**Executive Summary:**

Several eye banks have been contacted by hospitals to provide written documentation of compliance with Joint Commission standards for their upcoming Accreditation inspections. Therefore EBAA undertook an extensive review of the 699-page 2012 Hospital Accreditation Standards from The Joint Commission. The result is this 16-page document that outlines the specific standards that relate to contractors (e.g., eye banks).

Each hospital will have their own policies and procedures for complying with the Joint Commission’s standards, and we encourage you to communicate with the hospitals you serve to understand their specific requirements. While we encourage you to become familiar with all of these standards, we would highlight the following areas for which you may be required to provide documentation:

- Eye banks may be asked to provide documentation of recovery staff orientation and training, competencies, certification, and performance evaluations to the hospitals in which they work.

- Recovery technicians may be asked to provide documentation of annual screening for Tuberculosis and documentation of required immunizations.

- The Transplant Safety (TS) Chapter discusses the hospital’s responsibilities for organ and tissue donation and procurement; storage and handling of tissue; identification and tracking of tissue; and investigation and reporting of adverse events. Eye banks may be required to share the validation of their shipping containers with the hospital.

Eye banks have reported that the requested documentation has been time-consuming, with very short turnaround times. Therefore we urge our members to initiate work in these areas now.

EBAA will be developing additional tools and resources to help our members prepare for such inquiries. Please watch for notices from us with more details. Banks that have been asked to provide such information are asked to contact Jennifer DeMatteo to share your experience, which you may be asked to share in an upcoming EEI.
The Accreditation Process (ACC) Chapter – Contracted Services

The Joint Commission evaluates an organization’s management and oversight of the quality of care, treatment, and services (for which there are Joint Commission standards) provided under contractual arrangements. The Joint Commission reserves the right to evaluate, as part of its survey, the care, treatment, and services provided by another organization or provider on behalf of the applicant organization. It may survey performance issues between the contracted organization and the applicant organization, regardless of the accreditation decision of the contracted organization. The Joint Commission also surveys care, treatment, and services provided on site under contract.

Key Glossary Terms:

Clinical Staff – Individuals such as employees, licensed independent practitioners, contractors, volunteers, or temporary agency personnel who provide or have provided clinical services to the organization’s patients, residents, or individuals served.

Qualifications – Knowledge, education, training, experience, competency, licensure, registration, or certification related to specific responsibilities.

Standards are statements that define the performance expectations and/or processes which must be in place for a hospital to provide safe, quality patient care.

Elements of Performance (EPs) are statements that detail the specific performance expectations that must be in place. EPs are scored and determine a hospital’s overall compliance with a standard.

Environment of Care (EC) Chapter

This chapter stresses the importance of managing risks in the environment, including those associated with safety and security, fire, hazardous materials and waste, medical equipment and utility systems. All people who work within the hospital, patients, and anyone else who enters the hospital environment have a role in minimizing risks.

Standard EC.02.01.01 – The hospital manages safety and security risks

    EP 1 – The hospital identifies safety and security risks associated with the environment of care that could affect patients, staff and other people coming to the hospital’s facilities.

    EP 7 – The hospital identifies individuals entering its facilities.

    EP 8 – The hospital controls access to and from areas it identifies as security sensitive.

This is why eye bank technicians are required to wear hospital ID badges and why certain areas have controlled access, such as operating rooms, morgue, etc.
Standard EC.02.02.01 – The hospital manages risks related to hazardous materials and waste.

Hospitals are required to keep a current inventory of hazardous materials and waste that it uses, stores, or generates, including permits, licenses, manifests, and material safety data sheets (MSDS). Eye banks may need to forward a copy of the MSDS for any supplies they may bring into the hospital. Eye bank staff should know and follow hospital procedures regarding personal protective equipment (PPE), hazardous materials or waste spills or exposures.

Standard EC.02.03.03 – The Hospital conducts fire drills.

EP 4 - Staff who work in buildings where patients are housed or treated participate in drills according to the hospital’s fire response plan.

Eye bank staff will need to know what their response should be when fire drills are conducted; when and how to sound alarms, how to contain smoke and fire, how to use a fire extinguisher, and how to evacuate to areas of refuge.

Standard EC.03.01.01 - Staff and licensed independent practitioners are familiar with their roles and responsibilities relative to the environment of care.

