CSA Group

CAN/CSA-Z900.2.2-17
National Standard of Canada

Tissues for transplantation

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National Standard of Canada

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

Prepared by

CSA Group

Approved by

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Preface

This is the third edition of CAN/CSA-Z900.2.2, *Tissues for transplantation*. It supersedes the previous editions published in 2012 and 2003.

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.

The major changes to this edition include the following:

a) the terminology has been updated;
b) Clause 14 has been revised to align with CBS *Evidence-based leading practice guidelines for: Tissue recovery, microbial sampling, processing of musculoskeletal tissue, processing of cardiac tissue, and processing of skin tissue*;
c) exclusion criteria have been added for persons with a history or active or past Ebola infection in Clause 13.1.2; and
d) process and recovery times have been updated in Table 1.

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

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

1 Scope

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

1.2
This Standard applies to establishments and individuals involved in the following activities related to tissues intended for transplantation:

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

Notes:

1) *Examples of establishments or individuals include the following:*
   a) *tissue banks;*
   b) *tissue processing facilities;*
   c) *transplant programs and facilities (hospital and clinic);*
   d) *tissue retrieval organizations; and*
   e) *other tissue-dispensing services.*
2) *For guidance on autologous tissues, see AORN "Guideline for Autologous Tissue Management" in* Guidelines for Perioperative Practice.

1.3
This Standard is not intended to replace detailed specifications and standard operating procedures but is intended to be used in their preparation.

1.4
This Standard contains particular requirements for tissues for transplantation and is intended to be used with CAN/CSA-Z900.1. Where differences exist, the requirements of this Standard apply.

1.5
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

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

AATB (American Association of Tissue Banks)

Standards for Tissue Banking. 14th edition, McLean, Virginia, 2016

Guidance Document: Microbiological Process Validation and Surveillance Program, No. 5, version 2, May 27, 2016

AORN (Association of Perioperative Registered Nurses)

Guidelines for Perioperative Practice (2017)

CBS (Canadian Blood Services)

Leading Evidence Based Practice Guidelines for: Tissue recovery, microbial sampling, processing of musculoskeletal tissue, processing of cardiac tissue, and processing of skin tissue, Final report, October 2016

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.

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 in organ transplantation.

Note: *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's Regulations, SOR/2007-118 (see Section 1, "Definitions," Section 35, "Storage," and Section 67, "Requirements for Storage".)*

Microbial testing — testing used by standard clinical laboratory methodologies to detect the presence of aerobic and anaerobic bacterial species, and fungi (yeasts and rapidly growing moulds).

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

Processing — in respect of cells, tissues, and organs, means any of the following activities:
a) donor screening;
b) donor testing;
c) donor suitability assessment;
d) retrieval;
e) testing and measurements performed on the cells, tissues, or organs after they are retrieved;
f) preparation for use in transplantation;
g) preservation;
h) quarantine;
i) storage (including banking); and
j) packaging and labelling.
Note: *This definition is reproduced from CAN/CSA-Z900.1, and therefore includes references to cells and organs that are not within the Scope of this Standard.*

Sterility assurance level (SAL) — the probability of a single viable micro-organism occurring on a product after sterilization.
[Source: Adapted from CBS (2016)]

Sterilization — a validated process used to render a product (i.e., tissue) free from viable micro-organisms.
[Source: Adapted from CBS (2016)]

Terminal sterilization — a validated process used to render a product (i.e., tissue) within its primary package sterilized.
[Source: Adapted from CBS (2016)]

Tissue-dispensing service — any department, facility, organization, or program that receives, stores, and provides cells and/or tissue directly to an end user for immediate transplantation.

Tissue-distribution intermediary — any department, facility, organization, or program that receives and stores cells and/or tissue for future distribution.

Transplant establishment — the establishment responsible for the transplantation of tissues within the region or province that it serves.

