SECTION A - GENERAL INFORMATION

Current (13th edition, relevant parts only)
A2.000 DEFINITIONS OF TERMS

CONSIGNEE – Any *Tissue Bank*, *Tissue Distribution Intermediary* or *Tissue Dispensing Service* (whether individual, agency, institution, or organization) that receives tissue and assumes responsibility for the processing, storage, distribution and/or dispensing of such tissue.

DISTRIBUTION – A process that includes receipt of a request for tissue, selection and inspection of appropriate tissue, and inspection, and subsequent shipment and delivery of tissue to another *Tissue Bank, Tissue Distribution Intermediary,* or *Tissue Dispensing Service.*

NOTIFICATION – Provision and documentation of notice concerning an anatomical gift that was made by the *Donor* during the *Donor's* lifetime.

RECALL – An action taken by a tissue bank to locate and retrieve tissue from distribution and dispensary inventories.

STANDARD OPERATING PROCEDURES MANUAL (SOPM) – A group of standard operating procedures (SOPs) detailing the specific policies of a tissue bank and the procedures used by the staff/personnel. This includes, but is not limited to, procedures to: assess donor suitability; recovery; processing; quarantine; release to inventory; labeling; storage; distribution; and recalling tissue.

TISSUE DISPENSING SERVICE – Any entity that receives, stores, and provides tissue directly to an end-user for immediate transplantation. Tissue dispensing services may or may not be tissue banks, depending on what other functions they perform.

Provided for reference only, no changes proposed:

END-USER – A health care practitioner who performs transplantation procedures.

FINISHED TISSUE – Tissue that has been fully processed, enclosed in its final container, labeled, and released to distribution inventory.

TISSUE DISTRIBUTION INTERMEDIARY – An intermediary agent who acquires and stores tissue for further distribution and performs no other tissue banking functions.

(with amendments, relevant parts only)
A2.000 DEFINITIONS OF TERMS

CONSIGNEE – Any *Tissue Bank*, *Tissue Distribution Intermediary*, ~~or~~ *Tissue Dispensing*

Service, or End-User (whether individual, agency, institution, or organization) that receives *Finished Tissue* ~~tissue and assumes responsibility for the processing, storage, distribution and/or dispensing of such tissue~~.

CORRECTION *– The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of distributed tissue without its physical removal to some other location. Reference 21 CFR Part 7, 7.3(h).*

DISTRIBUTION – A process that includes receipt of a request for tissue, selection ~~and inspection~~ of appropriate ~~tissue~~ *Finished Tissue, preparation for transport*, ~~and~~ *any required* inspection*s*, and subsequent shipment and delivery of tissue to another *Tissue Bank, Tissue Distribution Intermediary,* ~~or~~ *Tissue Dispensing Service, or End-User*.

FIELD NOTIFICATION *– The provision of additional information pertaining to the safety, quality, identification, function and/or use of distributed tissue.*

MARKET WITHDRAWAL *– A Correction or Removal of distributed tissue that involves a minor violation that would not be subject to legal action by the FDA or that involves no violation (e.g., normal stock rotation practices). Reference 21 CFR Part 7, 7.3(j).*

NOTIFICATION *(OF GIFT)* – Provision and documentation of notice concerning an anatomical gift that was made by the *Donor* during the *Donor's* lifetime.

RECALL – ~~An action taken by a tissue bank to locate and retrieve tissue from distribution and dispensary inventories~~. *A Correction or Removal of distributed tissue initiated to reduce a risk to health posed by the tissue or to remedy a violation of regulatory requirements that may present a risk to health.*

REMOVAL *– The physical removal of distributed tissue from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. Reference 21 CFR Part 806, 806.2(i).*

STANDARD OPERATING PROCEDURES MANUAL (SOPM) – A group of standard operating procedures (SOPs) detailing the specific policies of a tissue bank and the procedures used by the staff/personnel *to carry out the functions of the tissue bank*. ~~This includes, but is not limited to, procedures to: assess donor suitability; recovery; processing; quarantine; release to inventory; labeling; storage; distribution; and recalling tissue.~~

STOCK RECOVERY *– A Correction or Removal of tissue that has not left the direct control of the tissue bank (manufacturer), i.e., the tissue is located on the premises owned, or under the control of, the tissue bank (manufacturer), and no portion of the affected tissue has been released for use. Reference 21 CFR Part 7, 7.3(k).*

TISSUE DISPENSING SERVICE – Any entity that receives, stores, and provides tissue directly to an ~~end-user~~ *End-User* for ~~immediate~~ transplantation. Tissue dispensing services

may or may not be tissue banks, depending on what other functions they perform.

