

# CHANGES TO AATB STANDARDS FOR TISSUE BANKING

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## SECTION G - LABELING

### G3.000 LABELING INFORMATION

#### G3.100 Container Labels

*Current (13<sup>th</sup> edition)*

#### G3.120 Content

Container labels shall include the *Tissue Identification Number*.

Following information shall be included on container label unless space limitations require use of a corresponding insert:

- 1) Descriptive name of the tissue;
- 2) Name(s) and address(es) of tissue bank(s) responsible for determining donor suitability, *Processing* and *Distribution*. Should more than two banks be involved, the name of all banks are required but the address is only required for the bank determining donor suitability;
- 3) Expiration date (if applicable), including the month and year;
- 4) Acceptable storage conditions, including recommended storage temperature and/or acceptable storage temperature range;
- 5) *Disinfection* or *Sterilization* procedure utilized (if applicable);
- 6) Preservative (if utilized) and/or method of *Preservation* (if applicable);
- 7) Quantity of tissue expressed as volume, weight, dimensions, or a combination of these units of measure, if applicable;
- 8) Potential residues of *Processing* agents/solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethylsulfoxide); and
- 9) A reference to the *Package Insert*.

*(with amendments)*

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banks are required but the address is only required for the bank determining donor suitability;

- 3) Expiration date (if applicable), including the month and year;
- 4) Acceptable storage conditions, including recommended storage temperature and/or acceptable storage temperature range;
- 5) *Disinfection* or *Sterilization* procedure utilized (if applicable);
- 6) Preservative (if utilized) and/or method of *Preservation* (if applicable);
- 7) Quantity *or other characteristics* of tissue expressed as *applicable (e.g., volume, weight, dimensions, cell density, number of viable cells, or a combination of these) units of measure, if applicable*;
- 8) Potential residues of *Processing* agents/solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethylsulfoxide); and
- 9) A reference to the *Package Insert*.

*(as amended)*

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- 7) Quantity or other characteristics of tissue expressed as applicable (e.g., volume, weight, dimensions, cell density, number of viable cells, or a combination of these);
- 8) Potential residues of *Processing* agents/solutions (e.g., antibiotics, ethanol, ethylene oxide, dimethylsulfoxide); and
- 9) A reference to the *Package Insert*.

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