3.2 Abbreviations

The following abbreviations shall apply in this Standard:

CJD — Creutzfeldt-Jakob disease

HBV — hepatitis B virus

HCV — hepatitis C virus

HIV — human immunodeficiency virus

HTLV — human T-cell lymphotropic virus

NAT — nucleic acid test

QA — quality assurance
QC — quality control
SAL — sterility assurance level
SOP — standard operating procedure
WNV — West Nile virus

4 Establishment requirements

4.1 Establishment identity

The requirements specified in Clause 4.1 of CAN/CSA-Z900.1 shall apply in this Standard.

4.2 Personnel

4.2.1 General

In addition to the requirements specified in Clause 4.2 of CAN/CSA-Z900.1, the requirements specified in Clause 4.2.2 of this Standard shall apply.

4.2.2 Medical director

In addition to the responsibilities of the medical director specified in Clause 4.2.3.5 of CAN/CSA-Z900.1, the medical director shall be ultimately responsible for determining the suitability of tissue for release for transplantation.

Note: *Clauses 4.2.3.7 and 4.2.3.8 of CAN/CSA-Z900.1 address the topic of delegation of responsibility by the medical director or scientific director, and the possible centralization of these roles in establishments that maintain multiple locations.*

4.3 Quality management

The requirements specified in Clause 4.3 of CAN/CSA-Z900.1 shall apply in this Standard. In addition, the tissue bank shall document and be able to demonstrate its protocol for the validation of its bioburden reduction processes.

5 Facilities

The requirements specified in Clause 5 of CAN/CSA-Z900.1 shall apply in this Standard.

6 Standard operating procedures

6.1 General

The requirements specified in Clause 6.1 of CAN/CSA-Z900.1 shall apply in this Standard.

6.2 Format

The requirements specified in Clause 6.2 of CAN/CSA-Z900.1 shall apply in this Standard.

6.3 Content

In addition to the requirements specified in Clause 6.3 of CAN/CSA-Z900.1, the requirements for the SOP manual shall include, where relevant, the following:

a) retention times for different types of tissues (i.e., shelf life);
b) procedures for tissue returns;
c) procedures for records management, forms, and documentation;
d) procedures for teaching and research; and
e) procedures for identification and documentation of quality assurance (QA) activities.

6.4 Approvals and reviews

The requirements specified in Clause 6.4 of CAN/CSA-Z900.1 shall apply in this Standard.

6.5 Extra copies

The requirements specified in Clause 6.5 of CAN/CSA-Z900.1 shall apply in this Standard.

6.6 Archives

The requirements specified in Clause 6.6 of CAN/CSA-Z900.1 shall apply in this Standard.

7 Records and tracking

7.1 General

The requirements specified in Clause 7.1 of CAN/CSA-Z900.1 shall apply in this Standard.

7.2 Donor identification

The requirements specified in Clause 7.2 of CAN/CSA-Z900.1 shall apply in this Standard.

7.3 Recordkeeping

7.3.1

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

7.3.2

The surgeon, physician, or dentist involved in the transplantation of a tissue shall be responsible for providing information regarding the disposition of that tissue to the providing establishment.

7.4 Tracking

7.4.1

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

7.4.2

The transplant centre shall keep accurate records of each tissue including the donor identification number, tissue type, identification number, and staff involved in procedures. The transplant centre records shall include the source of the tissue, storage, and disposition. If the tissue is transplanted, the

centre shall also record the identity of the recipient, the dates of transplantation, the staff involved in the procedure, and the tissue identification number.

8 Infection control and safety

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

9 Disposal of tissues

The requirements specified in Clause 9 of CAN/CSA-Z900.1 shall apply in this Standard.

10 Consent

10.1 General

10.1.1

In addition to the requirements specified in Clause 10.1 of CAN/CSA-Z900.1, the recommendation in Clause 10.1.2 of this Standard applies.

10.1.2

During consent procedures, the donor and/or next of kin should be informed of

a) the potential, when applicable, to send tissues outside of the country in which the tissue is donated; and
b) the intended use of the tissue.

10.2 Predonation counselling

10.2.1

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

10.2.2

Predonation counselling should include an explanation of donor and recipient anonymity.

10.3 Basis of consent

The requirements specified in Clause 10.3 of CAN/CSA-Z900.1 shall apply in this Standard.

