CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION G - LABELING

G2.000 LABELING PROCESS

Current (13the edition)
G2.100 General Requirements

There shall be SOPs designed and followed to ensure that correct labels, labeling, and packaging material are used for tissue. Each labeling phase for all tissue (e.g., unprocessed, processed, *Quarantined*, and released for *Distribution*) shall be documented.

G2.200 Re-Labeling

If tissue is to be re-labeled for any reason, such as label detachment or to correct a labeling *Error*, the tissue bank shall establish a re-labeling procedure delineating the methods to be utilized, conditions under which tissue may be re-labeled, and the staff authorized to perform such activities. The reasons for, and events surrounding, the re-labeling of tissue shall be documented in the records.

G2.300 Controls—General

There shall be appropriate labeling control procedures based upon the system and equipment used in labeling operations. *SOPMs* shall incorporate controls including the review of labels to ensure accuracy and the establishment of checks to prevent transcription and other labeling *Errors*. Electronic labeling systems shall possess adequate controls to prevent the erroneous labeling of tissue. There shall be documentation in the records to verify label accuracy and that labeling checks were performed. The labeling area shall be inspected prior to the start of labeling activities to ensure that all labels and packaging materials from previous labeling have been removed.

G2.310 Label Inspection

Labels shall meet appropriate written specifications and be approved by quality assurance staff prior to release for use by a designated person. Labels not meeting such specifications shall be discarded. Date of receipt, date of inspection, and the names of the staff involved in receipt and inspection shall be documented.

G2.320 Label Storage

The storage area for labels and *Labeling Materials* shall be clearly identified. Access should be restricted to authorized personnel only.

G2.330 Labeling Process Controls—Obsolete Labels

Procedures shall be established to retrieve obsolete and/or outdated labels and *Labeling Materials* from all labeling areas and inventory locations. As each type of label is removed from inventory, one label shall be retained for the archives and the surplus labels shall be discarded. The Master Label List and the *SOPM* shall be updated accordingly.

G2.340 Tissue and Container Visual Inspection

Prior to labeling a unit of processed tissue, the *Container* shall be inspected for evidence of impurities, defects, broken seals, or contamination that could compromise the quality, integrity, or *Safety* of the tissue. A sufficient area of the *Container* shall remain uncovered to permit inspection of the contents whenever possible. Any tissue or *Container* suspected to be of questionable quality shall be *Quarantined* immediately pending further investigation and *Resolution* following established procedures in the *SOPM*. This review shall be documented.

(with amendments, relevant parts only)
G2.200 Re-Labeling

If tissue is to be re-labeled for any reason, such as label detachment or to correct a labeling *Error*, the tissue bank shall establish a re-labeling procedure delineating the methods to be utilized, conditions under which tissue may be re-labeled, and the staff authorized to perform such activities. The reasons for, and events surrounding, the re-labeling of tissue shall be documented in the records. *Re-labeling methods shall consider storage conditions and label integrity (see G1.300).*

G2.320 Label Storage

The storage area for labels and *Labeling Materials* shall be clearly identified. Access should be restricted to authorized personnel only. *This is not applicable to labels included in tissue recovery packs.*

(as amended, relevant parts only)
G2.200 Re-Labeling

If tissue is to be re-labeled for any reason, such as label detachment or to correct a labeling *Error*, the tissue bank shall establish a re-labeling procedure delineating the methods to be utilized, conditions under which tissue may be re-labeled, and the staff authorized to perform such activities. The reasons for, and events surrounding, the re-labeling of tissue shall be documented in the records. Re-labeling methods shall consider storage conditions and label integrity (see G1.300).

G2.320 Label Storage

The storage area for labels and *Labeling Materials* shall be clearly identified. Access should be restricted to authorized personnel only. This is not applicable to labels included in tissue recovery packs.

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