

# CHANGES TO AATB STANDARDS FOR TISSUE BANKING

---

---

## SECTION G - LABELING

### G1.000 LABELS AND LABELING

*Current (13th edition)*

#### G1.100 Nomenclature

Nomenclature and units of measurement used to describe tissue and the *Processing* that tissue has received shall be specified in the *SOPM* and be applied consistently.

#### G1.200 Label List

If preprinted or computer-generated labels are used, a list of them shall be maintained, as well as an example of every label that is utilized by the tissue bank. Dates of use (start and discontinuance) shall be recorded.

#### G1.300 Labeling Integrity

Labels shall be designed and qualified to be legible, indelible, and affixed firmly to the container under all anticipated storage conditions for the shelf life of the tissue. Tissue labels and associated *Labeling Materials* applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling *Errors*.

#### G1.400 Claims

All labeling *claims* shall be clear, accurate, substantiated, and not misleading.

*(with amendments)*

#### G1.100 Nomenclature

Nomenclature ~~and units of measurement~~ used to describe tissue, *cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes)* and the ~~*Processing* that tissue has received~~ shall be specified in the *SOPM* and be applied consistently. *For Finished Tissue, units of measurement and the Processing that tissue has received shall also be specified in the SOPM.*

#### G1.200 Label List

~~If preprinted or computer-generated labels are used, a~~ *A* list of them *labels used* shall be maintained, as well as an example of every label that is utilized by the tissue bank. Dates of use (start and discontinuance) shall be recorded. *Changes pertaining to labels and communicating changes shall be expected from tissue banks that supply labels to other tissue banks.*

### **G1.300 Labeling Integrity**

Labels shall be designed and qualified to be legible, indelible, and affixed firmly to the *Container* under all anticipated storage conditions for the shelf life *length of use* of the tissue. ~~Tissue *Labels* and associated *Labeling Materials* applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling *Errors*. *When applicable, this also applies to Labeling Materials. Suppliers of labels deemed Critical are responsible for establishing specifications.*~~

### **G1.400 Claims**

All labeling *Claims* shall be clear, accurate, substantiated, and not misleading.

*(as amended)*

### **G1.100 Nomenclature**

Nomenclature used to describe tissue, cultures, blood specimens and other donor specimens (e.g., lesions, lymph nodes) shall be specified in the *SOPM* and be applied consistently. For *Finished Tissue*, units of measurement and the *Processing* that tissue has received shall also be specified in the *SOPM*.

### **G1.200 Label List**

A list of labels used shall be maintained, as well as an example of every label that is utilized by the tissue bank. Dates of use (start and discontinuance) shall be recorded. Changes pertaining to labels and communicating changes shall be expected from tissue banks that supply labels to other tissue banks.

### **G1.300 Labeling Integrity**

Labels shall be designed and qualified to be legible, indelible, and affixed firmly to the *Container* under anticipated storage conditions for length of use. Labels applied by tissue bank staff shall not be removed, altered, or obscured except to correct labeling *Errors*. When applicable, this also applies to *Labeling Materials*. Suppliers of labels deemed *Critical* are responsible for establishing specifications.

### **G1.400 Claims**

All labeling *Claims* shall be clear, accurate, substantiated, and not misleading.

Publication date: March 30, 2015 (AATB Bulletin No. 15-7)

Effective date: September 30, 2015 (in 6 months)