11 Compensation

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

12 Donor suitability assessment

The requirements specified in Clause 12 of CAN/CSA-Z900.1 shall apply in this Standard.

13 Donor screening

13.1 Contraindications or exclusion criteria

13.1.1

In addition to the requirements specified in Clause 13.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 13.1.2 to 13.1.5 of this Standard shall apply.

13.1.2

In addition to the contraindications or exclusion criteria listed in Clause 13.1.3 of CAN/CSA-Z900.1, a donor shall be excluded if any of the following contraindications apply:

a) persons with active malaria;
b) persons with active tuberculosis;
c) persons with HTLV-I or HTLV-II;
d) persons with a biological parent or blood-related sibling with a confirmed case of Creutzfeldt-Jakob disease (CJD);
e) persons with current diagnosis of lymphoma or leukemia;
f) persons with active syphilis; and
g) persons with history of active or past Ebola infection.

Notes:

1) *A lack of knowledge of CJD in response to Item d) is a presumed negative answer.*
2) *Other malignancies in addition to those stated in Item e) may be included upon the medical director's review and recommendation.*

13.1.3

Each tissue bank, donation agency, or transplant service shall establish guidelines for evaluation of other general or tissue-specific infections and contraindications. A clinical decision shall be necessary in the following situations:

a) untreated systemic infection;
b) jaundice;
c) systemic immunosuppression;
d) autoimmune diseases;
e) trauma to the potential retrieval site;
f) septicemia;
g) leprosy; and
h) systemic mycosis.

13.1.4

The following criteria, based on review and clinical interpretation by the medical director, should be considered as potential contraindications or exclusion criteria for donation of musculoskeletal and bone tissue:

a) rheumatoid arthritis;
b) systemic lupus erythematosus;
c) polyarteritis nodosa;
d) sarcoidosis; and
e) clinically significant metabolic bone disease.

13.1.5

The following criteria, based on review and clinical interpretation by the medical director, should be considered as potential contraindications or exclusion criteria for donation of cardiovascular tissue:

a) bacterial endocarditis;
b) rheumatic fever;
c) semilunar valvular disease;
d) cardiomyopathy of viral or idiopathic etiology;
e) Chagas' disease; and
f) for mitral valve donation, history of mitral valve disease, including mitral valve prolapse.

13.2 Physical examination

The requirements specified in Clause 13.2 of CAN/CSA-Z900.1 shall apply in this Standard.

Note: *See the current version of the AATB* Standards for Tissue Banking *and Appendix III of that document for the "Tissue Donor Physical Assessment Form".*

13.3 West Nile virus

Persons who have had a medical diagnosis or suspicion of West Nile virus (WNV) infection (based on symptoms and/or laboratory results, or confirmed WNV viremia) should be deferred for 120 days following diagnosis or onset of illness, whichever is later. A decision to use the tissue in this situation shall be subject to the approval of the medical director.

14 Testing

14.1 General

The requirements specified in Clause 14.1 of CAN/CSA-Z900.1 shall apply in this Standard.

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.

14.2.2 Blood tests

14.2.2.1

In addition to the requirements specified in Clause 14.2.2 of CAN/CSA-Z900.1, the requirements specified in Clause 14.2.2.2 of this Standard shall apply.

14.2.2.2

Donor blood testing results shall be considered acceptable if sample collection takes place within seven days before or after the time of death for deceased donors.

For living donors, sample collection shall occur within seven days prior to or up to six weeks following donation.

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, the requirements specified in Clause 14.2.6.2 of this Standard shall apply.

14.2.6.2
Donor testing for infectious diseases shall include tests for
a) HTLV-I and HTLV-II for viable leukocyte-rich tissues; and
b) syphilis.

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

14.2.7 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

14.2.8.1
In addition to the requirements specified in Clause 14.2.8 of CAN/CSA-Z900.1, the requirements specified in Clause 14.2.8.2 of this Standard shall apply.

14.2.8.2
The algorithm used to determine plasma dilution shall be documented in the SOP manual and in each donor's record, as appropriate.

14.3 Other testing

14.3.1 General
Additional testing specific to tissues for transplantation shall include the requirements specified in Clause 14.3.2.