Everyone who works in the hospital is responsible for safety, and it is important for them to know how to identify and minimize risks, what actions to take when an incident occurs, and how to report it. Eye bank staff should be trained and knowledgeable about their safety role and they may be questioned by TJC during accreditation audits.

Emergency Management (EM) Chapter

Standard EM.02.02.05 – As part of its Emergency Operations Plan, the hospital prepares for how it will manage security and safety during an emergency.

The hospital determines the type of access and movement to be allowed by staff, patients, visitors, emergency volunteers, vendors, and other individuals when emergency measures are initiated. Eye bank staff may not be allowed access during emergencies when the hospital is in “lock-down” or may be asked to leave the premises during emergency situations.

Human Resources (HR) Chapter

Standard HR.01.02.01 - The hospital defines staff qualifications.

EP 1 – The hospital defines staff qualifications specific to their job responsibilities.
Standard HR.01.02.05 - The hospital verifies staff qualifications.

EP 1 – When law or regulation requires care providers to be currently licensed, certified, or registered to practice their professions, the hospital verifies these credentials with the primary source and documents this verification when a provider is hired and when his or her credentials are renewed.

EP 2 – When the hospital requires licensure, registration, or certification not required by law or regulation, the hospital both verifies these credentials and documents this verification at the time of hire and when credentials are renewed.

EP 3 – The hospital verifies and documents that the applicant has the education and experience required by the job responsibilities.

EP 4 – The hospital obtains a criminal background check on the applicant as required by law and regulation or hospital policy. Criminal background checks are documented.

EP 5 – Staff comply with applicable health screenings as required by law and regulation or hospital policy. Health screening compliance is documented.

EP 6 – The hospital uses the following information from HR.01.02.05, Elements of Performance 1-5, to make decisions about staff job responsibilities:
   • Required licensure, certification, or registration verification
   • Required credentials verification
   • Education and experience verification
   • Criminal background check
   • Applicable health screenings

EP 7 – Before providing care, treatment, and services, the hospital confirms that nonemployees who are brought into the hospital by a licensed independent practitioner to provide care, treatment, or services have the same qualifications and competencies required of employed individuals performing the same or similar services at the hospital.

Standard HR.01.04.01 – The hospital provides orientation to staff

EP 1 – The hospital determines the key safety content of orientation provided to staff

Note: Key safety content may include specific processes and procedures related to the provision of care, treatment, and services; the environment of care; and infection control.

EP 2 – The hospital orients its staff to the key safety content before staff provides care, treatment, and services. Completion of this orientation is documented.

Standard HR.01.05.03 – Staff participate in ongoing education and training.
Standard HR.01.06.01 – Staff are competent to perform their responsibilities.

EP 1 - The hospital defines the competencies it requires of its staff who provide patient care, treatment, or services.

EP 2 – The hospital uses assessment methods to determine the individual’s competence in the skills being assessed

**Note** – *Methods may include test taking, return demonstration, or the use of simulation.*

EP 3 – An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence.

EP 5 – Staff competence is initially assessed and documented as part of orientation.

EP 6 – Staff competence is assessed and documented once every three years, or more frequently as required by hospital policy or in accordance to law and regulation.

EP 15 – The hospital takes action when a staff member’s competence does not meet expectations.

Standard HR.01.07.01 – The hospital evaluates staff performance.

EP 1 – The hospital evaluates staff based on performance expectations that reflect their job responsibilities.

EP 2 – The hospital evaluates staff performance once every three years, or more frequently as required by hospital policy or in accordance to law and regulation. This evaluation is documented.

EP 3 – When a licensed independent practitioner brings a nonemployee individual into the hospital to provide care, treatment, and services, the hospital reviews the individual’s competencies and performance at the same frequency as individuals employed by the hospital.

**Note:** *This review can be accomplished either through the hospital’s regular process or with the licensed independent practitioner who brought staff into the hospital.*

Eye banks may be asked to provide documentation of recovery staff orientation and training, competencies, certification, and performance evaluations to the hospitals they work in.

Infection Prevention and Control (IC) Chapter

Standard IC.02.01.01 – The hospital implements its infection prevention and control plan
EP 1 – The hospital implements its infection prevention and control activities, including surveillance to minimize, reduce, or eliminate the risk of infection.

EP 2 – The hospital uses standard precautions, including the use of personal protective equipment, to reduce the risk of infection.

