Tissue System Tracer

Requirement	Met	Not Met	Comments
Tissue Tracer			
Does the organization assign responsibility for overseeing the tissue program throughout the hospital including storage and issuance activity?			
Does the organization validate the source facilities that supply tissues and are they licensed by state agencies, and/or registered as a tissue establishment with the Food and Drug Administration?			
Does the organization coordinate tissue ordering, receipt, storage, and issuance throughout the hospital?			
Does the organization transport, handle, store, and use tissue according to the source facilities' or manufacturers' written directions?			
Does the organization log in all incoming tissue?			
Does the organization maintain continuous temperature monitoring for storage refrigerators and freezers?			
Does the organization maintain daily records to show that tissues were stored at the required temperatures?			
Does the organization's storage equipment have functional alarms and emergency backup?			
Does the organization comply with state and/or federal regulations when acting as a source facility that supplies tissues?			
Does the organization verify at receipt that package integrity is met and the transport temperature range was controlled and acceptable?			
Does the organization's records permit tracing of any tissue from the donor or source facility to all recipients or other final dispositions, including the discarding of tissue?			
Does the organization's records track and identify materials used to prepare or process tissues and instructions used for preparation?			
Does the organization's record identify the following: -Identify staff involved in preparing or issuing tissue? -Identify staff who accepts the tissue? -Dates and times of the preceding activities?			
Does the organization's records include documentation in the recipient's clinical record of tissue use, including documentation of the unique identifier of the tissue?			
Does the organization's records including storage temperatures, and all superseded procedures, manuals, and publications are retained for a minimum of ten years, or longer if required by state and/or federal laws?			
Does 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, or			

Applicable to the following Accreditation Programs: (X) Hospital (X) Critical Access Hospital ( ) Behavioral Health (X) Ambulatory Care ( ) Office Based Surgery ( ) Disease Specific Certification ( ) Staffing Certification

Requirement	Met	Not Met	Comments
longer if required by state and/or federal laws?			
Does 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?			
Are procedures in place to investigate recipient adverse events, including disease transmission or other complications, suspected of being directly related to tissue use?			
Are cases of post-transplant infections or adverse events promptly reported to the source facility?			
Are tissues reported by the source facility as the cause of possible infection or tissue involved in an event that may have contaminated the product sequestered?			
Are recipients of tissue from donors who 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?			
Have procedures been followed when adverse or suspected events have occurred?			