14.3.2 Microbial screening

14.3.2.1 General

14.3.2.1.1
The tissue bank shall ensure that microbial testing, wherever performed, is performed in accordance with validated procedures and by qualified staff in a laboratory that meets the requirements of the authority having jurisdiction. The test results shall be documented in the donor's permanent tissue bank record.

14.3.2.1.2

All methods, materials, and equipment used to test tissues for microbial contamination shall be suitable for their intended use and documented.

Note: *Examples of information to be documented are the name and manufacturer of the culture reagents, supplies, materials and equipment, lot number, expiration date, and other suitability criteria as appropriate.*

14.3.2.1.3

All protocols for testing shall be stated in the SOP manual.

14.3.2.2 Collection and testing of samples

14.3.2.2.1

The establishment shall establish tissue methods and sampling strategies for microbial testing, so that the samples reasonably represent all tissues retrieved from a particular donor.

Tissue sampling and testing methods shall be evaluated for sensitivity.

Tissue sampling and testing methods shall be evaluated to be appropriate and effective for each tissue type recovered and processed.

The protocol for sample collection shall be documented in the SOP manual.

The evaluation documentation shall be maintained by the program and updated prior to making any changes to tissue culturing and sampling strategies.

14.3.2.2.2

With the exception of surgical preparation for skin recovery, samples for microbial testing shall be taken before the tissue is exposed to any antibiotics, disinfecting chemicals, or sterilizing agents unless the suitability of the testing method(s) have been validated to account for inhibitory effect.

14.3.2.2.3

For tissues having positive testing results obtained before the tissue is exposed to any antibiotic-containing preparations, it is acceptable for transplantation if a suitable and validated protocol for disinfection is in place. The organisms found shall be identified to the genus level and the tissue shall be disinfected. Disinfection shall take place either during preparation or as part of a terminal sterilization event before transplantation. For skin tissue, the presence of normal skin flora before or after disinfection is acceptable for release.

The SOPs shall list the micro-organisms that, if found, would necessitate discard of the tissue, unless tissue will be subsequently sterilized with a process validated to eliminate the infectivity of the micro-organism. The list shall be based upon not only the type of tissue but also the method by which the tissue was prepared (e.g., cryopreserved tissues that cannot be sterilized and can only be disinfected).

Note: *Programs that disinfect tissues with antibiotics and/or antifungals should validate the rinsing process to ensure there are no inhibitory effects of carryover antimicrobials present in the sample tested that could impact the detection of pathogenic bacteria or fungi.*

14.3.2.2.4

Microbial testing shall be performed for both aerobic and anaerobic organisms, in accordance with approved protocols, so that both rapid- and slow-growing organisms will be detected.

The test method shall be evaluated for sensitivity.

Note: *This Clause refers to both pre- and post-preparation.*

14.3.2.3 Blood cultures

14.3.2.3.1

The results of any blood cultures, if performed, shall be documented in the donor record and the medical director shall assess the suitability of the donation.

14.3.2.3.2

The protocol for blood cultures shall be documented in the SOP manual if such cultures are performed by the tissue bank.

14.3.2.4 Transplantation prior to receipt of culture results

In situations where tissue transplantation is performed for medical reasons before culture results are available (e.g., fresh osteochondral allografts, which, because of tissue viability issues, must be transplanted promptly), the culture results, if performed, shall be forwarded to the transplanting physician as soon as they become available and these results shall be documented in the donor record.

The tissue bank shall document the established protocol in its SOPs.

14.3.2.5 Evaluation of data

14.3.2.5.1

The medical director or designate shall review the results of all cultures for each tissue. Evaluation of the safety of that tissue shall be determined before the tissue is released for transplantation. The medical director or designate shall document the suitability of a tissue donor before tissues are released.

14.3.2.5.2

Tissues failing to meet the suitability criteria outlined in the SOP manual shall not be used. Suitability criteria shall include a list of unacceptable micro-organisms if identified pre-, post-, or in-processing. The SOPs shall list the micro-organisms that, if detected, would render the tissue not suitable for release. The list should be based upon the type of tissue and the method by which the tissue was prepared (e.g., cryopreserved tissues that cannot be sterilized and can only be disinfected).

