

Changes to Standards to Deter “Veterinary use”

INTRODUCTION

Current (13th edition, see last bullet)

- In addition, unless otherwise stated, these *Standards* apply only to tissue intended for clinical use or transplantation (including insemination and fertilization). Accreditation will be based upon compliance with these *Standards*.

(with amendments)

- In addition, unless otherwise stated, these *Standards* apply only to tissue intended for clinical use or transplantation *to Recipients* (including ~~insemination and fertilization~~ *use in Assisted Reproductive Technology procedures*). Accreditation will be based upon compliance with these *Standards* *and the Accreditation Policies for Transplant Tissue Banks*.

(as amended)

- In addition, unless otherwise stated, these *Standards* apply only to tissue intended for clinical use or transplantation to *Recipients* (including use in Assisted Reproductive Technology procedures). Accreditation will be based upon compliance with these *Standards* and the *Accreditation Policies for Transplant Tissue Banks*.

SECTION A - GENERAL INFORMATION

A2.000 DEFINITIONS OF TERMS

Current (13th edition)

RECIPIENT – An individual into whom tissue is transplanted.

(with amendments)

RECIPIENT – ~~An individual~~ *A person* into whom tissue is transplanted.

(as amended)

RECIPIENT – A person into whom tissue is transplanted.

Current (13th edition)

TRANSPLANTATION – The transfer of allograft tissue to a recipient. This includes musculoskeletal, skin, cardiovascular, and fetal tissue, as well as reproductive tissue used in assisted reproductive procedures.

(with amendments)

TRANSPLANTATION – The transfer of allograft tissue to a *Recipient*. ~~This includes musculoskeletal, skin, cardiovascular, and fetal tissue, as well as reproductive tissue used in assisted reproductive procedures.~~

(as amended)

TRANSPLANTATION – The transfer of allograft tissue to a *Recipient*.

Changes to Standards to Deter “Veterinary use”

Current (13th edition)
None

(new term)
[VETERINARY USE – treatment of a condition or disease in a non-human animal.](#)

(final)
VETERINARY USE – treatment of a condition or disease in a non-human animal.

SECTION H - DISTRIBUTION AND DISPENSING

H1.000 DISTRIBUTION AND DISPENSING – GENERAL

Current (13th edition)
H1.100 Tissue Distribution and Dispensing Restrictions

Provision of tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, *Tissue Dispensing Services*, and *End-Users* (e.g., physicians, dentists, podiatrists or other medical professionals). If tissue is provided to a *Tissue Distribution Intermediary*, the *Tissue Distribution Intermediary* shall meet the requirements of Section M of these *Standards*.

(with amendments)
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Provision of tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, *Tissue Dispensing Services*, and *End-Users* (e.g., physicians, dentists, podiatrists or other medical professionals) [for use in Recipients. Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.](#) If tissue is provided to a *Tissue Distribution Intermediary*, the *Tissue Distribution Intermediary* shall meet the requirements of Section M of these *Standards*.

(as amended)
H1.100 Tissue Distribution and Dispensing Restrictions

Provision of tissue for transplantation shall be restricted to hospitals, free-standing medical facilities, tissue banks, *Tissue Dispensing Services*, and *End-Users* (e.g., physicians, dentists, podiatrists or other medical professionals) for use in *Recipients*. Human tissue for transplantation shall not be offered, distributed or dispensed for *Veterinary Use*. If tissue is provided to a *Tissue Distribution Intermediary*, the *Tissue Distribution Intermediary* shall meet the requirements of Section M of these *Standards*.

SECTION L - TISSUE DISPENSING SERVICES

L3.000 RELEASE

Changes to Standards to Deter “Veterinary use”

Current (13th edition)

L3.100 Dispensing

Tissue shall not be dispensed without an order from a physician or other authorized health professional. Tissue shall be transported and prepared for transplantation in accordance with the source tissue bank’s written procedures and directions. All associated *Labeling Material*, including the *Package Insert*, shall be made available to the *End-User* physician and/or other qualified medical professionals.

(with amendments)

L3.100 Dispensing

Tissue shall not be dispensed *for use in Recipients* without an order from a physician or other authorized health professional. *Human tissue shall not be offered or dispensed for Veterinary Use.* Tissue shall be transported and prepared for transplantation in accordance with the source tissue bank’s written procedures and directions. All associated *Labeling Material*, including the *Package Insert*, shall be made available to the *End-User* physician and/or other qualified medical professionals.

(as amended)

L3.100 Dispensing

Tissue shall not be dispensed for use in *Recipients* without an order from a physician or other authorized health professional. Human tissue shall not be offered or dispensed for *Veterinary Use*. Tissue shall be transported and prepared for transplantation in accordance with the source tissue bank’s written procedures and directions. All associated *Labeling Material*, including the *Package Insert*, shall be made available to the *End-User* physician and/or other qualified medical professionals.

L4.000 RECORDS

Current (13th edition)

L4.200 Dispensing Records

Disposition of tissue shall be documented. When tissue is dispensed for transplantation, the following information shall be recorded:

- 1) Name, address, and telephone number of the tissue bank from whom the tissue was obtained;
- 2) Type and quantity of tissue and unique *Tissue Identification Number(s)*;
- 3) *Recipient’s* name and hospital record number or social security number;
- 4) Transplantation site and date and time of release;
- 5) Name of the ordering physician or other health professional;
- 6) Name of the person dispensing the tissue; and
- 7) Name of the person preparing the tissue(s) for use, if tissue is prepared at the site of dispensing.

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This information shall be maintained in the *Tissue Dispensing Service* records in a log format. The tissue *Recipient's* medical records shall contain, at a minimum, the first five items to permit tracing of each tissue from the source tissue bank to each *Recipient*.

The tissue bank's tissue tracing forms shall be completed, specifying the *Disposition* of the tissue, and returned to the tissue supplier.

(with amendments)

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Disposition of tissue shall be documented. When tissue is dispensed for transplantation, the following information shall be recorded:

- 1) Name, address, and telephone number of the tissue bank from whom the tissue was obtained;
- 2) Type and quantity of tissue and unique *Tissue Identification Number(s)*;
- 3) *Recipient's* name and ~~hospital~~ medical record number, or social security number or similar unique identifier;
- 4) Transplantation site and date and time of release;
- 5) Name of the ordering physician or other authorized health professional;
- 6) Name of the person dispensing the tissue; and
- 7) Name of the person preparing the tissue(s) for use, if tissue is prepared at the site of dispensing.

This information shall be maintained in the *Tissue Dispensing Service* records ~~in a log format~~. The tissue *Recipient's* medical records shall contain, at a minimum, the first five items to permit tracing of each tissue from the source tissue bank to each *Recipient*.

The tissue bank's tissue tracing forms shall be completed, specifying the *Disposition* of the tissue, and returned to the tissue supplier.

(as amended)

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SECTION M - TISSUE DISTRIBUTION INTERMEDIARIES

M3.000 DISTRIBUTION—GENERAL

Current (13th edition)

M3.100 Tissue Distribution Restrictions

Distribution of tissue for transplantation shall be restricted to requests from tissue banks and *Tissue Dispensing Services*. *Tissue Distribution Intermediaries* shall have procedures that describe evaluation of requests from new customers for tissue.

(with amendments)

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(as amended)

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Distribution of tissue for transplantation shall be restricted to requests from tissue banks and *Tissue Dispensing Services* for use in *Recipients*. *Tissue Distribution Intermediaries* shall have procedures that describe evaluation of requests from new customers for tissue. Human tissue for transplantation shall not be offered or distributed for *Veterinary Use*.

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