EP 3 – The hospital implements transmission-based precautions in response to the pathogens that are suspected or identified within the hospital’s service setting and community.


EP 6 – The hospital minimizes the risk of infection when storing or disposing of infectious waste.

EP 7 – The hospital implements its methods to communicate responsibilities for preventing and controlling infection to licensed independent practitioners, staff, visitors, patients, and families. Information for visitors, patients and families includes hand and respiratory hygiene practices.

EP 8 – The hospital reports infection surveillance, prevention, and control information to the appropriate staff within the hospital

EP 9 – The hospital reports infection surveillance, prevention, and control information to local, state, and federal public health authorities in accordance with law and regulation.

Everyone who works in the hospital has a role in prevention and control of infections. Standard and transmission-based precautions should be used and any outbreaks of infection within the hospital should be investigated. Eye bank staff should be knowledgeable about Standard/Universal Precautions, the use of PPE, handling of medical waste, and demonstrate good hand hygiene (handwashing or use of alcohol-based handrubs).

**Standard IC.02.02.01 – The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.**

*This standard addresses the proper cleaning, disinfection, sterilization, use and storage of medical equipment, devices, and supplies.*

**Standard IC.02.03.01 – The hospital works to prevent the transmission of infectious disease among patients, independent practitioners, and staff.**

EP 1 – The hospital makes screening for exposures and/or immunity to infectious disease available to licensed independent practitioners and staff who come in contact with infections in the workplace.

EP 2 – When licensed independent practitioners or staff have, or are suspected of having an infectious disease that puts others at risk, the hospital provides them with or refers them for assessment and potential testing, prophylaxis/treatment, or counseling.
EP 3 - When licensed independent practitioners or staff have been occupationally exposed to an infectious disease, the hospital provides them with or refers them for assessment and potential testing, prophylaxis/treatment, or counseling.

EP 4 – When patients have been exposed to an infectious disease, the hospital provides them with or refers them for assessment and potential testing, prophylaxis/treatment, or counseling.

Eye bank staff should be screened annually for TB and have documentation of immunizations or immunity to various infectious diseases (such as MMR, Varicella, Tdap, and Hepatitis B). Staff should be knowledgeable about what procedures to follow if they sustain a needlestick, laceration, or splash exposure.

Standard IC.02.04.01 – The hospital offers vaccination against influenza to licensed independent practitioners and staff.

EP 1 – The hospital establishes an annual influenza vaccination program that is offered to licensed independent practitioners and staff.

EP 2 – The hospital educates licensed independent practitioners and staff about, at a minimum, the influenza vaccine; non-influenza control and prevention measures; and the diagnosis, transmission, and impact of influenza.

EP 3 – The hospital provides influenza vaccination at sites accessible to licensed independent practitioners and staff.

EP 4 – The hospital annually evaluated vaccination rates and the reasons given for declining influenza vaccination.

EP 5 – The hospital takes steps to increase influenza vaccination rates.

Procurement staff may be asked to get annual influenza vaccinations or sign a declination form to show compliance with this standard. Some hospitals require non-vaccinated staff to wear a surgical mask during influenza season. Please note that influenza vaccination coverage among healthcare personnel is a proposed CMS measure for reporting in CY 2013 for CY 2016 payment determination.

Information Management (IM) Chapter

Standard IM.02.01.01 – The hospital protects the privacy of health information.

EP 1 – The hospital has a written policy addressing the privacy of health information.

EP 2 – The hospital implements its policy on the privacy of health information.

EP 3 – The hospital uses health information only for purposes permitted by law and regulation or as further limited by its policy on privacy.
EP 4 – The hospital discloses health information only as authorized by the patient or as otherwise consistent with law and regulation.


**Standard IM.02.01.03 – The hospital maintains the security and integrity of health information.**

EP 1 – The hospital has a written policy that addresses the security of health information, including access, use, and disclosure.

EP 2 – The hospital has a written policy addressing the integrity of health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.

EP 3 – The hospital has a written policy addressing the intentional destruction of health information.

EP 4 – The hospital has a written policy that defines when and by whom the removal of health information is permitted.

*Note: Removal refers to those actions that place health information outside the hospital’s control.*

EP 5 – The hospital protects against unauthorized access, use, and disclosure of health information.

EP 6 – The hospital protects health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.

