CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION K - QUALITY ASSURANCE

K1.000 QUALITY ASSURANCE PROGRAM

Current (13th edition)

K1.200 Qualification, Verification, and Validation Requirements

Protocols shall be developed, implemented, and documented for the *Qualification*, *Verification*, or *Validation* of significant components of facilities, processes, equipment, reagents, labels, *Containers*, packaging materials, and electronic systems. Process validations shall be performed where the results of a process cannot be fully verified by subsequent inspection and test of which elements or items are to be qualified, verified, or validated shall be made by individuals responsible for *Quality Assurance* and regulatory compliance. Evaluation of parameters tested shall be performed and adequacy of the study to demonstrate necessary outcomes shall be determined.

K1.210 Validation of Shipping Containers

(C, V) *Qualification* studies of the transportation devices and methods for temporary storage of *Cryopreserved* cardiac and vascular tissue shall demonstrate maintenance of the temperature of the frozen tissue at required storage temperatures for the entire requisite time.

K1.220 Validation Procedures—Packaging and Freezing Protocols

(C, V) Individual *Processing* facilities shall establish and document validated packaging and freezing protocols.

(with amendments)

K1.200 Qualification, Verification, and Validation Requirements

Protocols shall be developed, implemented, and documented for the *Qualification*, *Verification*, or *Validation* of significant components of facilities, processes, equipment, reagents, labels, *Containers*, packaging materials, and electronic systems. Process validations shall be performed where the results of a process cannot be fully verified by subsequent inspection and test. *Validations shall be assessed when process changes are made and revalidation performed as indicated.* Determination of *the frequency and* which elements or items are to be qualified, verified, or validated shall be made by individuals responsible for *Quality Assurance* and regulatory compliance. Evaluation of parameters tested shall be performed and adequacy of the study to demonstrate necessary outcomes shall be determined.

K1.210 Validation of Shipping Containers

(C, V, *CT*)

Qualification studies of the transportation devices and methods for temporary storage ~~of *Cryopreserved* cardiac, and vascular tissue~~ shall demonstrate maintenance of the temperature *and appropriate characteristics* of the ~~frozen~~ tissue at required storage temperatures for the entire requisite time.

K1.220 Validation Procedures—Packaging and Freezing Protocols

(C, V, *CT*)

~~Individual *Processing* facilities shall establish and document validated~~ ~~p~~*P*ackaging and freezing protocols*, to meet pre-specified tissue characteristics, shall be established and documented.*

(as amended)

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K1.210 Validation of Shipping Containers

(C, V, CT)

Qualification studies of the transportation devices and methods for temporary storage shall demonstrate maintenance of the temperature and appropriate characteristics of the tissue at required storage temperatures for the entire requisite time.

K1.220 Validation Procedures—Packaging and Freezing Protocols

(C, V, CT)

Packaging and freezing protocols, to meet pre-specified tissue characteristics, shall be established and documented.

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