

CONSULTATION SUBMISSION- TGA

Therapeutic Goods Order No:XX

Standards for banked human musculoskeletal tissue



**HUMAN TISSUE PROCESSING FACILITY,
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1. Section 4. Interpretations

Clean Collection Environment: The definition as given states the following:

Clean Collection Environment means an area or facility, such as a mortuary or equivalent facility with the following conditions:

- (a) Air-conditioning to regulate temperature, humidity and particulates required for maintenance of tissue quality; and..... ,

Retrieving tissue banks won't be able to comply, mortuary facilities in Australia have, as their core business the practice of performing autopsies on deceased, be they Coroner's cases or routine hospital post-mortems. No mortuaries maintain records detailing daily readings of temperature, humidity and particulates.

In the recently published 12th Edition of Standards for Tissue Banking the American Association of Tissue Banks¹ state the following:

"All tissue shall be recovered in an aseptic or clean fashion using standard surgical preparation with Sterile packs, instrumentation, and technique. Prior to recovery, the Recovery Site must be evaluated for suitability using pre-established criteria designed to control contamination and cross-contamination (see AATB Guidance Document N. 2). The Recovery Site evaluation must be documented."

The 2nd Edition of the Council of Europe Guide to Safety and Quality Assurance for Organs, Tissue and Cells² states:

"The ideal procurement environment should be an operating room, or another suitably validated location, depending on specific requirements for the tissue procured.

The following points should be considered for the tissue retrieval procedure :

Every effort should be made to minimise contamination during procurement;

Tissues may be removed using aseptic technique The general site of retrieval should be documented and area access should be restricted. All working surfaces used during retrieval should be disinfected."

Recommend:

Re-word the definition to read:

"Clean collection environment means an area or facility, such as a mortuary or equivalent facility with the following conditions:

- (a) control measures to limit access to qualified and operational persons;*
- (b) sufficient space to perform the tissue recovery and avoid cross contamination;*
- (c) work surfaces able to be adequately cleaned prior to commencing retrieval.*

Prior to commencing the retrieval the facility must be evaluated for suitability using pre-established criteria designed to ensure the control of contamination and cross-infection. Findings must be documented.

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Grade 8, Grade C and Grade D - definitions should be as per Annex 1 cGMP Manufacture of Medical devices

2. Section 7 General Requirements

(7) (b) (ii) Insitu carcinoma of the uterine cervix - Grade 3 is invasive.

Recommend:

Re-word to read:

(7) (b) all forms of malignancy except:

- i. *Basal cell carcinoma*
- ii. *Non-metastising primary brain tumours;*
- iii. *In istu carcinoma of the uterine cervix Grades 1 and 2*

(7) 3. (b) (iii) for surgical bone donors , squamous cell carcinoma of the skin which has been fully excised and not recurred for the last 5 years..

Recommend:

Delete - no difference as to whether a surgical or deceased donor.

(7) 4. (b) Donor Age Requirements for musculoskeletal tissue:

Age limits such as these are "set in concrete" and make no allowance for suitable donors of soft tissue who may be just outside the accepted age range. There needs to be an allowance for risk assessment to ensure those donors who are suitable, but may have an age range outside these parameters, to be accepted.

Recommend:

ORe-word as follows:

Deceased donors of osteochondral grafts and soft musculoskeletal tissue grafts should be between the ages of 15 t 55 years. Where a donor of these grafts is deemed to be acceptable formal documented risk assessment must be performed and included as an integral part of the donor records.

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(7) 11. Musculoskeletal tissue must be sealed within a sterile container and at least double packaged and sealed so as to :

New, novel technologies allow for the processing and packaging of musculoskeletal in non-sterile packaging prior to performance of "sterilisation". This statement doesn't allow for the introduction of such technologies.

Recommend:

DRe-word as follows:

Unless validated methods dictate otherwise Musculoskeletal tissue should be sealed within a sealed container and at least double packaged and sealed .

3. References:

- 1, American Association of Tissue Banks. Standards for Tissue Banking. 12th Edition. 2008 .
2. Council of Europe Publishing. Guide to safety and quality assurance for organs, tissues and cells. 2rd edition: 2004 version. 2004.