At a minimum, the list shall include the following:

a) for cardiac tissue:
   i) fungi (yeasts, moulds);
   ii) Clostridium; and
   iii) Streptococcus pyogenes (group A streptococcal);
b) for skin tissue:
   i) Staphylococcus aureus;
   ii) Streptococcus pyogenes (group A streptococcal);
   iii) Enterococcus sp.;
   iv) gram negative bacilli;
   v) Clostridium; and
   vi) fungi (yeasts, moulds); and

c) for musculoskeletal tissue:
   i) Clostridium; and
   ii) Streptococcus pyogenes (group A strep.).

Note: *Tissues not acceptable for transplantation may be used for other applications (e.g., research, training, and QA).*

14.3.2.5.3

The criteria used for evaluating culture results shall be documented in the SOP manual.

14.3.2.6 Repeated microbial testing

14.3.2.6.1

For each preparation step in which tissue is unwrapped and rewrapped, microbial testing should be performed to rule out contamination during the procedure, unless the tissue is processed using a validated sterilization method or appropriate final packaging sterility testing is performed. Any occurrence of contamination shall be documented in the donor record.

14.3.2.6.2

The protocol for microbial testing shall be documented in the SOP manual.

14.3.2.7 Microbial quality control testing prior to release for transplant

14.3.2.7.1

Representative samples for microbial testing shall be obtained for all tissues to be released for human transplantation, unless the release is based on sterilization parameters having been met in accordance with a validated process. The results of microbial testing shall be documented in the donor record.

14.3.2.7.2

The medical director or designate shall evaluate the data specified in Clause 14.3.2.7.1 before tissue is released for transplantation.

14.3.2.7.3

If final microbial results are positive, the tissue shall not be released, except for skin tissue where the culture results identify normal skin flora.

14.3.2.8 Microbial testing at time of transplantation

14.3.2.8.1

In the absence of a bioburden reduction protocol (as defined by the tissue bank), swab cultures or sterile biopsies of each tissue shall be taken immediately upon unwrapping the tissue in the operating room at the time of transplantation. Where cultures are performed, aerobic and anaerobic culture results shall be forwarded for placement in the recipient's medical record. If positive culture results are obtained, these shall be forwarded to the source establishment.

14.3.2.8.2

The protocol for microbial testing at the time of transplantation shall be documented in the SOP manual.

14.3.3 Disinfection and sterilization of tissues

Disinfection or sterilization processes shall be validated by a quantitative process. Qualitative analysis, such as calculation of discard and/or contamination rates, is acceptable for process verification but shall not be used as a surrogate for the quantitative validation of log reduction. The bioburden log reduction shall be determined for any sterilization method used. Disinfection procedures for musculoskeletal and cardiac tissue shall be validated with quantification of log reduction, with challenging known micro-organisms.

Notes:

1) *The default sterility assurance level to be demonstrated in the sterilization of allografts should be 10-6 SAL. Sterility assurance level values may also be selected based on evidence-based risk assessment.*
2) *If irradiation methods are used for sterilization, the dose and temperature should be chosen to preserve tissue quality.*
3) *Programs considering the use of antifungals on tissue where cellular viability can be affected should carefully assess and consider the risks as many antifungals are cytotoxic and will reduce cellular viability.*
4) *Programs that incubate with antibiotics should use broad spectrum antibiotics active against common bacterial contaminants and in a concentration and temperature effective to kill the micro-organisms.*
5) *For further guidance, see AATB* Guidance Document: Microbiological Process Validation and Surveillance Program *and CBS* Leading Practice Guidelines for: Tissue recovery, microbial sampling, processing of musculoskeletal tissue, processing of cardiac tissue, and processing of skin tissue.

15 Retrieval, preparation, preservation, and storage

15.1 General

The requirements specified in Clause 15.1 of CAN/CSA-Z900.1 shall apply in this Standard.

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

In addition to the requirements specified in Clause 15.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 15.3.2 to 15.3.4 of this Standard shall apply.

