons for not using it, and the organ shall be returned to the ODO, or be disposed of in accordance with Clause 9 if it is deemed not transplantable by the ODO's medical director.

The ODO may attempt to place the organ with another transplant program. If the organ is not placed with another program, it shall be disposed of in accordance with Clause 9.

18.6.3
The disposal of an organ shall be documented in both the coordinator's process log in the ODO and in the recipient's medical record in the transplant program.

18.6.4
The SOPs of the transplant program shall document each of the transplant surgeons who is qualified and authorized by the medical director of the transplant program to perform the recipient operation as the responsible operating surgeon for each of the organs transplanted by the program.

18.6.5
The transplant surgeon shall be responsible for ensuring that the correct patient receives the allocated organ.

18.6.6
The transplant surgeon shall be responsible for documenting the operative details in the recipient's chart and ensuring that the donor identification number (see Clause 7.2 of CAN/CSA-Z900.1) appears on the recipient's chart.

18.7 Exceptional distribution

18.7.1
In addition to the requirements specified in Clause 18.4 of CAN/CSA-Z900.1, the requirements specified in Clauses 18.7.2 to 18.7.6 of this Standard shall apply.

Notes:

1) *The risk/benefit analysis of NAT in organ transplantation differs from that in blood and tissue donation. Current practices in blood and tissue donation cannot be extrapolated to the screening of organ donors.*
2) *See Annex A.*

18.7.2
Exceptional distribution of an organ by the medical director (or designate) of the ODO may be made in response to a request for exceptional distribution by the medical director (or designate) of the transplant program. The ODO's medical director shall notify the donor coordinator of this exceptional circumstance. Both the ODO and transplant program shall describe in their SOPs those individuals who are authorized to act as a designate for the purposes of exceptional distribution.

18.7.3
The notice of exceptional distribution shall include the test(s) not completed or condition(s) not met and the reasons that justify the exceptional distribution. This documentation shall also include the date and time of the authorization, as well as the signature of the transplant physician involved in the exceptional distribution. A copy of the notice of exceptional distribution shall be provided to the ODO within five working days, for its records.

18.7.4
Exceptional distribution shall not preclude the requirement for completion of all donor testing.

18.7.5

The donor coordinator shall document the details of the exceptional distribution in the donor log (or donor record). In addition to the information required under Clause 18.4.6 of CAN/CSA-Z900.1, the documentation shall include

a) the name of the transplanted organ;
b) the reason why the organ did not meet the release criteria specified in SOPs at the time of its distribution;
c) justification for the distribution that formed the basis for the transplant physician's decision;
d) the name of the source establishment that distributed the organ;
e) the name of the transplant establishment and transplant physician 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 transplant physician.

18.7.6

The SOPs of the transplant program shall document the policy for informing the recipient and/or next of kin regarding the need for exceptional distribution, including the extenuating circumstances and the risks of proceeding, versus not proceeding, with the organ transplant. The process of informing the patient or next of kin shall be documented in the patient's chart.

18.8 Organs for medical research

18.8.1

The SOPs shall describe the manner in which requests for research are to be reviewed and approved by the medical director of the ODO. The SOPs shall identify all the research programs authorized to receive organs and tissues from donors.

18.8.2

The ODO shall maintain records that permit tracking of tissue used for research.

18.8.3

Next of kin authorization shall indicate the specific organs and tissues to be recovered for research. The SOPs shall describe the information to be transmitted to the family to ensure free and informed consent. The SOPs shall identify the persons authorized to obtain this consent.

19 Error, accident, and adverse reaction investigation and reporting

The requirements specified in Clause 19 of CAN/CSA-Z900.1 shall apply in this Standard.

20 Continuous improvement

The requirements specified in Clause 20 of CAN/CSA-Z900.1 shall apply in this Standard.

Table 1
Mandatory information to be maintained and collected by the source establishment
(See Clause 7.3.3.)