(as amended, relevant parts only)
A2.000 DEFINITIONS OF TERMS

CONSIGNEE – Any *Tissue Bank*, *Tissue Distribution Intermediary, Tissue Dispensing Service*, or *End-User* (whether individual, agency, institution, or organization) that receives *Finished Tissue.*

CORRECTION – The repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of distributed tissue without its physical removal to some other location. Reference 21 CFR Part 7, 7.3(h).

DISTRIBUTION – A process that includes receipt of a request for tissue, selection of appropriate *Finished Tissue*, preparation for transport, any required inspection*s*, and subsequent shipment and delivery of tissue to another *Tissue Bank, Tissue Distribution Intermediary, Tissue Dispensing Service,* or *End-User.*

FIELD NOTIFICATION – The provision of additional information pertaining to the safety, quality, identification, function and/or use of distributed tissue.

MARKET WITHDRAWAL – A *Correction* or *Removal* of distributed tissue that involves a minor violation that would not be subject to legal action by the *FDA* or that involves no violation (e.g., normal stock rotation practices). Reference 21 CFR Part 7, 7.3(j).

NOTIFICATION (OF GIFT) – Provision and documentation of notice concerning an anatomical gift that was made by the *Donor* during the *Donor's* lifetime.

RECALL – A *Correction* or *Removal* of distributed tissue initiated to reduce a risk to health posed by the tissue or to remedy a violation of regulatory requirements that may present a risk to health.

REMOVAL – The physical removal of distributed tissue from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. Reference 21 CFR Part 806, 806.2(i).

STANDARD OPERATING PROCEDURES MANUAL (SOPM) – A group of standard operating procedures (SOPs) detailing the specific policies of a tissue bank and the procedures used by the staff/personnel to carry out the functions of the tissue bank.

STOCK RECOVERY – A *Correction* or *Removal* of tissue that has not left the direct control of the tissue bank (manufacturer), i.e., the tissue is located on the premises owned, or under the control of, the tissue bank (manufacturer), and no portion of the affected tissue has been released for use. Reference 21 CFR Part 7, 7.3(k).

TISSUE DISPENSING SERVICE – Any entity that receives, stores, and provides tissue directly to an *End-User* for transplantation. Tissue dispensing services may or may not be tissue banks, depending on what other functions they perform.

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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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SECTION J - GENERAL OPERATIONS

J1.000 STANDARD OPERATING PROCEDURES MANUAL (SOPM)

Current (13th edition, relevant parts only)
J1.200 Contents

The *SOPM* shall specifically include, but shall not be limited to:

6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery*, *Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:
…

d) requiring notification of *Management with Executive Responsibility* of any *Recalls*, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);

e) for the *Recall* of tissue unacceptable for transplantation. (H5.000, L6.000 and M6.000);

…

(with amendments, relevant parts only)
J1.200 Contents

The *SOPM* shall specifically include, but shall not be limited to:

6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection, Recovery*, *Processing*, packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:
…

d~~e~~) ~~for the *Recall* of tissue unacceptable for transplantation~~ *for the performance of Corrections and Removals, if applicable, and/or the timely notification of affected parties regarding information related to tissue safety or regulatory requirements*. (H5.000, L6.000 and M6.000);

e~~d~~) requiring notification of *Management with Executive Responsibility* of any *Corrections or Removals* ~~*Recalls*~~, investigations, inspection reports, or regulatory actions (H5.000 and K4.000);

…

(as amended)
J1.200 Contents

The SOPM shall specifically include, but shall not be limited to:

1) Donor policies and procedures, including *Informed Consent* or *Authorization*, donor

suitability criteria, donor screening methods, time limits for tissue recovery, notification of confirmed positive test results, information sharing and, if applicable, reconstruction and final disposition of a deceased donor's body (D2.000, D3.000, D4.000 and D5.000);