15.3.2

Tissues shall be retrieved using aseptic or clean techniques, as appropriate for the intended use of the tissue. If no subsequent sterilization is to be done, retrieval shall be performed aseptically. Tissues shall be preserved within time intervals for the retention of biological functions and in a way that is compatible with the intended use of the tissues.

15.3.3

Time constraints for post-mortem retrieval and the appropriate temperature for holding the body of a deceased donor until retrieval shall be determined and documented in the SOP manual of the retrieval establishment. This information shall be documented for each donor when the retrieval begins. See Table 1.

15.3.4

The SOP manual shall describe

a) appropriate retrieval techniques and the records to be maintained; and
b) all tissues retrieved and staff involved.

The description of techniques shall include any procedures to determine the appropriateness and acceptability of the tissue.

15.4 Preparation and preservation

15.4.1 General

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 Records of preparation and preservation

In addition to the requirements specified in Clause 15.4.4 of CAN/CSA-Z900.1, records of preparation and preservation shall include the following:

a) the time of preparation and preservation;
b) the residual moisture content, if applicable; and
c) the type, amount, and concentrations of additives (e.g., antibiotics), if applicable.

15.4.3 Autologous tissues

The medical director shall institute appropriate standard operating procedures for autologous tissues that are manipulated, altered, or preserved in the tissue bank, to prevent injury or harm to other preserved tissues or tissue recipients.

Those standard operating procedures shall ensure that autologous tissues are stored separately, not used as an allograft, and appropriately labelled, e.g., “FOR AUTOLOGOUS USE ONLY”.

15.4.4 Adjunct vessels

15.4.4.1

Adjunct vessels that are retrieved simultaneously with a perfusable organ for the prospect of aiding organ transplantation shall be considered to be an “organ” and shall be managed in accordance with the requirements of CAN/CSA-Z900.2.3.

15.4.4.2

If the vessels are transplanted in the same procedure and to the same recipient as the perfusable organ, the ODO shall be considered to be the source establishment.

15.4.4.3

If the adjunct vessels are not immediately transplanted with the organ with which they were retrieved, the vessels may be stored and used within a scientifically-based predetermined number of days. In this case, the establishment that stores and uses the vessels shall be considered to be the “relevant tissue bank” and, therefore, the source establishment.

Note: *Depending on which establishment stores and uses the adjunct vessels, any of the following may assume the roles and responsibilities of a source establishment:*

a) *designated vessel banks;*

b) *ODOs;*
c) *establishments that bank other types of tissue; or*
d) *transplant establishments.*

15.4.5 Expiration date

15.4.5.1
Maximum recommended storage periods shall be established for each type of tissue in accordance with Table 1.

Note: *Table 1 specifies maximum storage values for different tissues and storage environments.*

15.4.5.2
The SOP manual shall describe the assignment of expiration dates to each tissue and its proper documentation.

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 Clause 15.6.2 of this Standard shall apply.

15.6.2
Donations in storage shall be
a) physically separated in clearly defined areas;
b) prominently labelled; and
c) in the case of adjunct vessels not used immediately in the transplantation of the organ with which they were retrieved, stored and used within a scientifically-based predetermined number of days. See Clause 15.4.4.

16 Labels, packaging, inserts, and accompanying documentation

16.1 General

16.1.1
In addition to the requirements specified in Clause 16.1 of CAN/CSA-Z900.1, Clause 16.1.2 of this Standard applies.

16.1.2
The unique tissue identification code may be used instead of the unique donor identification code provided that it can be tracked back to the donor.

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

16.3.2
In addition to the requirements specified in Clause 16.3.1 of CAN/CSA-Z900.1, the label and/or insert shall identify

a) the presence of known sensitizing substances;
b) the results of relevant infectious disease screening tests;
c) the results of relevant microbiological testing methods;
d) the expiration date, if applicable;
e) the disinfection or sterilization procedure used, if applicable;
f) the preservative(s) used and concentration, if applicable;
g) the type and amount of antimicrobials used, if applicable;
h) blood types and Rh factor, if applicable; and
i) the amount, size, dimensions, weight, and/or anatomical details of the tissue, if applicable.