ODO identification
Name of ODO and identification of coordinator(s)

Centre identification
Referring centre:
Date of referral
Identification of referring centre
Physician in charge
Chart number
Admission date

Retrieving centre (if different from referring centre):
Identification of retrieving centre
Physician in charge
Chart number
Admission date

Donor identification
Donor name
Unique donor identification code
Race, sex, age, and date of birth
ABO blood grouping
Height and weight

Medico-legal information
Consent
Name and relationship of consenter
Consenter address and telephone number
Organs and/or tissues consented to

Declaration of death (for deceased donors)
Neurologic death
Date and time of death and dates and times of clinical exams
Cardio-circulatory death
Names of attesting physicians and hospital
Coroner/medical examiner's name and consent for donation, if applicable

Donor/organ evaluation
Medical/social history obtained and documented by a standardized questionnaire
Documentation of the physical exam and name of practitioner

Serology results and plasma dilution calculation
(See Clauses 14.2.6.3 and 14.2.6.4)
HIV types 1 and 2
HBsAg
Anti-HCV
Anti-HTLV-I and anti-HTLV-II
HBC antibody
CMV
EBV
Syphilis
For heart donors, toxoplasmosis

Laboratory and other studies
ABO blood grouping
HLA typing – donor (if available)
CBC
Creatinine
Serum electrolytes
Serum glucose
PT or INR
Biochemistry (additional testing for specific organs):
  Bilirubin, AST or ALT, ALP,
  GGT, LDH
  Amylase or lipase
  CPK, CK MB, and/or troponin
  ABG
  Urinalysis
Cardiology: ECG (12 lead)
Radiology: chest X-ray
Microbiology: all positive cultures, urine, sputum, and blood cultures and sensitivities
Pulmonary (for potential lung donors):
  ABGs on fraction of inspired oxygen (FiO_2) 100% and PEEP +5 for a minimum of 10 min (only for deceased donors)
  Bronchoscopy
Consults:
  Documentation of significant findings

(Continued)

Table 1 (Concluded)

Clinical history and events	**Offer of organ and recipient selection**
Cause of death (for deceased donors)	Organ offered
Documentation of cardiorespiratory arrest and resuscitation manoeuvres: date, time, duration, and treatments	Date of offer
	Hospital/ODO and name of contact
	Date of acceptance/refusal
Documentation of all significant hypotensive and hypertensive periods: date, time, duration, and treatments	Recipient identification code
	Transplanting centre
Documentation of all surgical interventions since admission	**Notice of exceptional distribution** (if applicable)
Documentation of all current and recent medications: date, time, duration, and dosages	**Peri-operative information**
	Retrieving centre and surgeon for each organ
Documentation of all blood product use: date, time, and volumes	Clamp date and time
	Type and volume of perfusion solution
Documentation of vital signs, hemodynamic monitoring, and urine output	Description of organ and abnormalities
	Reason organ not retrieved

Table 2
Mandatory information to be maintained and collected by the transplant program
(See Clause 7.3.5.2.)

Recipient identification
Name
Transplant centre hospital identifier (medical record number)
Provincial health number
Recipient identification code
Race, sex, age, and date of birth
ABO blood grouping
Height, weight, and chest circumference where applicable

Medico-legal information on consent
Name and relation of consenter
Address and telephone number
Copy or photocopy of the consent

Preoperative clinical history and events
Full medical history and physical examination
Diagnosis of end stage organ disease, with documentation of the investigative procedures and tests used to establish the diagnosis
Diagnosis of coexisting illness and documentation of the appropriate tests and investigations relevant to those illnesses
Documentation of all previous surgical procedures
Documentation of all current medications and dosages
Documentation of vital signs

Preoperative evaluation
Results of all preoperative investigations relevant to the transplant, including
a) investigation of the primary disease;
b) investigation of the anaesthetic and operative risk;
c) all consultations; and
d) histocompatibility laboratory results.

