CSA Group

CAN/CSA-Z900.2.4-17
National Standard of Canada

Ocular tissues 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.

National Standard of Canada

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

Prepared by

CSA Group

Approved by

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Preface

This is the third edition of CAN/CSA-Z900.2.4, *Ocular 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. 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) terminology has been updated;
b) donor screening has been updated, notably the exclusion criteria in Clause 13.1.3 for persons with
   i) active leukemia or active lymphoma;
   ii) a history of active or past Ebola infection; or
   iii) a history of melanoma with known metastatic disease (unless irradiated ocular tissue).
c) an exclusion regarding scleral tissue has been added in Clause 13.1.6 for persons with
   i) a history of melanoma with or without metastasis; or
   ii) a history of solid, cancerous, non melanoma tumor with metastasis;
d) a general exclusion has been added regarding persons with an intrinsic eye disease that would preclude good success of the transplant or have a risk of transmitting disease, to address other emerging pathogens/diseases; and
e) the timeframe for the collection of donor blood for laboratory testing (Clause 14.2.1.3) has been updated.

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 Ocular 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:*
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   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.*

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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:*
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   b) *relevant clause, table, and/or figure number;*
   c) *wording of the proposed change; and*
   d) *rationale for the change.*

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

1 Scope

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

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

a) donor suitability assessment;
b) retrieval;
c) processing;
d) preservation;
e) packaging;
f) labelling;
g) storage;
h) quarantine;
i) evaluation;
j) recordkeeping;
k) error, accident, and adverse reaction investigation and reporting; and
l) distribution, importation or exportation, and recall.

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 ocular 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 publication

This Standard refers to the following publication, 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

3 Definitions and abbreviations

3.1 Definitions

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

Satellite laboratory — an establishment with a direct administrative and/or financial connection with a parent eye bank.

3.2 Abbreviations

The following abbreviations shall apply in this Standard:

ALK — anterior lamellar keratoplasty

DALK — deep anterior lamellar keratoplasty

DMEK — Descemet's membrane endothelial keratoplasty

DSAEK — Descemet's stripping automated endothelial keratoplasty

DSEK — Descemet's stripping endothelial keratoplasty

HIV — human immunodeficiency virus

HTLV — human T-cell lymphotropic virus

LASIK — laser in-situ keratomileusis

SOP — standard operating procedures

WNV — West Nile virus

4 Eye banks and other establishment requirements

Note: *In this Standard, where the term "eye banks" is used, this is to be read as "eyes banks and other establishments".*

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

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 directors

4.2.3.1

In addition to the requirements in Clause 4.2.3 of CAN/CSA-Z900.1, the requirements in Clauses 4.2.3.2 to 4.2.3.6 of this Standard shall apply.

4.2.3.2

The medical director of a stand-alone eye bank (i.e., one that is not part of a larger tissue bank) shall be an ophthalmologist who has completed a corneal fellowship or who has demonstrated an expertise in external eye disease, corneal surgery, or research or teaching in cornea and/or external eye disease.

4.2.3.3

An establishment that processes ocular tissues but is not a stand-alone eye bank (e.g., a tissue bank) may have a medical director who does not meet all of the qualifications specified in Clause 4.2.3.2; however, in this case, the establishment shall have a formal, documented consulting relationship with an ophthalmologist who meets the qualifications specified in Clause 4.2.3.2. The standard operating procedures (SOPs) shall include clear guidance on when such consultation is needed (e.g., a decision tree).

4.2.3.4

The medical director shall complete relevant continuing education at least once every three years. Documentation demonstrating fulfillment of this requirement shall be filed in the medical director's personnel file.

4.2.3.5

The medical director shall oversee and provide advice on all medical aspects of the eye bank operations, including, but not limited to,

a) the formulation, approval, and implementation of medical policies and procedures;
b) participation in training and supervision of technical staff with regard to tissue retrieval, tissue preservation, and tissue evaluation; and
c) participation in the establishment and operation of a quality assurance program.

4.2.3.6

The eye bank shall replace the medical director within a reasonable period of time and shall notify the appropriate authorities within three months of the new appointment. Eye banks should have an alternate medical director.

Note: *An example of a reasonable period of time is approximately three months.*

4.2.4 Technical staff

Each eye bank shall have at least one eye bank technician who has undergone specialized training and is qualified in accordance with the requirements of an accepted professional organization. The medical director may fulfill the role of the eye bank technician.

