

History Tracking Report: 2010 to 2009 Requirements

Accreditation Program: Laboratory 2010 Chapter: Transplant Safety

Standard TS.03.01.01

2010 Standard Text:

The organization uses standardized procedures for managing tissues.

2010 Standard: TS.03.01.01**2010 EP:** 1**2010 EP Text:**

The organization assigns responsibility to one or more individuals for overseeing the acquisition, receipt, storage, and issuance of tissues throughout the organization.

Note: Responsibility for this oversight involves coordinating efforts to provide standardized practices throughout the organization. An organization may have a centralized process (one department responsible for the ordering, receipt, storage, and issuance of tissue throughout an organization) or a decentralized process (multiple departments responsible for the ordering, receipt, storage, and issuance of tissue throughout the organization).

2010 Standard: TS.03.01.01**2010 EP:** 2**2010 EP Text:**

The organization develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of tissues. (See also TS.03.02.01, EP 5)

Standard QC.5.300

2009 Standard Text:

The laboratory uses standardized procedures to acquire, receive, store, and issue tissues.

2009 Standard: QC.5.300**2009 EP:** 1**2009 EP Text:****Revision Code:** Split

The laboratory develops, maintains, and follows procedures to do the following: Assign responsibility for overseeing the tissue program throughout the laboratory , including storage and issuance activity.

2009 Standard: QC.5.300**2009 EP:** 1**2009 EP Text:****Revision Code:** Split

The laboratory develops, maintains, and follows procedures to do the following: Assign responsibility for overseeing the tissue program throughout the laboratory , including storage and issuance activity.

2010 Standard: TS.03.01.01 **2010 EP:** 3
2010 EP Text:
 The organization 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.
 Note: This element of performance does not apply to autologous tissue- or cellular-based products considered tissue for the purposes of these standards but classified as medical devices by the FDA.
 Footnote: For U.S. Food and Drug Administration (FDA) registration, the supplier registration status may also be checked annually by using the FDA's online database: <http://www.fda.gov/cber/tissue/tissregdata.htm>.

2009 Standard: QC.5.300 **2009 EP:** 2
2009 EP Text: **Revision Code:** Retain
 The laboratory develops, maintains, and follows procedures to do the following: Validate that source facilities who supply tissues are licensed by state agencies, and/or registered as a tissue establishment with the Food and Drug Administration (FDA).

2010 Standard: TS.03.01.01 **2010 EP:** 4
2010 EP Text:
 The organization coordinates its acquisition, receipt, storage, and issuance of tissues throughout the organization.

2009 Standard: QC.5.300 **2009 EP:** 3
2009 EP Text: **Revision Code:** Retain
 The laboratory develops, maintains, and follows procedures to do the following: Coordinate tissue ordering, receipt, storage, and issuance throughout the laboratory.

2010 Standard: TS.03.01.01 **2010 EP:** 5
2010 EP Text:
 The organization follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue.

2009 Standard: QC.5.300 **2009 EP:** 4
2009 EP Text: **Revision Code:** Retain
 The laboratory develops, maintains, and follows procedures to do the following: Transport, handle, store, and use tissue according to the source facilities' or manufacturers' (for example, synthetic tissue) written directions.

2010 Standard: TS.03.01.01 **2010 EP:** 6
2010 EP Text:
 The organization documents the receipt of all tissues. (See also TS.03.02.01, EPs 3 and 6)

2009 Standard: QC.5.300 **2009 EP:** 5
2009 EP Text: **Revision Code:** Retain
 The laboratory develops, maintains, and follows procedures to do the following: Log in all incoming tissue.

2010 Standard: TS.03.01.01**2010 EP:** 7**2010 EP Text:**

The organization 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. (See also TS.03.02.01, EP 6)

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.

Note 2: Tissues requiring no greater control than “ambient temperature” (generally defined as the temperature of the immediate environment) for transport and storage would not need to have the temperature verified on receipt.

2010 Standard: TS.03.01.01**2010 EP:** 8**2010 EP Text:**

The organization maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures. (See also TS.03.02.01, EP 5)

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.

2010 Standard: TS.03.01.01**2010 EP:** 9**2010 EP Text:**

The organization continuously monitors the temperature 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.

2009 Standard: QC.5.300**2009 EP:** 10**2009 EP Text:****Revision Code:** Retain

The laboratory develops, maintains, and follows procedures to do the following: Verify at receipt that package integrity is met and transport temperature range was controlled and acceptable.

2009 Standard: QC.5.300**2009 EP:** 7**2009 EP Text:****Revision Code:** Retain

The laboratory develops, maintains, and follows procedures to do the following: Maintain daily records to show that tissues were stored at the required temperatures. Note: Main types of tissue storage used are: “ambient” or room temperature (for example: freeze-dried bone), refrigerated, frozen (for example: deep freezing colder than -40°C), and liquid nitrogen.

2009 Standard: QC.5.300**2009 EP:** 6**2009 EP Text:****Revision Code:** Retain

The laboratory develops, maintains, and follows procedures to do the following: Maintain continuous temperature monitoring for storage refrigerators and freezers.

2010 Standard: TS.03.01.01**2010 EP:** 10**2010 EP Text:**

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.

2010 Standard: TS.03.01.01**2010 EP:** 11**2010 EP Text:**

The organization complies with state and/or federal regulations when it acts as a tissue supplier.