EP 7 – The hospital controls the intentional destruction of health information.

EP 8 – The hospital monitors compliance with its policies on the security and integrity of health information.

**Leadership (LD) Chapter**

**Standard LD.03.06.01 – Those who work in the hospital are focused on improving safety and quality.**

EP 1 – Leaders design work processes to focus individuals on safety and quality issues.

EP 3 – Leaders provide for a sufficient number and mix of individuals to support safe, quality care, treatment, and services.
EP 4 – Those who work in the hospital are competent to complete their assigned responsibilities.

EP 5 – Those who work in the hospital adapt to changes in the environment.

EP 6 – Leaders evaluate the effectiveness of those who work in the hospital to promote safety and quality.

*This standard applies to all those who work in or for the hospital, including staff and licensed independent practitioners.*

**Standard LD.04.01.05 – The hospital effectively manages its programs, services, sites or departments.**

EP 1 – Leaders of the program, service, site or department oversee operations.

EP 4 – Staff are held accountable for their responsibilities.

*Leaders may delegate work to qualified staff, but the leaders are responsible for the care, treatment and services provided in their areas.*

**Standard LD.04.03.09 – Care, treatment, and services provided through contractual agreement are provided safely and effectively.**

EP 2 – The hospital describes, in writing, the nature and scope of services provided through contractual agreements.

EP 3 – Designated leaders approve contractual agreements

EP 4 – Leaders monitor contracted services by establishing expectations for the performance of the contracted services.

EP 5 – Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted services.

EP 6 – Leaders monitor contracted services by evaluating these services in relation to the hospital’s expectations.

EP 7 – Leaders take steps to improve contracted services that do not meet expectations.

EP 8 – When contractual agreements are renegotiated or terminated, the hospital maintains the continuity of patient care.

*This standard requires hospital leaders to oversee contracted services to make sure that patient care is provided safely and effectively. Monitoring of contracted services should reflect basic principles of risk reduction, safety, staff competence and performance improvement. See HR.01.06.01, EC.01.01.01,*
EC.02.01.01, and PI.01.01.01. Leaders have the same responsibility for oversight of contracted services outside the hospital’s expertise as they do for contracted services within their expertise.

Standard LD.04.04.05 – The hospital has an organization-wide, integrated patient safety program within its performance improvement activities.

EP 1 – The leaders implement a hospital-wide patient safety program.

EP 3 – The scope of the safety program includes the full range of safety issues, from potential or no-harm errors (sometimes referred to as near misses, close calls, or good catches) to hazardous conditions and sentinel events.

EP 4 – All departments, programs, and services within the hospital participate in the safety program.

National Patient Safety Goals (NPSG) Chapter

Standard NPSG. 01.01.01 – Use at least two patient identifiers when providing care, treatment, and services.

EP 1 – Use at least two patient identifiers when administering medications, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures. The patient’s room number or physical location is not used as an identifier.

Acceptable patient identifiers may be the individual’s name, an assigned identification number, or other person-specific identifier.

Standard NPSG.07.01.01 – Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health organization (WHO) hand hygiene guidelines.

EP 1 – Implement a program that follows categories 1A, 1B,  and 1C of either the current CDC or current WHO hand hygiene guidelines.

EP 2 – Set goals for improving compliance with hand hygiene guidelines.

EP 3 – Improve compliance with hand hygiene guidelines based on established goals.

An organization must assess compliance with hand hygiene guidelines through a comprehensive program that provides a hand hygiene policy, fosters a program of hand hygiene, and monitors compliance and provides feedback.
Record of Care, Treatment, and Services (RC) Chapter

Standard RC.01.05.01 – The hospital retains its medical records.

EP 1 – The retention time of the original or legally reproduced medical record is determined by its use and hospital policy, in accordance with law and regulation.

EP 2 – Original medical records are not released unless the hospital is responding to law and regulation.

Rights and Responsibilities of the Individual (RI) Chapter

Standard RI.01.01.01 – The hospital respects, protects, and promotes patient rights.

EP 4 – The hospital treats the patient in a dignified and respectful manner that supports his or her dignity.

EP 6 – The hospital respects the patient’s cultural and personal values, beliefs, and preferences.

EP 7 – The hospital respects the patient’s right to privacy.

Standard RI.01.05.01 – The hospital addresses patient decisions about care, treatment, and services received at the end of life.