Notes:

1) *In Canada, certification from the Eye Bank Association of America is generally accepted as a qualification for eye bank technicians.*
2) *Provincial/territorial licensing requirements can apply.*

4.3 Quality management

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

4.4 Satellite laboratories

4.4.1

Satellite laboratories that process and distribute tissues shall have an eye bank technician designated by the eye bank having authority and be supervised by and have access to a qualified medical director or designate.

Note: *This Clause applies to establishments involved in processing and distribution.*

4.4.2

Satellite laboratories shall be affiliated with a parent eye bank and shall meet the requirements of this Standard.

5 Facilities

5.1 General

The requirements specified in Clause 5.1 of CAN/CSA-Z900.1 shall apply in this Standard.

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

In addition to the requirements specified in Clause 5.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 5.3.2 to 5.3.4 of this Standard shall apply.

5.3.2

The refrigerator shall be maintained for the exclusive use of the eye bank and shall contain clearly defined and labelled areas for all tissue stored (e.g., quarantined tissue, surgical tissue awaiting distribution, and research tissue).

5.3.3

A laminar airflow cabinet or hood or equivalent environment shall be provided for the preparation of any ocular tissue in the laboratory.

5.3.4
In the event of a power failure, there shall be provision for immediate notification and corrective action, which may include the provision of an emergency power supply to maintain refrigeration.

5.4 Eye bank laboratory
The requirements in Clauses 5.1.3 c) and e), 5.1.4, 5.2.1, and 5.3.1 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
The requirements specified in Clause 6.3 of CAN/CSA-Z900.1 shall apply in this Standard.

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. In addition, each eye bank shall maintain copies of the documentation for each procedure used, along with a record of the length of time that the procedure was used.

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
The requirements specified in Clause 7.3 of CAN/CSA-Z900.1 shall apply in this Standard.

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 Clauses 7.4.2 to 7.4.4 of this Standard shall apply.

7.4.2

Regarding corneal tissue, the eye bank shall seek follow up with a postoperative inquiry within a reasonable period of time (e.g., between three and six months) following distribution to assess the transplant. The follow-up record shall include the following:

a) the tissue identification number;
b) the recipient identification number;
c) the status of transplant; and
d) the occurrence of any adverse reaction or primary tissue failure.

7.4.3

The receiver of any ocular tissue shall be responsible for verifying and documenting the receipt of shipment in good order.

7.4.4

The receiver of any ocular tissue shall promptly provide to the issuing eye bank the recipient information described in Clause 7.5.1 and information on any complications or technical problems with the transportation and shipment of the ocular tissue(s).

7.5 Minimum information to be retained

7.5.1 Donor and recipient information

Note: *See also Clause 16.*

Forms for retaining donor and recipient information shall be established for permanent record and shall be readily accessible for inspection by the authority having jurisdiction. Eye bank records shall include, at a minimum, the following information:

a) the eye bank identifier;
b) the preservation type, media lot numbers, and expiry dates (see Clause 15.2.5);
c) the unique donor identification number;
d) the name of the donor (or, in the case of imported tissue, the name of the importing eye bank and its unique identifier);
e) the age of the donor;
f) the date, time, and cause of death;
g) the date and time of enucleation or in situ excision, as well as the name of the enucleator, evaluator, or technician;
h) the date and time of preparation of the tissue (e.g., pre-cutting for DSAEK, and pre-stripping for DMEK), as well as the name of the processor or technician;
i) the date and time of preservation;
j) a slit-lamp report;
k) the results of specular microscopy (if done);
l) the name of the surgeon receiving the tissue;
m) the recipient identification number, readily traceable to each unique tissue identification number;
n) the date, time, and method of transportation;

o) the use of the tissue (i.e., surgical, research, or training);
p) the printed/electronic results of all required screening tests;
q) the microbiological screening results (if performed);
r) the microbiological reports of positive donor rim cultures from the receiving surgeon (if reported); and
s) errors, accidents, and adverse reactions.

7.5.2 Recipient follow-up information

7.5.2.1
Each eye bank shall retain recipient information from each surgeon using tissue, for each tissue used. This information shall be provided by the transplant surgeon and retained by the distributing eye bank.

