

CHANGES TO AATB STANDARDS FOR TISSUE BANKING

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 inspections*, 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 inspections, 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.

Publication date: April 6, 2015 (AATB Bulletin No. 15-8)

Effective date: October 6, 2015 (in 6 months)