CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION H - DISTRIBUTION AND DISPENSING

Current (13th edition)
H5.000 RECALLS — GENERAL

Tissue banks shall have specific written policies and procedures for the initiation and performance of a *Recall.*

H5.100 Circumstances That May Require Recall

Tissue that was released to distributable inventory or shipped to a *Consignee* and subsequently determined to be unsuitable for transplantation shall be *Recalled*.

H5.200 Notification Responsibilities

Upon discovery of the need for *Recall*, the tissue bank shall promptly notify all entities to which affected tissue was distributed or dispensed as well as the tissue bank that recovered the tissue, if applicable.

H5.300 Handling of Tissue

All tissues not already transplanted, which are subject to *Recall*, shall be located and *Quarantined* pending *Resolution* of the *Recall*.

H5.400 Recall of Transplanted Tissue

If the tissue being *Recalled* has been transplanted or used for research, the subsequent investigation, in-house action, and notification of *End-Users* or *Recipients* shall be handled as a potential *Adverse Outcome* investigation in accordance with Section K4.300 of these *Standards*.

H5.500 Recall Records

All information relating to the *Recall* of tissue and resulting communications shall be documented and retained on file 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 the following information:

1) Events precipitating the *Recall*;

2) Steps taken to retrieve *Recalled* tissue;

3) Documentation of all communications regarding the *Recall* (i.e., phone calls and/or written correspondence, including copies of letters and a list of those to whom notice was sent);

4) Quarantining steps;

5) Final *Disposition* of the tissue;

6) Corrective actions recommended and implemented; and

7) Documentation of review; if of a medical nature, review by the Medical Director or licensed physician designee.

(with amendments)
H5.000 ~~RECALLS~~ *CORRECTIONS AND REMOVALS* — GENERAL

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

1) Evaluation and determination by a Responsible Person(s);

2) Timely identification and management of affected inventory;

3) Assessment of associated health risk;

4) Field communications (e.g., Field Notification);

5) Types of Corrections or Removals (e.g., Recall, Market Withdrawal, Stock Recovery);

6) Reporting requirements;

7) Evaluation of effectiveness;

8) Termination or closure;

9) Documentation and record requirements; and

10) Review by Management with Executive Responsibility.

Tissue banks not directly responsible for conducting Corrections or Removals, but that perform activities that could lead to the need for a correction or removal (e.g., tissue recovery, donor screening, donor testing) shall have policies and procedures for the timely notification of all affected parties regarding information related to tissue safety or regulatory requirements.

H5.100 Circumstances That May Require ~~Recall~~ *Correction or Removal*

The need to perform a Correction or Removal may be identified as a result of a Complaint, Adverse Outcome, Accident, Error, Deviation, Audit, or by any other means. An evaluation to determine if correction or removal is warranted should be made whenever distributed tissue may not meet specifications related to safety, quality, identification, function and/or use. This

evaluation must consider both risk to health posed by the tissue and applicable regulatory requirements, and be documented. ~~Tissue that was released to distributable inventory or shipped to a *Consignee* and subsequently determined to be unsuitable for transplantation shall be *Recalled*.~~

H5.200 Notification Responsibilities

Upon discovery of the need for ~~*Recall*~~ *a Correction or Removal*, the tissue bank shall promptly notify all entities to which affected tissue was distributed or dispensed as well as the tissue bank that recovered the tissue, if applicable.

H5.300 Handling of Tissue

All tissues not already transplanted, which are subject to ~~*Recall*~~ *Correction or Removal*, shall be located and *Quarantined* pending *Resolution* of the ~~*Recall*~~ *issue*.

~~**H5.400 Recall of Transplanted Tissue**~~

~~If the tissue being *Recalled* has been transplanted or used for research, the subsequent investigation, in-house action, and notification of *End-Users* or *Recipients* shall be handled as a potential *Adverse Outcome* investigation in accordance with Section K4.300 of these *Standards*.~~

H5.400 Reporting Requirements

Tissue banks shall comply with all Correction and Removal reporting requirements for applicable federal, state and international government/competent authorities under which they operate or distribute tissue.