7.5.2.2
The recipient information shall include the following:
a) two unique identifiers (e.g., patient's name, patient's date of birth, provincial health number, hospital identification number, passport number);
b) the patient's diagnosis;
c) the name of the surgeon receiving the transplant tissue;
d) the date of the surgery;
e) the location of the surgery; and
f) tissue-related postoperative complications.

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
The requirements specified in Clause 10 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

12.1 General

12.1.1
In addition to the requirements specified in Clause 12.1 of CAN/CSA-Z900.1, the requirements specified in Clause 12.1.2 of this Standard shall apply.

12.1.2
Each eye bank shall have a consistent policy for examination and documentation of a prospective donor's available medical records and death investigation. Review of all available donor records shall be performed by an individual who is qualified by profession, education, or training to do so, and who is familiar with the intended use of the tissue.

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 Donor age
The specification of the upper and lower age limit for donation shall be at the discretion of the medical director.

Note: *No definite relationship has been established between age and the quality of donor tissue.*

12.2.3 Assessment of living donors
Ocular tissue that is removed and processed for surgical use from a living donor shall be subject to the same requirements as those tissues from deceased donors (e.g., the same donor medical history, the same records, serology).

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 to 13.1.6 of this Standard shall apply.

13.1.2 Use of contraindicated ocular tissues
The contraindications associated with specific uses of ocular tissues are outlined in Clauses 13.1.3 to 13.1.6. Ocular tissues from donors excluded under the contraindications listed in Clause 13.1.3 shall not be offered for surgical purposes. Ocular tissues may be offered for surgical purposes under the conditions and for the purposes specifically permitted in Clauses 13.1.4 to 13.1.6.

Notes:

1) *The use of contraindicated tissues represents a potential health threat for the recipient(s) of that tissue and can pose a risk to the success of the surgery.*
2) *Clauses 13.1.4 to 13.1.6 include permissible uses for certain tissues from donors that are otherwise excluded.*

13.1.3 Exclusion criteria for ocular tissues

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

Note: *The following are in addition to the contraindications specified in Clause 13.1.3 of CAN/CSA-Z900.1.*

a) persons with congenital rubella;
b) persons who have had Reye's syndrome within the previous three months;
c) persons with active septicemia (bacteremia, fungemia, viremia);
d) persons with active bacterial or fungal endocarditis;
e) persons with active leukemia;
f) persons with myeloma or active lymphoma;
g) persons with Down's Syndrome, except in the case of scleral tissue, posterior lamellar keratoplasty, and keratolimbal or conjunctival grafts;
h) persons with congenital or acquired disorders of the eye that would preclude a successful outcome for the intended use (e.g., keratoconus, keratoglobus, or a central corneal scar for an intended penetrating keratoplasty);
i) persons with a history or signs of anterior segment surgery or other corneal disorders;
j) persons with a history of active or past Ebola infection;
k) persons with a history of melanoma with known metastatic disease, with the exception of irradiated ocular tissue; and
l) persons with intrinsic eye disease that would preclude good success of the transplant or would have a risk of transmitting disease.

Notes:

1) *If a person with an intrinsic eye disease has only one eye that is affected, the unaffected eye may be considered for use.*
2) *Examples of intrinsic eye disease include, but are not limited to,*
   a) *malignant tumours of the eye whether of primary or metastatic origin (e.g., retinoblastoma, melanoma, adenocarcinoma);*
   b) *active ocular or intraocular inflammation (conjunctivitis, keratitis, scleritis, iritis, uveitis, vitreitis, choroiditis, retinitis); and*
   c) *history of past herpes simplex virus corneal infection.*

13.1.4 Penetrating keratoplasty

For penetrating keratoplasty, the donor exclusion criteria in Clause 13.1.3 of CAN/CSA-Z900.1 and Clause 13.1.3 of this Standard shall apply. In addition, a donor of ocular tissues for penetrating keratoplasty shall be excluded if any of the following contraindications apply:

a) laser photoablative surgery [e.g., photorefractive keratectomy and laser in-situ keratomileusis (LASIK)]; and
b) disorders of the cornea involving the central optical area (e.g., pterygium, corneal scar).

