



TISSUE TRACKCORE™

AN MTF VALUE-ADDED SOLUTION

ARE YOU IN COMPLIANCE?

MTF and Tissue TrackCore provide a clear path to compliance that simplifies processes to barcode scanning and mouse clicks.

Tissue TrackCore keeps you in compliance with the following JCAHO requirements, which became effective on July 1, 2005.

JCAHO requirements met by Tissue TrackCore APPLICABLE TO HOSPITALS

Standard PC.17.10 - The organization uses standardized procedures to acquire, receive, store, and issue tissues.

Elements of Performance for PC.17.10 - The organization develops, maintains, and follows procedures to do the following:

- A 1. Assign responsibility for overseeing the tissue program throughout the organization including storage and issuance activity.
- B 3. Coordinate tissue ordering, receipt, storage, and issuance throughout the organization.
- C 4. Transport, handle, store, and use tissue according to the source facilities' or manufacturers' (for example, for synthetic tissue) written directions.
- C 5. Log in all incoming tissue.
- C 7. Maintain daily records to show that tissues were stored at the required temperatures.
- C 10. Verify at receipt that package integrity is met and transport temperature range was controlled and acceptable.

Standard PC.17.20 - The organization's record keeping permits the traceability of all tissues from the donor or source facility to all recipients or other final disposition.

Elements of Performance for PC.17.20

- A 1. The organization's records permit tracing of any tissue from the donor or source facility to all recipients or other final dispositions, including discarding of tissue.
- C 2. The organization's records track and identify materials used to prepare or process tissues and instructions used for preparation.
- A 3. The organization's records identify the following:
 - Identity of staff involved in preparing or issuing tissue
 - Identity of staff who accepts the tissue
 - Dates and times of the preceding activities
- A 4. The organization's records include documentation in the recipient's clinical record of tissue use, including documentation of the unique identifier of the tissue.
- C 5. The organization's records including storage temperatures and all superseded procedures, manuals, and publications are retained for a minimum of ten years or longer if required by state and/or federal laws.
- A 6. The organization's records document the source facility, the original numeric or alphanumeric donor and lot identification, all recipients or other final dispositions of each tissue, and expiration dates, and are retained for a minimum of ten years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest), or longer if required by state and/or federal laws.
- B 7. The organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities.

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JCAHO requirements met by Tissue TrackCore

APPLICABLE TO LABORATORIES

Transplant or Implant Tissue Storage and Issuance

Standard QC.5.300 - The organization uses standardized procedures to acquire, receive, store, and issue tissues.

Elements of Performance for QC.5.300 - The organization develops, maintains, and follows procedures to do the following:

- A 1. Assign responsibility for overseeing the tissue program throughout the organization, including storage and issuance activity.
- C 4. Transport, handle, store, and use tissue according to the source facilities' or manufacturers' (for example, for synthetic tissue) written directions.
- C 4-5. Log in all incoming tissue.
- C 10. Verify at receipt that package integrity is met and transport temperature range was controlled and acceptable.

Standard QC.5.310 - The organization's record keeping permits the traceability of all tissues from the donor or source facility to all recipients or other final disposition.

Elements of Performance for QC.5.310

- A 1. The organization's records permit tracing of any tissue from the donor or source facility to all recipients or other final dispositions, including discarding of tissue.
- C 2. The organization's records track and identify materials used to prepare or process tissues and instructions used for preparation.
- A 3. The organization's records identify the following:
 - Identity of staff involved in preparing or issuing tissue
 - Identity of staff who accepts the tissue
 - Dates and times of the preceding activities
- A 4. The organization's records include documentation in the recipient's clinical record of tissue use, including documentation of the unique identifier of the tissue.
- C 5. The organization's records including storage temperatures and all superseded procedures, manuals, and publications are retained for a minimum of ten years or longer if required by applicable state and/or federal laws.
- A 6. The organization's records document the source facility, the original numeric or alphanumeric donor and lot identification, all recipients or other final dispositions of each tissue, and expiration dates, and are retained for a minimum of ten years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest), or longer if required by state and/or federal laws.
- B 7. The organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities.

Standard QC.5.320 - The organization has a defined process to investigate adverse events to tissue or donor infections.

Elements of Performance for QC.5.320

- B 1. Procedures are in place to investigate recipient adverse events, including disease transmission or other complication(s), suspected of being directly related to tissue use.
- A 2. Cases of post-transplant infections or adverse events are promptly reported to the source facility.
- A 3. Tissue reported by the source facility as the cause of possible infection or tissue involved in an event that may have contaminated the product are sequestered.
- A 4. Recipients of tissue from donors who are subsequently found to have HIV, HTLV-I/II, viral hepatitis, or other infectious agents known to be transmissible by tissue, are identified and informed of infection risk.
- B 5. Procedures have been followed when adverse or suspected events have occurred.



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THE ALLOGRAFT LEADERSM

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