

# CHANGES TO AATB STANDARDS FOR TISSUE BANKING

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## SECTION M - TISSUE DISTRIBUTION INTERMEDIARIES

*Current (13<sup>th</sup> edition)*

### **M6.000 RECALLS — GENERAL**

*Tissue Distribution Intermediaries* shall have specific, written policies and procedures for the performance of a *Recall*.

#### **M6.100 Recall Records**

The specifics relating to the *Recall* of tissue and resulting communications shall be documented and retained in a permanent file for at least ten years beyond date of *Distribution*, date of transplantation (if known), *Disposition*, or expiration of the tissue, whichever is latest. The file shall include, but not be limited to:

- 1) Reason for the *Recall*;
- 2) Steps taken to retrieve *Recalled* tissue;
- 3) Documentation of all communications regarding the *Recall* (e.g., phone calls and written correspondence, including a copy of the notification of *Recall* (*Recall* letter) and a list of those to whom it was sent);
- 4) Quarantining steps;
- 5) Final *Disposition* of the tissue;
- 6) Corrective actions recommended and implemented; and
- 7) Documentation of review.

*(with amendments)*

### **M6.000 RECALLS CORRECTIONS AND REMOVALS — GENERAL**

*Tissue Distribution Intermediaries* shall have specific, written policies and procedures for the performance of a *Recall Correction or Removal*. *Procedures shall include, but are not limited to, the following:*

- 1) *Designation of a Responsible Person(s);*
- 2) *Location and quarantine of affected inventory, in a timely manner;*
- 3) *Communication with the tissue bank (manufacturer, tissue source facility);*
- 4) *Communication with the End-User; and*

5) Documentation and record requirements.

**M6.100 Recall Correction and Removal Records**

The ~~specifies~~ All information relating to the ~~Recall~~ Correction or Removal of tissue and resulting communications shall be documented and retained ~~in a permanent~~ on file for at least ~~ten~~ 10 years beyond the date of *Distribution*, the date of transplantation (if known), *Disposition*, or expiration of the tissue, whichever is latest. The file shall include, but not be limited to:

- 1) Reason for the ~~Recall~~ Correction or Removal;
- 2) Identification and location of affected tissue in a timely manner, including quarantine steps;
- 3) Steps taken to correct or retrieve *Recalled* tissue;
- 4) Documentation of all related communications ~~regarding the Recall~~ (e.g., phone calls and/or written correspondence, including ~~a copy~~ copies of the Field Notifications ~~of~~ or ~~Recall (Recall letters)~~ and a list of those to whom it notice was sent);
- 4) ~~Quarantining steps~~;
- 5) Final *Disposition* of the tissue;
- 6) Corrective actions recommended and implemented; and
- 7) Documentation of review.

(as amended)

**M6.000 CORRECTIONS AND REMOVALS — GENERAL**

*Tissue Distribution Intermediaries* shall have specific, written policies and procedures for the performance of a *Correction* or *Removal*. Procedures shall include, but are not limited to, the following:

- 1) Designation of a *Responsible Person(s)*;
- 2) Location and quarantine of affected inventory, in a timely manner;
- 3) Communication with the tissue bank (manufacturer, tissue source facility);
- 4) Communication with the *End-User*; and
- 5) Documentation and record requirements.

**M6.100 Correction and Removal Records**

All information relating to the *Correction* or *Removal* of tissue and resulting communications shall be documented and retained on file for at least 10 years beyond the date of *Distribution*,

the date of transplantation (if known), *Disposition*, or expiration of the tissue, whichever is latest. The file shall include, but not be limited to:

- 1) Reason for the *Correction* or *Removal*;
- 2) Identification and location of affected tissue in a timely manner, including quarantine steps;
- 3) Steps taken to correct or retrieve tissue;
- 4) Documentation of all related communications (e.g., phone calls and/or written correspondence, including copies of *Field Notifications* or letters and a list of those to whom notice was sent);
- 5) Final *Disposition* of the tissue;
- 6) Corrective actions recommended and implemented; and
- 7) Documentation of review.

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