Notes:

1) *Corneas from donors with anterior segment surgery (e.g., cataract and/or intraocular lens surgery, glaucoma surgery) may be considered for use in penetrating keratoplasty if they are screened by specular microscopy and slit-lamp exam and meet the eye bank's endothelial cell count standards as outlined in the SOPs.*
2) *If only one eye is affected, the unaffected eye may be considered for use.*

13.1.5 Lamellar grafts and keratolimbal or conjunctival grafts

13.1.5.1 Lamellar grafts

13.1.5.1.1 General: Lamellar grafts

For lamellar grafts, the exclusion criteria in Clause 13.1.3 of CAN/CSA-Z900.1 and Clause 13.1.3 of this Standard shall apply. In addition, the contraindications in Clauses 13.1.5.1.2 and 13.1.5.1.3 shall apply to donors of tissue for anterior lamellar procedures and donors of tissue for posterior lamellar procedures, respectively.

Notes:

1) *Corneal tissue from donors with anterior segment surgery (e.g., cataract and/or intraocular lens surgery, glaucoma surgery) may be used for lamellar grafts if the cornea has undergone a slit-lamp exam to confirm its suitability.*
2) *If only one eye is affected, the unaffected eye may be considered for use.*
3) *Lamellar graft procedures involve the transplant of one or more layers of the cornea. The contraindications for each type of lamellar graft depend on what layer(s) of the cornea will be used. Lamellar graft procedures currently include*
   a) *patch grafts;*
   b) *Descemet's stripping automated endothelial keratoplasty (DSEK or DSAEK);*
   c) *Descemet's membrane endothelial keratoplasty (DMEK);*
   d) *deep anterior lamellar keratoplasty (DALK); and*
   e) *anterior lamellar keratoplasty (ALK).*

13.1.5.1.2 Anterior lamellar keratoplasty

A donor of ocular tissues for anterior lamellar procedures (e.g., patch grafts and DALK) shall be excluded if any of the following contraindications apply:

a) previous laser or non-laser corneal surgery that compromises the corneal stroma or epithelium; and

   Note: *Examples of non-laser corneal surgery include*
   a) *radial and astigmatic keratotomy;*
   b) *conductive keratoplasty;*
   c) *intracorneal rings or inlays; and*
   d) *collagen cross-linking.*

b) disorders of the cornea involving the central optical area (e.g., pterygium, corneal scar).

Note: *Ocular tissue from persons with local eye disease affecting only the corneal endothelium may be considered for use for anterior lamellar procedures. However, such tissue should be used at the surgeon's discretion for DALK because of the possible need to convert to penetrating keratoplasty during the surgery.*

13.1.5.1.3 Posterior lamellar keratoplasty

A donor of ocular tissues for posterior lamellar procedures involving the corneal endothelium (e.g., DSEK/DSAEK or DMEK) shall be excluded if the following contraindication applies:

a) eye disease or previous surgery affecting the corneal endothelium involving the central optical zone, in the case of DMEK;
b) eye disease or previous surgery affecting the corneal endothelium and/or posterior stroma involving the central optical zone, in the case of DSEK/DSAEK; or
c) tissue that does not meet the endothelial cell count criteria for posterior lamellar keratoplasty, as outlined in the SOPs.

Note: *The transplanting surgeon/physician should be notified of any tissue offered for posterior lamellar keratoplasty that has undergone previous refractive surgery.*

13.1.5.2 Limbal grafts

For procedures involving keratolimbal or conjunctival limbal grafts, the donor exclusion criteria in Clause 13.1.3 of CAN/CSA-Z900.1 and Clause 13.1.3 of this Standard shall apply.

A donor of ocular tissues for keratolimbal or conjunctival limbal grafts (i.e., limbal transplants) shall be excluded if any of the following contraindications apply:

a) disorders of the cornea affecting the limbal area or corneal epithelium (e.g., pterygium, corneal scar);
b) irregular or desiccated epithelium indicating potential poor health of the limbal cells;
c) previous laser or non-laser corneal surgery that compromises the corneal epithelium or limbal area (e.g., collagen cross-linking, radial, or astigmatic keratotomy); or
d) local or systemic malignancies.

13.1.6 Scleral tissue

For procedures involving scleral tissue, the donor exclusion criteria in Clause 13.1.3 of CAN/CSA-Z900.1 and Clause 13.1.3 of this Standard shall apply.

Notes:

1) *A donor of ocular tissues for scleral transplantation should be excluded where ocular or orbital malignant disease (primary or metastatic) is present. It should also be excluded if there is a history of melanoma (with or without metastasis) or of solid, cancerous, nonmelanoma tumor with metastasis, unless the donated tissue is irradiated.*
2) *For scleral procedures, ocular tissue may be considered for use from persons with non-infectious eye disease affecting only the cornea and persons who have undergone laser or non-laser corneal or anterior segment surgery.*

13.2 Physical examination

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

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 ocular 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 General

14.2.1.1

In addition to the requirements specified in Clauses 14.2.1 to 14.2.8 of CAN/CSA-Z900.1, the requirements specified in Clauses 14.2.1.2 to 14.2.5 of this Standard shall apply.