2) *Tissue Collection*, *Recovery* and handling policies and procedures, including supplies and methods used in all aspects of the operation involving the assessment of the *Recovery Site*, *Recovery, Processing*, packaging, quarantine, labeling, storage, donor suitability review, and/or release of tissue (D5.000, D6.000 and Sections E, F and G);

3) Laboratory procedures for tests performed in-house, including establishment of appropriate specifications, standards, and test procedures to assure that tissue is safe; and for contracted laboratory testing, policies and procedures defining which tests shall be performed and how test results shall be received, reviewed, interpreted, and managed (D4.350);

4) Policies and procedures for purchasing controls, order receipt, unit selection, final inspection of *Container,* and package and shipping of tissue, as well as criteria for returning and reissuing tissue (K1.300, M3.000, M4.000, M5.000 and Section H);

5) Record management policies and procedures designed to maintain *Traceability* and facilitate (if necessary) product *Recall* and *Recipient* notification by documentation of each step of tissue production from the point of *Collection*, *Recovery* and identification to final *Distribution* of the tissue (C1.000, C1.400, H5.000, L4.000, M6.000 and M7.000);

6) *Quality Assurance* and *Quality Control* policies and procedures for supplies, equipment, instruments, reagents, labels, and processes employed in tissue *Collection*, *Recovery*, *Processing,* packaging, labeling, storage, *Distribution*, and preparation of tissue for transplantation, including policies and/or procedures:

   a) for labeling of cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) (D4.350, D5.000 and Section G);

   b) for monitoring storage temperatures, for defining *Tolerance Limits*, and for describing what, when, and how corrective actions are to be taken for implementing emergency transfers and determining alternative storage and monitoring methods for tissue and reagents (E4.000, F4.200 and M2.000);

   c) the investigation, documentation, and reporting of *Accidents*, *Errors*, *Complaints*, and *Adverse Outcomes* (K4.000);

   d) for the performance of *Corrections* and *Removals*, if applicable, and/or the timely notification of affected parties regarding information related to tissue safety or regulatory requirements. (H5.000, L6.000 and M6.000);

   e) requiring notification of *Management with Executive Responsibility* of any *Corrections* or *Removals*, investigations, inspection reports, or regulatory actions

(H5.000 and K4.000);

f) that establish which supplies, reagents, materials and equipment are considered *Critical* (D5.100, E1.300, J5.100);

g) and schedules for equipment inspection, maintenance, repair and calibration for the purpose of maintaining equipment (J5.000);

h) describing the receipt, identification, storage, handling, sampling, testing, and subsequent approval or rejection of *Containers*, packaging materials, labels, reagents, and supplies (D5.000, E1.000, E2.000, J5.500 and Section G); and

i) for monitoring *In-Process Controls* and managing events such as failed test runs and failure of a *Lot* to meet established specifications (Section K).

7) Policies and procedures for assigning expiration dates (E4.200, H3.300 and K1.200);

8) Policies and procedures for handling requests for research tissue (H2.000);

9) Procedures for disposal of medical waste and other hazardous waste (J3.000);

10) Emergency and safety policies and procedures, including reporting of staff injuries and potential exposure to blood-borne pathogens (J3.000);

11) Procedures assigning responsibility for the sanitation of facilities and describing the cleaning schedules, methods, equipment and materials to be used (J4.000);

12) Policies and procedures describing manual methods for tissue banking activities in the event of electronic or equipment malfunction (K6.000);

13) Policies and procedures describing requirements of training programs for technical and *QA* staff (J2.000); and

14) Policies and procedures for identification and control of procedures and forms including requirements (J1.100, J1.400).

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SECTION K - QUALITY ASSURANCE

Current (13th edition, relevant part only)
K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA Program.

K1.100 Basic Elements

…

8) Documentation of formal conclusion of all *Accident*, *Error*, *Complaint*, *Adverse Outcome,* and *Recall* incidents;

…

(with amendments, relevant part only)
K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA Program.

K1.100 Basic Elements

…

8) Documentation of formal conclusion of all *Accident*, *Error*, *Complaint*, *Adverse Outcome,* and ~~*Recall*~~ *Correction or Removal* incidents;

…

(as amended)
K1.000 QUALITY ASSURANCE PROGRAM

All tissue banks shall have a QA Program.

