

Date of publication: 9 November 2010

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 11 - 2010

Long-term storage of tissue products

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 7th Edition 2005

Addendum 2007 – Replacement Chapters 21 to 24 Human Tissues and Cells

The storage period for frozen, freeze-dried and cryopreserved tissue products has been extended from three years to five years. For tissues (eg heart valves) where there needs to be a wide range of sizes available this will remain at 10 years. This will require the following changes.

23.5 General guidelines for tissue processing

Table 23.1 Temperature/time relationships for banked tissues

Please delete

Long-term storage

Frozen tissue may be stored

1. At -20°C or lower for up to six months.
2. At -40°C or lower for up to three years. Temporary storage of frozen musculoskeletal tissue between -20°C and -40°C is limited to six months in total. Grafts stored at this temperature must then be transferred to -40°C or colder to give an expiry of up to a maximum of three years from donation.

Cryopreserved tissue should be stored

1. At -135°C or lower to claim a 10-year expiry for all grafts to maintain a reasonable inventory of size matched grafts (e.g. heart valves and menisci). Other cryopreserved tissues should have a three year expiry.
2. At higher temperatures up to -80°C; the same expiry pertains providing it has been validated.

Glycerol preserved tissue

1. Skin preserved in high concentration (>90%) glycerol may be stored at 0-10°C for up to two years.
2. Amnion preserved in low concentration (50%) glycerol may be stored below -40°C for up to two years.

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Replace with

Long-term storage *Frozen tissue* may be stored

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2. Amnion preserved in low concentration (50%) glycerol may be stored below -40°C for up to two years.

Freeze-dried tissue may be stored at ambient temperature for up to five years.

23.5 General guidelines for tissue processing

Please delete ***Freeze-drying***

Where tissues are freeze-dried, a sample of each type of tissue from each freeze-drying run must be analysed for residual moisture content which must be less than 5% (weight/ weight) of the dry weight of the graft to allow a three-year expiry at ambient temperature.

Replace with ***Freeze-drying***

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Please delete *Cryopreservation*

Cryopreserved tissue must be stored below -135°C to allow a 10-year expiry for size matched grafts and three-year expiry for other tissues. For storage at higher temperatures, validation must be performed to demonstrate that the required properties of the graft are maintained for the stated expiry.

Replace with *Cryopreservation*

Cryopreserved tissue must be stored below -135°C to allow a 10-year expiry for size matched grafts and five-year expiry for other tissues. For storage at higher temperatures, validation must be performed to demonstrate that the required properties of the graft are maintained for the stated expiry.

23.9 Additional guidelines for skeletal tissue retrieval and processing

Processing of skeletal tissue

Please delete The maximum storage period for frozen skeletal tissues depends upon the degree of prior processing and the storage temperature. Frozen bone should be stored at temperatures of -40°C or colder with the exception of short term storage (less than six months), which can be at -20°C or lower. Storage at -40°C or lower for up to three years is accepted current practice (see Table 23.1).

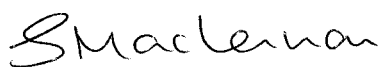
Replace with The maximum storage period for frozen skeletal tissues depends upon the degree of prior processing and the storage temperature. Frozen bone should be stored at temperatures of -40°C or colder with the exception of short term storage (less than six months), which can be at -20°C or lower. Storage at -40°C or lower for up to five years is accepted current practice (see Table 23.1).

23.6 Tissue Storage


Insert a new paragraph above the subheading '**Tissue Release**'


In the event of a substantial change to the JPAC Tissue Donor Selection Guidelines a Risk Assessment must be performed as to the impact on the current stock and whether a change to expiry or other actions were required to be carried out.

Further information: The supporting paper, JPAC 10-50 Long term storage of tissue products, leading to this Change Notification can be found in the Document Library/Supporting Papers of the JPAC website
<http://www.transfusionguidelines.org.uk/Index.aspx?Publication=DL&Section=12&pageid=7528>



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