14.2.1.2

Where testing for anti-HTLV-I and anti-HTLV-II have been performed as part of a workup for a non-ocular tissue or organ donor and any such tests are positive, ocular tissue may be used for transplantation subject to the approval of the medical director.

Where testing for syphilis has been performed as part of a workup for a non-ocular tissue or organ donor and a confirmatory test is reactive, the ocular tissue may be used for transplantation subject to the approval of the medical director.

14.2.1.3

Donor blood testing results shall be considered acceptable if sample collection takes place

a) within seven days prior to death;
b) after the time of death for deceased donors; or
c) within seven days of donation for living donors.

14.2.2 Gross examination

The whole globe or corneoscleral disc shall be initially examined grossly for clarity, epithelial defects, foreign objects, contamination, or scleral colour, e.g., jaundice.

14.2.3 Slit-lamp examination

14.2.3.1

The cornea shall be examined for epithelial and stromal pathology and, in particular, endothelial disease.

If in situ corneal excision is performed, examination of the donor eye anterior segment shall be performed with a penlight or a portable slit-lamp. After corneal excision, the corneoscleral disc shall be evaluated by slit-lamp biomicroscopy to ensure that damage to the corneal endothelium or surgical detachment of Descemet's membrane did not occur.

14.2.3.2

The eye bank's SOPs shall outline the minimum information to be documented with slit-lamp biomicroscopy.

14.2.4 Specular microscopy

Specular microscopy shall be performed when the endothelium is included in the tissue transplanted in order to provide useful information in screening donor corneal tissue to determine suitability for transplantation. The SOPs shall outline how the results of the specular microscopy are to be used. In the exceptional event that specular microscopy cannot be performed (e.g., mechanical failure), suitability shall be determined by the medical director.

14.2.5 Microbiological culturing

Microbiological culturing of ocular tissue at the time of processing shall be at the discretion of the medical director. If culturing is performed, the results shall be communicated to the recipient eye bank or the receiving surgeon.

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
An eye bank's specific retrieval procedures shall be outlined in the SOPs. These procedures shall be based on documented evidence and consistent with standard aseptic practice. The retrieval procedures shall be subject to approval of the medical director.

Note: *Documented evidence refers to activities, processes, and technical procedures that have been validated by the establishment, or, as appropriate, that have been established in standards developed by recognized professional organizations, based on established practice, or that are supported by information available in scientific literature.*

15.2 Reagents and supplies

15.2.1
In addition to the requirements specified in Clause 15.2 of CAN/CSA-Z900.1, the requirements specified in Clauses 15.2.2 to 15.2.6 of this Standard shall apply.

15.2.2
Adequate instrumentation shall be available to provide for the aseptic enucleation of whole eyes and excision of corneas.

15.2.3
The frequency of instrument inspections shall be such that proper function is assured.

15.2.4
Where an autoclave is used to sterilize instruments, the eye bank shall adhere to the maintenance procedures specific to the particular autoclave. Where instruments are sterilized outside of the eye bank or other establishment, documentation of appropriate sterilization shall be provided.

15.2.5
Reagents, such as corneal preservation solution, shall be marked with expiry dates and shall not be used after their expiry date. Packaged sterile instruments and supplies with an expiry date shall not be used after their expiry date. For medical devices sterilized on site, inventory control procedures shall be documented in the SOPs.

Note: *Inventory control can be based on event-related sterility or the use of expiry dates.*

15.2.6
Designated personnel, as specified in the SOPs, shall inspect the manufactured medium for damage on its arrival at the eye bank.

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 15.3.5 of this Standard shall apply.

15.3.2 Time intervals

Acceptable time intervals between death, enucleation or excision, and preservation can vary according to the circumstances of death and the interim means of storage of the body. Corneal preservation should occur as soon as possible after death.

15.3.3 Recording of time intervals

All time intervals for each donor (i.e., the time of death to the time of enucleation and preservation and/or the time to corneal excision) shall be recorded. If the donor has been refrigerated prior to enucleation or in situ corneal excision, this information shall be noted.