K1.100 Basic Elements

QA programs shall include, at a minimum:

1) Designation and management of *Quality Control* functions, including:

   a) Environmental monitoring at designated intervals;

   b) Performance and documentation in maintenance records or logs of periodic equipment and facility inspections;

   c) Review of equipment monitoring records for maintenance within specified *Tolerance Limits,* and reviewing records of other equipment or *Processing* functions that have specified *Tolerance Limits*;

   d) Inspection and monitoring *In-Process Control* results, including collection and testing of representative samples;

   e) Performing qualification of reagents, supplies, materials, or equipment when deemed *Critical* or applicable; and

f) Monitoring laboratory performance, if applicable.

2) *Process Validation Studies* are performed where the results of a process cannot be fully verified by subsequent inspection and test. Each tissue bank shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each tissue bank shall ensure that validated processes are performed by qualified individual(s). For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented. When changes or process deviations occur, the tissue bank shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented;

3) *Equipment Qualification Studies* are performed as necessary;

4) Purchasing controls are established;

5) Procedures are established for implementing corrective and preventive action is taken when appropriate. The procedures shall include requirements for:

   a) Analyzing processes, work operations, concessions, quality audit reports, quality records, errors, accidents, complaints, returns, and other sources of quality data to identify existing and potential causes of nonconforming tissue, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

   b) Investigating the cause of nonconformities relating to tissue, processes, and the quality system;

   c) Identifying the action(s) needed to correct and prevent recurrence of quality problems;

   d) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the *Finished Tissue*;

   e) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

   f) Ensuring that information related to quality problems is disseminated to those directly responsible for assuring the quality of *Finished Tissue* or the prevention of such problems; and

   g) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review;

6) Review and approval of donor screening, *Informed Consent* or *Authorization*, *Recovery* or *Collection*, and *Processing* records prior to release of tissue for transplantation;

7) Performance of audit procedures;

8) Documentation of formal conclusion of all *Accident*, *Error*, *Complaint*, *Adverse Outcome,* and *Correction* or *Removal* incidents;

9) Maintenance of documentation including, but not limited to:

   a) Master copy of current *SOPM*s;

   b) For those authorized to perform or review tasks, records of names, signatures, initials or identification codes and inclusive dates of employment shall be maintained (e.g., by Human Resources, Quality Assurance, or by department);

   c) Reports and conclusions of process *Validation* and *Equipment Qualification Studies*;

   d) Records of supply and reagent acceptance or rejection;

   e) Archived documents; and

   f) Master lists of preprinted labels.

10) Evaluation of training of personnel and, where possible, the *Competency* of personnel, and requiring that staff are appropriately oriented and trained concerning any modifications to the *SOPM*;

11) Maintenance of labeling controls, including all brochures, pamphlets, and promotional materials; and

12) A process for sharing information with other *Tissue Banks* that are known to have recovered and/or received tissue from the same donor.

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SECTION L - TISSUE DISPENSING SERVICES

Current (13th edition)
L6.000 RECALLS

The *Tissue Dispensing Service* shall have written procedures for the *Recall* of tissue.

(with amendments)
L6.000 ~~RECALLS~~ *CORRECTIONS AND REMOVALS*

The *Tissue Dispensing Service* shall have *specific* written *policies and* procedures for the ~~*Recall* of tissue.~~ *performance of a Correction or Removal, if applicable. 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.

(as amended)
L6.000 CORRECTIONS AND REMOVALS

The *Tissue Dispensing Service* shall have specific written policies and procedures for the performance of a *Correction* or *Removal*, if applicable. 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.

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SECTION M - TISSUE DISTRIBUTION INTERMEDIARIES

Current (13th 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 specifics~~ *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~~2~~) Steps taken to *correct or* retrieve ~~*Recalled*~~ tissue;

*4*3) Documentation of all *related* communications ~~regarding the *Recall*~~ (e.g., phone calls and*/or* written correspondence, including ~~a copy~~ *copies* of ~~the~~ *Field N*otification*s* ~~of~~ *or* ~~*Recall* (*Recall*~~ letter*s*~~)~~ 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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