17 Quarantine and release

17.1 General

17.1.1
In addition to the requirements specified in Clause 17.1 of CAN/CSA-Z900.1, the requirements specified in Clauses 17.1.2 to 17.1.4 of this Standard shall apply.

17.1.2
All tissues awaiting acceptance for the next procedural step or decision regarding a final disposition shall be quarantined.

17.1.3
The SOP manual shall include mandatory procedures for tissue release for transplantation. These procedures shall include a technical review, medical director review, and quality QA/QC review.

All required information shall be complete and compiled in a standardized format prior to final review and determination of donor and tissue acceptability for transplantation. The information shall include

a) the date, time, and individuals involved; and
b) the lot numbers and expiry dates of supplies used.

17.1.4
The SOP manual shall ensure that tissues released from quarantine can be visually distinguished from those remaining in quarantine.

17.2 Living donor quarantine
Note: *Post-quarantine testing before release of tissues from infant donors might require surrogate testing, as described in Clause 14.2.6.2 of CAN/CSA-Z900.1.*

17.2.1

Allograft tissues that have been collected from living donors and will be stored shall be held in quarantine for at least 180 days, at which time the donor shall be retested for the following, unless NAT was used (see Clause 17.2.2):

a) HIV;
b) HBV;
c) HCV; and
d) HTLV-I and HTLV-II for viable leukocyte-rich tissues.

17.2.2

If, in a living donor, the donation sample is additionally tested using a NAT for HIV-1 and HCV, the retesting specified in Clause 17.2.1 is not required.

17.3 Release for distribution

17.3.1 General

The tissue bank shall identify the responsible personnel to perform and document the following activities before releasing the tissue for distribution:

a) complete the donor suitability assessment and testing (see Clauses 12, 13, and 14);
b) complete the reviews specified in Clauses 17.3.2, 17.3.3, and 17.3.4; and
c) demonstrate compliance with the QA/QC tests and procedures outlined in the SOP manual.

17.3.2 Technical review

Once the donor record is complete, a technical review of the donor record shall be undertaken. The review shall include, but not be limited to, the following:

a) a review of the donor record for errors, omissions, and inconsistencies;
b) a review of tissues processed for consistency with specific tissue requirements;
c) a review of all required infectious disease test results;
d) a review of all retrieval, preparation, and packaging microbiology results for completeness and acceptability;
e) a review of completeness and acceptability of any test results generated;
f) a review of all recorded lot numbers and expiration dates for reagents and other supplies to verify completeness and verify that all were within acceptable ranges;
g) a review of all processing records for completeness and accuracy as well as verification that tissues were processed in accordance with the SOP manual;
h) a review of all tissues retrieved to ensure that disposition of each tissue is traceable;
i) verification that all incident variances (if any) potentially related to the safety or quality of the tissues from the donor have been resolved; and
j) verification that all processing was accomplished within the time limits and technical specifications in the SOP manual.

17.3.3 Medical director review

The medical director or designate shall perform a donor and tissue suitability assessment prior to the release of tissue for transplantation. This review shall include, but not be limited to, the following:

a) the acceptability of the consent;
b) all past and present medical history information documented on tissue donor information forms;
c) the autopsy report, if an autopsy was performed;
d) the medical history and behavioural risk questionnaire;

e) all results of laboratory testing to determine donor suitability;
f) any plasma dilution calculations used to determine the acceptability of the blood sample used for testing;
g) all microbial testing results;
h) pertinent circumstantial and donor screening information relayed to staff at the time of referral;
i) the physical examination; and
j) any other information gathered for the purposes of disease screening.

The medical director or designate shall date, sign, and document acceptability of all tissues for transplant and document directives regarding tissue disposition.

17.3.4 Final quality assurance/quality control review to release tissue

The donor chart shall be subjected to final review to document that all QA/QC measures were performed and found acceptable. This review shall include the following:
a) a review of tissues processed for consistency with specific tissue requirements;
b) a review and comparison of tissues recovered and grafts produced from each tissue to ensure that the disposition of each tissue recovered is traceable;
c) the final verification that any error and accident reports potentially related to the safety or quality of the tissues from the donor have been resolved;
d) the final verification that all processing was accomplished within time limits and in accordance with technical specifications stated in the SOP manual;
e) verification that the medical director or designate has made a decision regarding donor suitability; and
f) verification that all directives of the medical director or designate regarding the donor were followed up on or implemented.