EP 15 – The hospital documents the patient’s wishes concerning organ donation when he or she makes such wishes known to the hospital or when required by the hospital’s policy, in accordance with law and regulation.

EP 16 – The hospital honors the patient’s wishes concerning organ donation within the limits of the hospital’s capability and in accordance with law and regulation.

Transplant Safety (TS) Chapter

Standard TS.01.01 – The hospital with the medical staff’s participation, develops and implements written policies and procedures for donating and procuring organs and tissues.

EP 1 – The hospital has a written agreement with an organ procurement organization (OPO) and follows its rules and regulations.

EP 2 – The hospital’s written policies and procedures identify the OPO with which it is affiliated.
EP 3 – The hospital has a written agreement with at least one tissue bank and at least one eye bank to cooperate in retrieving, processing, preserving, storing, and distributing tissues and eyes.

**Note 1:** This process should not interfere with organ procurement.

**Note 2:** It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services, nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement, and is free to have an agreement with the tissue bank or eye bank of its choice.

EP 4 – The hospital works with the organ procurement organization (OPO) and tissue and eye banks to do the following:

- Review death records in order to improve identification of potential donors
- Maintain potential donors while the necessary testing and placement of potential donated organs, tissues, and eyes takes place in order to maximize the viability of donor organs for transplant.
- Educate staff about issues surrounding donation.
- Develop a written donation policy that addresses opportunities for asystolic recovery that is mutually agreed upon by the hospital, its medical staff, and the designated OPO. When the hospital and its medical staff agree not to provide for asystolic recovery and cannot achieve agreement with the designated OPO, the hospital documents its efforts to reach an agreement with its OPO, and the donation policy addresses the hospital’s justification for not providing asystolic recovery.

EP 5 – Staff education includes training in the use of discretion and sensitivity to the circumstances, beliefs, and desires of the families of potential organ, tissue, or eye donors.

EP 6 – The hospital develops, in collaboration with the designated organ procurement organization, written procedures for notifying the family of each potential donor about the option to donate or decline to donate organs, tissues, and eyes.

EP 7 – The individual designated by the hospital to notify the family regarding the option to donate or decline to donate organs, tissues, and eyes is an organ procurement representative, an organizational representative of a tissue or eye bank, or a designated requestor.

A designated requestor is an individual who has completed a course offered or approved by the organ procurement organization. This course is designed in conjunction with the tissue and eye bank community to provide a methodology for approaching potential families and requesting organ and tissue donation.

EP 8 – The individual designated by the hospital documents that the patient or family accepts or declines the opportunity for the patient to become an organ, tissue, or eye donor.
EP 9 – The hospital notifies the organ procurement organization (OPO) of patients who have died and of mechanically ventilated patients whose death is imminent, according to the following:

- Clinical triggers defined jointly with its medical staff and the designated OPO
- Within the time frames (ideally, within one hour of death for patients who have expired) jointly agreed on by the hospital and the designated OPO.
- For mechanically ventilated patients, prior to the withdrawal of life-sustaining therapies including medical or pharmacological support.

EP 10 – In Department of Defense hospitals, Veterans Affairs medical centers, and other federally administered health care agencies, notification to the organ procurement organization of patients who have died or whose death is imminent is done according to procedures approved by the respective agency.

EP 11 – The organ procurement organization determines medical suitability of organs for organ donation and, in the absence of alternative arrangements by the hospital, it determines the medical suitability of tissues and eyes for donation.

EP 12 – The hospital maintains records of potential organ, tissue, or eye donors whose names have been sent to the organ procurement organization and tissue and eye banks.

Standard TS.02.01.01 – The hospital complies with organ transplantation responsibilities.

EP 1 – The hospital performing organ transplants belongs to and abides by the rules of the Organ Procurement and Transplantation Network (OPTN) established under section 372 of the Public Health Service (PHS) Act.

EP 2 – If requested, the hospital provides all data related to organ transplant to the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry, or the hospital’s designated organ procurement organization (OPO), and when requested by the Office of the Secretary, directly to the U.S. Department of Health & Human Services.

Standard TS.03.01.01 – The hospital uses standardized procedures for managing tissue.

EP 1 – The hospital assigns responsibility to one or more individuals for overseeing the acquisition, receipt, storage, and issuances of tissues throughout the hospital.