Donor organ
Donor unique identification code
Donor ABO blood type, CMV status, and, where appropriate, HLA typing and cross-match results
Information regarding any anomalies or abnormalities of the organ
HIV types 1 and 2
HBsAg
Anti-HCV
Anti-HTLV-I and anti-HTLV-II
HBC antibody
CMV
EBV
Syphilis
For heart donors, toxoplasmosis

Annex A (informative)
Summary of exceptional distribution criteria

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

A.1

Exceptional distribution is followed where any of the following contraindications apply:

a) persons whose probable cause of death cannot be adequately determined by the critical care attending team or medical director;
b) persons who died from neurological disease of an unestablished etiology, including but not limited to, multiple sclerosis, Alzheimer's, Parkinson's, and amyotrophic lateral sclerosis or Lou Gehrig's disease;
c) persons with prion-related disease, including but not limited to, CJD, variant CJD, and other transmissible spongiform encephalopathies;
d) persons with a family history of Creutzfeldt-Jakob disease;
e) persons who have received human-derived growth hormone or dura mater;
f) persons with active encephalitis or meningitis of infectious or unknown etiology;

   Note: *Viruses associated with meningitis or encephalitis include, but are not limited to, enteroviruses, mumps virus, herpes simplex virus, WNV, varicella zoster virus.*
g) persons with active infections of clinical significance;
h) persons with a history of dementia or degenerative neurologic disorders of viral or unknown etiology, including but not limited to, Parkinson's disease, subacute sclerosing panencephalitis, progressive multifocal leukoencephalopathy, and amyotrophic lateral sclerosis or Lou Gehrig's disease;

   Note: *Viruses that can be associated with dementia or degenerative neurologic disorder include the HIV and HTLV.*
i) persons with rabies or persons who, within the past six months, were bitten by an animal and treated as if the animal was rabid;
j) persons who have had a malignancy, except for a cutaneous basal cell or squamous cell carcinoma that has been treated;
k) persons with syphilis;
l) persons with HTLV-I or HTLV-II;
m) persons with HIV, HBV, or HCV;
n) persons at high risk for HIV, HBV, or HCV as defined by
   i) men who have had sex with another man in the preceding 12 months;
   ii) persons who report non-medical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding five years;
   iii) persons with a history of intranasal cocaine use, unless HCV NAT is performed and found to be negative;
   iv) persons who have engaged in sex in exchange for money or drugs in the preceding five years;
   v) persons who have had sex in the preceding 12 months with any persons described in Items i) to iv) or with a person known or suspected to have HIV, or clinically active HBV or clinically active HCV;
   vi) 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, non-intact skin, or mucous membrane;
   vii) persons who have been in a youth correctional facility, jail, or prison for more than 72 consecutive hours in the preceding 12 months;

viii) 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);
ix) 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);
x) persons who have been breastfed within the past 12 months of donation by women with or at risk for HIV, HBV, or HCV; and
xi) persons less than 18 months of age who are born to women with or at risk for HIV, HBV, or HCV infection;

o) serology which is incomplete, unavailable, or tested from a blood sample meeting criteria for plasma dilution;
p) donor suitability assessment is not complete (e.g., incomplete medical and social questionnaire);
q) a donor with any of the following physical examination contraindications: unexplained lymphadenopathy mass or mucocutaneous lesions; palpable mass; blue or purple spots on the skin or mucous membranes suggestive of Kaposi's sarcoma; or needle tracks or other signs of injection drug abuse; and
r) any other potential risk factor as determined by the Medical Director, based on their clinical judgement,

A.2

Exceptional distribution is followed if any of the following minimal organ specific screening tests are not complete:

a) kidneys: serum electrolyte testing, urea testing, urinalysis, and creatinine;
b) heart: chest x-ray, electrocardiogram (ECG), and 2D echocardiography;
c) lungs: chest x-ray, a tracheal or bronchial airway gram stain and specimen for culture, and an O_2 challenge;
d) liver: bilirubin testing, AST or ALT, and either PT or INR; and
e) pancreas (including donation for islet cells): blood sugar and amylase or lipase.