For additional information, refer to FDA Guidance for Industry: Product Recalls, Including Removals and Corrections at: http://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm

H5.500 ~~Recall~~ *Correction and Removal* Records

All information relating to the ~~*Recall*~~ *Correction or Removal* of tissue and resulting communications shall be documented and retained on file 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 the following information:

1) Events precipitating the ~~*Recall*~~ *Correction or Removal*;

2) Identification and location of affected tissue, including quarantine steps;

3) Associated risk assessment;

4) Type of Correction or Removal (e.g., Recall, Market Withdrawal, Stock Recovery);

5~~2~~) Steps taken to *correct or* retrieve ~~*Recalled*~~ tissue;

6~~3~~) Documentation of all *related* communications ~~regarding the *Recall*~~ (~~i.e.,~~ *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);

~~4) Quarantining steps;~~

7~~5~~) Final *Disposition* of the tissue;

8) Copies of reports to regulatory authorities, accreditation organizations and certification bodies, if required;

9~~6~~) Corrective actions recommended and implemented; and

10~~7~~)Documentation of review; if of a medical nature, review by the Medical Director or licensed physician designee.

(as amended)

H5.000 CORRECTIONS AND REMOVALS — GENERAL

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

1) Evaluation and determination by a *Responsible Person*(s);

2) Timely identification and management of affected inventory;

3) Assessment of associated health risk;

4) Field communications (e.g., *Field Notification*);

5) Types of *Corrections* or *Removals* (e.g., *Recall*, *Market Withdrawal*, *Stock Recovery*);

6) Reporting requirements;

7) Evaluation of effectiveness;

8) Termination or closure;

9) Documentation and record requirements; and

10) Review by *Management with Executive Responsibility*.

Tissue banks not directly responsible for conducting *Corrections* or *Removals*, but that perform activities that could lead to the need for a correction or removal (e.g., tissue recovery, donor screening, donor testing) shall have policies and procedures for the timely notification of all affected parties regarding information related to tissue safety or regulatory requirements.

H5.100 Circumstances That May Require Correction or Removal

The need to perform a *Correction* or *Removal* may be identified as a result of a *Complaint*, *Adverse Outcome*, *Accident*, *Error*, *Deviation*, *Audit*, or by any other means. An evaluation to determine if correction or removal is warranted should be made whenever distributed tissue may not meet specifications related to safety, quality, identification, function and/or use. This evaluation must consider both risk to health posed by the tissue and applicable regulatory requirements, and be documented.

H5.200 Notification Responsibilities

Upon discovery of the need for a *Correction* or *Removal*, the tissue bank shall promptly notify all entities to which affected tissue was distributed or dispensed as well as the tissue bank that recovered the tissue, if applicable.

H5.300 Handling of Tissue

All tissues not already transplanted, which are subject to *Correction* or *Removal*, shall be located and *Quarantined* pending *Resolution* of the issue.

H5.400 Reporting Requirements

Tissue banks shall comply with all *Correction* and *Removal* reporting requirements for applicable federal, state and international government/competent authorities under which they operate or distribute tissue.

For additional information, refer to FDA Guidance for Industry: Product Recalls, Including Removals and Corrections at:
http://www.fda.gov/safety/recalls/industryguidance/ucm129259.htm

H5.500 Correction and Removal Records

All information relating to the *Correction or Removal* of tissue and resulting communications shall be documented and retained on file 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 the following information:

1) Events precipitating the *Correction* or *Removal*;

2) Identification and location of affected tissue, including quarantine steps;

3) Associated risk assessment;

4) Type of *Correction* or *Removal* (e.g., *Recall, Market Withdrawal, Stock Recovery*);

5) Steps taken to correct or retrieve tissue;

6) 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);

7) Final *Disposition* of the tissue;

8) Copies of reports to regulatory authorities, accreditation organizations and certification bodies, if required;

9) Corrective actions recommended and implemented; and

10) Documentation of review; if of a medical nature, review by the Medical Director or licensed physician designee.

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