Guidelines for the Blood Transfusion Services

21.6: Tissue storage

http://www.transfusionguidelines.org/red-book/chapter-21/21-6-tissue-storage

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Refrigeration devices containing tissue shall be suitable for the use intended and procedures for monitoring such devices shall be validated so that tissues are maintained at the required storage temperature. Continuous monitoring and recording of temperature, together with suitable alarm systems, shall be employed on all storage refrigerators, freezers and liquid nitrogen tanks.

Every effort should be made to avoid cross-contamination of material stored in liquid nitrogen vessels. Material should be stored in the vapour phase of liquid nitrogen, not immersed in the liquid phase. Liquid nitrogen storage vessels should be designed to incorporate automatic filling systems to avoid transfer of filling hoses between vessels. Thermocouple temperature probes should be placed in storage vessels, with at least one probe located in the warmest position, as determined by temperature mapping.

Frozen and cryopreserved tissue should be double wrapped during storage. The seals and the material employed must be validated for their use at the designated storage temperature and the conditions of use, to demonstrate integrity of the packaging and labelling. This is crucially important for storage in liquid nitrogen vessels because of the high levels of accumulated microbial contaminants found within these vessels.

Quarantined and released tissue must be stored in physically segregated, clearly designated locations distinct from each other.

21.6.1: Tissue release

Prior to any tissue being cleared for issue, all relevant records including donor records, processing and storage records, and post-processing quality control test results must have been reviewed, approved and documented as acceptable by the individual(s) responsible according to the relevant local standard operating procedures. Responsibilities for setting policies for exceptional release of tissues reside with the authorised medical officer.

21.6.2: Tissue discard

There must be a documented policy for the discard of tissue unsuitable for clinical use. Records should include details of date and method of discard and reason for discard. Tissues for discard should be appropriately handled and disposed of in a manner compliant with local control of infection guidelines. Traceability records must be retained in the same way as for tissue used in human application.

21.6.3: Labelling and packaging of tissues for issue

Packaging must ensure integrity and maintain sterility of the contents of the final container and must also comply with current legislation.

The container must be labelled with the graft-specific identification (tissue type, batch and shipment number if applicable), expiry date and supplying Tissue Establishment, storage instructions and barcoded product description and instruction to see pack insert, as a minimum. In addition, more detailed information should be provided either on the label or package insert or both as follows:

- sizing information, if applicable
- antimicrobial processing procedure used (if applicable)
- preservative and any other additives used and their concentration (if applicable)
- special instructions (e.g. ‘Do not freeze’), thawing, dilution instructions
- presence of known sensitising substances
- type of antibiotics added during processing (if applicable)
- any other potential residual processing agent
- RhD type (where appropriate)
- a statement that the tissue was prepared from a donor who was non-reactive for current mandatory markers of infection, with the added rider that all biological tissue carries some risk of disease transmission
- storage instructions
- instructions for reconstitution (if appropriate)
- a warning on loss of package integrity
- instructions on dealing with queries, reporting adverse events/reactions and return or disposal of unsuitable or unused tissue
- a statement that tissue use must be authorised by a medical/dental practitioner
- a statement should accompany each tissue product stating that it may not be sterilised after leaving the Tissue Establishment
- a statement should accompany each package stipulating that each package is for single-patient use only
- if the package insert carries graft-specific information it must be labelled with the unique graft-specific identification code
- instructions to the user regarding the need for a documented system for the tracking and follow-up of the fate of the tissue
- when cells are known to be positive for a relevant infectious disease marker, it must be marked as a BIOLOGICAL HAZARD.

- in the case of autologous donations, the label must state ‘for autologous use only’
- in the case of directed donations, the label must identify the intended recipient.

21.6.4: External labelling of the shipping container

For transport, the primary container must be placed in a shipping container that must be labelled with at least the following information:

- identification of the originating Tissue Establishment, including an address and telephone number and a contact person in the event of problems
- identification of the organisation responsible for human application of destination, including address and telephone number and the person to be contacted to take delivery of the container
- a statement that the package contains human tissue/cells and HANDLE WITH CARE
- where living cells are required for the function of the graft, such as stem cells, gametes and embryos, the following must be added: ‘DO NOT IRRADIATE’
- recommended transport conditions (e.g. keep cold, in upright position etc)
- safety instructions/method of cooling (when applicable)
- The date and time that the product was prepared for transportation
- in the case of autologous donors, the following indication: ‘FOR AUTOLOGOUS USE ONLY’
- Specifications concerning storage conditions (such as DO NOT FREEZE).

21.6.5: Distribution

All reasonable efforts must be made to ensure that tissues are sent to qualified individuals/organisations who have accepted responsibility for their proper handling and use. A written agreement must be in place between the Tissue Establishment and the organisation ordering the tissue.

Where tissue is transported in a refrigerated or frozen condition, adequate safeguards should be taken to ensure that the tissue remains at the designated temperature. Monitoring of temperature should be undertaken wherever practicable but if not, the method should at least have been validated to show that appropriate temperatures are maintained. Consideration should be given to the potential for extremes of external temperature during transportation.

21.6.6: Relevant Material and Storage Licenses

The Human Tissue Act defines ‘Relevant Material’ as: “material, other than gametes, which consists of or includes human cells.” Tissue Establishments must determine for each type of graft they prepare, and the processing applied, whether or not a graft type is classified as Relevant Material. If so, the Tissue Establishment must hold a Human Tissue Authority storage licence if it holds the tissue for more than 48 hours. Tissue Establishments should inform hospitals if a graft is classified as Relevant Material, and ensure that the hospital has an appropriate storage licence if they intend to hold the graft for more than 48 hours.