Note: 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.

Footnote: Please refer to the following Web site:

<http://www.fda.gov/cber/tissue/tisreg.htm>.

2009 Standard: QC.5.300**2009 EP:** 8**2009 EP Text:****Revision Code:** Retain

The laboratory develops, maintains, and follows procedures to do the following: Storage equipment has functional alarms and emergency back-up.

2009 Standard: QC.5.300**2009 EP:** 9**2009 EP Text:****Revision Code:** Retain

The laboratory complies with state and/or federal regulations when acting as a source facility that supplies tissues.

Standard TS.03.02.01

2010 Standard Text:

The organization traces all tissues bi-directionally.

2010 Standard: TS.03.02.01

2010 EP: 1

2010 EP Text:

The organization's records 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.

2010 Standard: TS.03.02.01

2010 EP: 2

2010 EP Text:

The organization identifies, in writing, the materials and related instructions used to prepare or process tissues.

2010 Standard: TS.03.02.01

2010 EP: 3

2010 EP Text:

The organization documents the dates, times, and staff involved when tissue is accepted, prepared, and issued. (See also TS.03.01.01, EP 6)

2010 Standard: TS.03.02.01

2010 EP: 4

2010 EP Text:

The organization documents in the recipient's clinical record the tissue type and its unique identifier.

2010 Standard: TS.03.02.01

2010 EP: 5

2010 EP Text:

The organization retains tissue records on storage temperatures, outdated procedures, manuals, and publications for a minimum of 10 years. If required by state and/or federal laws, organizations may have to retain tissue records longer than 10 years. (See also TS.03.01.01, EPs 2 and 8)

Standard QC.5.310

2009 Standard Text:

The laboratory's record keeping permits bi-directional traceability of all tissues.

2009 Standard: QC.5.310

2009 EP: 1

2009 EP Text:

Revision Code: Retain

The laboratory's records permit tracing of any tissue from the donor or source facility to all recipients or other final dispositions, including discarding of tissue, and from the final disposition or recipient back to the donor or source facility.

2009 Standard: QC.5.310

2009 EP: 2

2009 EP Text:

Revision Code: Retain

The laboratory's records track and identify materials used to prepare or process tissues and instructions used for preparation.

2009 Standard: QC.5.310

2009 EP: 3

2009 EP Text:

Revision Code: Retain

The laboratory'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

2009 Standard: QC.5.310

2009 EP: 4

2009 EP Text:

Revision Code: Retain

The laboratory's records include documentation in the recipient's clinical record of tissue use, including documentation of the unique identifier of the tissue.

2009 Standard: QC.5.310

2009 EP: 5

2009 EP Text:

Revision Code: Retain

The laboratory'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.

2010 Standard: TS.03.02.01

2010 EP: 6

2010 EP Text:

The organization 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, organizations 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

(See also TS.03.01.01, EPs 6 and 7)

2010 Standard: TS.03.02.01

2010 EP: 7

2010 EP Text:

The organization completes and returns tissue usage information cards requested by the tissue supplier.

Footnote: 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))

2009 Standard: QC.5.310

2009 EP: 6

2009 EP Text:

Revision Code: Retain

The laboratory's records including the source facility, the original numeric or alphanumeric donor and lot identification, all recipients or other final dispositions of each tissue, 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.

2009 Standard: QC.5.310

2009 EP: 7

2009 EP Text:

Revision Code: Retain

The laboratory that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities. Note: Regarding protected health information, the HIPAA Privacy Rule provides at 45 CFR §164.512: "Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.... (h) Standard: uses and disclosures for cadaveric organ, eye or tissue donation purposes."

Standard TS.03.03.01

2010 Standard Text:

The organization investigates adverse events related to tissue use or donor infections.

2010 Standard: TS.03.03.01

2010 EP: 1

2010 EP Text:

The organization 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.

2010 Standard: TS.03.03.01

2010 EP: 2

2010 EP Text:

The organization investigates tissue adverse events, including disease transmission or other complications that are suspected of being directly related to the use of tissue. (See also IC.01.03.01, EP 3)

2010 Standard: TS.03.03.01

2010 EP: 3

2010 EP Text:

As soon as the organization 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.

2010 Standard: TS.03.03.01

2010 EP: 4

2010 EP Text:

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

2010 Standard: TS.03.03.01

2010 EP: 5

2010 EP Text:

The organization 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.

Standard QC.5.320

2009 Standard Text:

The organization has a defined system to investigate adverse reactions to tissue or donor infections.

2009 Standard: QC.5.320

2009 EP: 1

2009 EP Text:

Revision Code: Retain

Procedures are in place to investigate recipient adverse events, including disease transmission or other complication(s), suspected of being directly related to tissue use.

2009 Standard: QC.5.320

2009 EP: 5

2009 EP Text:

Revision Code: Retain

Procedures have been followed when adverse or suspected events have occurred.

2009 Standard: QC.5.320

2009 EP: 2

2009 EP Text:

Revision Code: Retain

Cases of post-transplant infections or adverse events are promptly reported to the source facility.

2009 Standard: QC.5.320

2009 EP: 3

2009 EP Text:

Revision Code: Retain

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.

2009 Standard: QC.5.320

2009 EP: 4

2009 EP Text:

Revision Code: Retain

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.