The QA/QC review should not be performed by any person involved in the donor case and shall be documented. The documentation shall include the date and the reviewer's signature.

18 Distribution

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 and 18.1.3 of this Standard shall apply.

18.1.2

In addition to the establishments listed in Clause 18.1.1 of CAN/CSA-Z900.1 that are authorized to distribute tissues, tissue-distribution intermediaries and tissue-dispensing services shall be authorized to distribute tissues for transplantation.

18.1.3

The tissue bank shall make all reasonable efforts to inform the physician of the risks of transplanted tissues, by providing an information sheet, where possible, prior to the transplantation procedure. The physician may also give this information to the patient.

18.2 Transportation

The requirements specified in Clause 18.2 of CAN/CSA-Z900.1 shall apply in this Standard.

18.3 Receiver of tissues

The requirements specified in Clause 18.3 of CAN/CSA-Z900.1 shall apply in this Standard.

18.4 Exceptional distribution

The requirements specified in Clause 18.4 of CAN/CSA-Z900.1 shall apply in this Standard.

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
Timelines for recovery, storage conditions, and expiration dates for commonly transplanted tissues
(See Clauses 15.3.3 and 15.4.5.1.)

Tissue	Process	Processing/recovery times	Storage conditions	Expiration dates
Cardiovascular	Frozen, cryopreserved	Warm ischemic time shall not exceed 24 h from asystole if the body was cooled or refrigerated within 12 h of asystole. The time limit shall not exceed 15 h if the body was not cooled or refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled shall not exceed 15 cumulative hours.	–100 °C or colder	5 years from preparation or as determined by tissue bank in accordance with packaging limitations and best practice
Dura	Lyophilized	Not established.	Ambient	According to results of the product stability study
Musculo-skeletal	Refrigerated	The skin prep shall begin within 24 h of cardiac death provided that the body was placed at refrigerated temperatures within 12 h of death. Tissue excision shall begin within 15 h of death if the deceased donor has not been refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled shall not exceed 15 cumulative hours. The maximum time that retrieved tissue shall remain at wet ice temperatures, prior to either preparation or freezing, shall be not longer than 72 h.	1 °C to 10 °C	72 h from retrieval
	Frozen	Same as “Musculo-skeletal, refrigerated”.	–20 °C to –39 °C	6 months from preparation
	Frozen	Same as “Musculo-skeletal, refrigerated”.	–40 °C or colder	5 years from preparation*
	Lyophilized	Same as “Musculo-skeletal, refrigerated”.	Ambient	According to the results of the product stability study

(Continued)

Table 1 (Concluded)

Tissue	Process	Processing/recovery times	Storage conditions	Expiration dates
Skin	Refrigerated	The skin prep shall begin within 24 h of cardiac death provided that the body was placed at refrigerated temperatures within 12 h of death. The skin prep shall begin within 15 h of death if the deceased donor has not been refrigerated. If the body is cooled for a period of time then not cooled for a period of time, the time period the body is not cooled shall not exceed 15 cumulative hours.	1 °C to 10 °C	14 days from retrieval, as long as the media are changed every 72 h
	Frozen, cryopreserved	Can be cryopreserved up to 10 days following retrieval as long as it is maintained between 1 °C and 10 °C and the media are changed every 72 h. If the media are not changed, the tissue shall be cryopreserved within 96 h.	–40 °C or colder	5 years from preparation or as determined by tissue bank in accordance with packaging limitations and best practice
	Lyophilized	Same as “Skin, frozen, cryopreserved”.	Ambient	According to the results of the product stability study
Soft tissue (parathyroid)	Frozen, cryopreserved	Not established.	–40 °C or colder	Not established

* *Expiration dates of cryopreserved or lyophilized tissue shall not exceed 5 years from the date of preparation unless a longer expiration date has been validated.*