15.3.4 Preparation of ocular tissue for transplantation

Ultimate responsibility for personnel performing recovery, laboratory excision, or surgical preparation of tissue shall rest with the medical director.

Note: *Provincial/territorial regulations can apply.*

15.3.5 In situ and laboratory excision of the corneoscleral disc

15.3.5.1

Excision of corneoscleral discs shall be performed using aseptic techniques by individuals specifically trained to carry out in situ retrieval and/or laboratory excision of the corneoscleral disc.

15.3.5.2

Laboratory excision of corneoscleral discs shall be performed within a laminar airflow hood or equivalent environment that meets applicable requirements. Where in situ corneal excision occurs, the eye shall be examined with a penlight or portable slit-lamp prior to excision.

Notes:

1) *Provincial/territorial regulations can apply to laminar airflow hoods and cabinets.*
2) *See Clauses 14.2.2 to 14.2.4 for requirements regarding examination of ocular tissue.*

15.4 Preparation and preservation

15.4.1 General

15.4.1.1

In addition to the requirements specified in Clause 15.4 of CAN/CSA-Z900.1, the requirements specified in Clauses 15.4.1.2 to 15.4.5 of this Standard shall apply.

15.4.1.2

The establishment may use open or closed container techniques for preparation of ocular tissues. Preparation shall take place in an aseptic environment, and techniques shall be used to ensure the maintenance of aseptic environment during all phases of preparation and subsequent storage or transportation.

15.4.2 Short- and intermediate-term preservation

15.4.2.1
For short- and intermediate-term preservation, eye banks shall use an appropriate corneal storage solution that has been prepared in accordance with applicable requirements.

Note: *Provincial/territorial and federal laws and regulations can apply.*

15.4.2.2
Designated personnel, as specified in the SOPs, shall record the lot number of the preservation solution used for each cornea on the tissue report form, along with the unique identification number of the tissue, to allow for tracking and recall.

15.4.3 Long-term preservation
Some eye banks provide long-term preservation of corneal tissue through such means as organ culturing, although this is not common practice. An eye bank that provides long-term preservation shall carefully document the procedures for this practice in its SOPs, adhere to those procedures, and maintain rigid aseptic techniques.

15.4.4 Whole globe preservation

15.4.4.1
Procedures for whole globe preservation shall be outlined in the SOPs.

15.4.4.2
Eye banks that store whole eyes for lamellar or refractive keratoplasty shall employ the aseptic techniques and preservation methods outlined in the SOPs. The selected preservation method shall be documented in the SOPs.

15.4.5 Scleral preservation

15.4.5.1
The various methods of preserving sclera shall be listed in the SOPs. Eye banks shall preserve scleral tissue aseptically using one of the listed methods. The selected preservation method shall be documented in the SOPs.

15.4.5.2
Designated personnel, as specified in the SOPs, shall indicate a preservation date for scleral tissue.

15.4.5.3
Scleral tissue stocked at an establishment should be labelled as being for single-patient use only.

15.4.6 Expiration date
Each ocular tissue shall have its own expiration date and which shall documented in the SOPs.

Note: *In the unique case of limbal tissue from living donors, the current practice is to use the tissue within a very short period of time after retrieval, and therefore the expiration date as indicated on the storage solution does not apply.*

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 15.6.5 of this Standard shall apply.

15.6.2

Each tissue shall be individually packaged and sealed with a tamper-proof wrap.

15.6.3

Each tissue shall be packed in waterproof packaging material that is able to maintain the temperature of the tissue at an acceptable level.

15.6.4

The packaging of each tissue shall be such that the package insert and tissue label do not become wet.

15.6.5

All tissue shall be stored at a temperature appropriate to the method of preservation used. Eye banks shall precisely document their procedures for storage of ocular tissue, whether it is in the form of the whole eye or the cornea or sclera only.

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, the requirements specified in Clause 16.1.2 of this Standard shall apply.

16.1.2

A unique identification number shall be associated with each ocular tissue, or fraction thereof, that is distributed for surgical use.

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 and 16.3.3 of this Standard shall apply.

16.3.2 Labels

In addition to the requirements specified in Clause 16.3.1 of CAN/CSA-Z900.1, the following information shall be included on interior labels or package inserts (see Table C.3 in CAN/CSA-Z900.1):

a) the date and time, as specified in the SOPs, of corneal/scleral preservation;
b) the preservation date for long-term preserved tissue;
c) a statement that the tissue is intended for single-patient application only and is not to be considered sterile; and
d) the type of storage solution.