EP 2 – The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuances of tissues.
EP 3 – The hospital confirms that tissue suppliers are registered with the U.S. Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.

EP 4 – The hospital coordinates its acquisition, receipt, storage, and issuances of tissues throughout the hospital.

EP 5 – The hospital follows the tissue suppliers’ or manufacturers’ written directions for transporting, handling, storing, and using tissue.

EP 6 – The hospital documents the receipt of all tissues.

EP 7 – The hospital verifies at the time of receipt that package integrity is met and transport temperature range was controlled and acceptable for tissues requiring a controlled environment. This verification is documented.

*Note 1:* If the distributor uses validated shipping containers, then the receiver may document that the shipping container was received undamaged and within the stated time frame.

EP 8 – The hospital maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures.

*Note 1:* Types of tissue storage include room temperature, refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen storage.

*Note 2:* Tissues requiring no greater control than “ambient temperature” (defined as the temperature of the immediate environment) for storage would not require temperature monitoring.

EP 9 – The hospital continuously monitors the temperatures of refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues.

*Note 1:* Continuous temperature recording is not required but may be available with some continuous temperature monitoring systems.

*Note 2:* For tissue stored at room temperature, continuous temperature monitoring is not required.

EP 10 – Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues at a controlled temperature have functional alarms and an emergency back-up plan.

*Note:* For tissue stored at room temperature, alarm systems are not required.

EP 11 – The hospital complies with state and/or federal regulations when it acts as a tissue supplier.
The U.S. Food and Drug Administration (FDA) considers the routine policy or practice of shipping tissue to another facility as distribution which requires FDA registration. Returning unused tissue back to the tissue supplier is not considered distribution and does not require FDA registration.

**Standard TS.03.02.01 – The hospital traces all tissues bi-directionally.**

EP 1 – The hospital’s record allow any tissue to be traced from the donor or tissue supplier to the recipient(s) or other final disposition, including discard, and from the recipient(s) or other final disposition back to the donor or tissue supplier.

EP 2 – The hospital identifies, in writing, the materials and related instructions used to prepare or process tissues.

EP 3 – The hospital documents the dates, times, and staff involved when tissue is accepted, prepared, and issued.

EP 4 – The hospital documents in the recipient’s medical record the tissue type and its unique identifier.

EP 5 – The hospital retains tissue records on storage temperature, outdated procedures, manuals, and publications for a minimum of 10 years. If required by state and/or federal laws, hospitals may have to retain tissue records longer than 10 years.

EP 6 – The hospital retains tissue records for a minimum of 10 years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest). If required by state and/or federal laws, hospitals may have to retain tissue records longer than 10 years. Records are kept on all of the following:

- The tissue supplier

  **Note:** For medical devices, the manufacturer may be the tissue supplier.

- The original numeric or alphanumeric donor and lot identification
- The name(s) of the recipient(s) or the final disposition of each tissue
- The expiration dates of all tissues.

EP 7 – The hospital completes and returns tissue usage information cards requested by the tissue supplier.
Standard TS.03.03.01 – The hospital investigates adverse events related to tissue use or donor infection.

EP 1 - The hospital has a written procedure to investigate tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue.

EP 2 – The hospital investigates tissue adverse events, including disease transmission or other complication that are suspected of being directly related to the use of tissue.

EP 3 – As soon as the hospital becomes aware of a post-transplant infection or other adverse event related to the use of tissue, it reports the infection or adverse event to the tissue supplier.

EP 4 – The hospital sequesters tissue whose integrity may have been compromised or that is reported by the tissue supplier as a suspected cause of infection.

EP 5 – The hospital identifies and informs tissue recipients of infection risk when donors are subsequently found to have human immunodeficiency virus (HIV), human T-lymphotropic virus–I/II (HTLV-I/II), viral hepatitis, or other infectious agents known to be transmitted through tissue.

According to the health Insurance Portability and Accountability Act (HIPAA) regulations regarding protected health information, “A covered entity may disclose protected health information for public health activities or other purposes to a person subject to the jurisdiction of the Food and Drug Administration (FDA) for the following purposes:

- To track products if the disclosure is made to a person required or directed by the FDA to track the product
- To enable product recalls, repairs or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems” (Refer to 45 CFR 164.512(b)(iii)(B) and (C).