CHANGES TO AATB STANDARDS FOR TISSUE BANKING
14th Edition

SECTION D
AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY, COLLECTION, AND ACQUISITION

Current (14th Edition)
D6.000 STORAGE OF TISSUE

D6.100 Quarantine Areas
Quarantine tissue storage areas including *storage* areas within freezers, refrigerators or other *tissue storage* equipment, *shall* be physically separated and clearly labeled as "*quarantine*."

With Amendments
D6.000 STORAGE OF TISSUE

D6.100 Quarantine ~~Areas~~ *Controls*
~~*Quarantine tissue storage* areas including *storage* areas within freezers, refrigerators or other *tissue storage* equipment, *shall* be physically separated and clearly labeled as "*quarantine*."~~
Adequate controls must exist to prevent mix-ups, contamination, cross-contamination, and ensure tissue is identified as acceptable or unacceptable during all stages of recovery, receipt, storage, processing and distribution. If physical segregation is deemed unnecessary, justification must be established, and must include a risk assessment and use of a validated electronic system. Considerations for the risk assessment shall include:

1) *potential severity of impact if controls fail to prevent mix-up, contamination or cross-contamination;*
2) *probability of failure to occur;*
3) *likelihood of identifying a failure before it reaches a customer;*
4) *existing controls to prevent failure; and*
5) *back-up plan for failure of validated electronic system.*

If physical segregation is deemed necessary, segregated areas must be appropriately labeled.

As Amended
D6.000 STORAGE OF TISSUES

D6.100 Quarantine Controls
Adequate controls *must* exist to prevent mix-ups, contamination, *cross-contamination*, and ensure *tissue* is identified as acceptable or unacceptable during all stages of *recovery*, receipt, *storage*, *processing* and *distribution*. If physical segregation is deemed unnecessary, justification *must* be established, and *must* include a risk assessment and use of a *validated electronic system*. Considerations for the risk assessment *shall* include:

1) potential severity of impact if controls fail to prevent mix-up, contamination or *cross-contamination*;
2) probability of failure to occur;
3) likelihood of identifying a failure before it reaches a customer;
4) existing controls to prevent failure; and
5) back-up plan for failure of *validated electronic system*.

If physical segregation is deemed necessary, segregated areas *must* be appropriately labeled.

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