Note: *The information in Item d) may be on the package insert if there is not sufficient space on the label.*

16.3.3 Package inserts

16.3.3.1

A package insert shall accompany the tissue for transplantation. The package insert shall meet applicable requirements.

Note: *Health Canada regulations include packaging and labelling requirements for human tissues for transplantation.*

16.3.3.2

In addition to the requirements specified in Clause 16.3.1 of CAN/CSA-Z900.1, the package insert shall include the following:

a) the recommended storage temperature, with specific emphasis on precautions against freezing;
   Note: *An example of appropriate wording is "DO NOT FREEZE" or "NE PAS CONGELER."*
b) notification that the surgeon check for integrity of the seal, and that he or she immediately report to the eye bank any evidence of possible tampering;
c) notification that colour change, in accordance with the manufacturer's guidelines, can indicate a change in pH, in which case the tissue should not be used and a report should immediately be made to the eye bank;
d) notification whether presurgical microbiological cultures were performed by the eye bank, including the advisory that cultures of the donor tissue should be performed at the time of surgery; and
e) notification advising the receiving surgeon that the tissues are delivered with no warranty as to merchantability or fitness for a particular purpose, and that the receiving surgeon is ultimately responsible for judging the suitability of the tissue for use.

16.4 Forms

A copy of the tissue report form shall accompany the tissue. The forms accompanying the tissue shall contain the following information:

a) the name of the (source) eye bank;
b) the location of the eye bank;
c) the telephone number of the eye bank;
d) the eye bank identification number unique to each tissue;
e) the type of storage solution;
f) the age of the donor;
g) the cause of death;
h) the date and time of death;
i) the date and time of preservation;

j) the name of the technician who
   i) enucleated and/or excised the tissue; and
   ii) evaluated the tissue;
k) the slit-lamp report (including the date that the slit-lamp examination was performed);
l) the specular microscopy report (including the date that the specular microscopy was performed);
m) the results of the relevant infectious disease screening tests; and
n) the results of the relevant bacteriological cultures, if applicable.

16.5 Nonsurgical donor tissue

16.5.1
If donor tissue is provided for purposes other than surgery (e.g., research or practice surgery) and if that donor tissue is not screened for HIV, hepatitis, or prion-related disease, a label meeting the applicable requirements shall be attached to the packaging material used for the donor tissue storage and/or transport.

Note: *Federal transportation laws and regulations can apply.*

16.5.2
Documentation for nonsurgical donor tissue shall be retained for 10 years, or in accordance with applicable requirements.

Note: *Provincial/territorial and federal laws and regulations can apply.*

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

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 to 18.1.3 of this Standard shall apply.

18.1.2
Prior to distribution of tissue for transplantation, the medical director or designate shall review and document that the medical and laboratory information is in accordance with applicable standards. Eye banks shall establish and document a system of distribution that is just and equitable to all patients served by the eye bank.

18.1.3
Documentation of distribution (e.g., time and date of requests for, offers of, and delivery of eye tissue) shall be available for inspection by authorities having jurisdiction.

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 Clause 18.2.2 of this Standard shall apply.

18.2.2
For corneas returned unopened and then redistributed, tissue transportation and storage information shall be documented and made available to the eye bank and transplanting surgeon.

18.3 Receiver of ocular tissue

18.3.1
In addition to the requirements specified in Clause 18.3 of CAN/CSA-Z900.1, the requirements specified in Clauses 18.3.2 to 18.3.4 of this Standard shall apply.

18.3.2
Tissue shall be distributed only to physicians, research facilities, tissue processing facilities, tissue banks, and eye banks.

18.3.3
Tissue from Canadian eye banks distributed to eye banks in Canada or other countries shall comply with applicable requirements, and with this Standard.

Note: *Health Canada regulations include requirements for the processing and distribution of human tissue for transplantation.*

18.3.4
Each establishment should consider culturing of the corneoscleral disc for corneal transplantation, or a piece of sclera for scleral implantation, at the time of surgery. Positive results in cases of postoperative infection shall be reported to the eye bank that retrieved the tissue, as well as to the eye bank that distributed the tissue.

Note: *Culturing may be performed either before or at the time of surgery, or both.*

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.