

Submission on TGA consultation: Proposed standards for human blood and blood components, human tissues and human cellular therapy products

Organisation: NSW Bone Bank

Thank you for providing your comments using the template below.

- Rows may be added or deleted as required. Tables may be left blank or deleted if no comments are to be made on other documents.
- 'Reference' indicates the specific section/ subsection/ paragraph where relevant, e.g. In the infectious disease Order, 8(1)(b) would be used to reference requirements for donor interview timeframe in Part 3, Section 8, Subsection (1), paragraph (b).
- 'Issue' invites a short statement to summarise the comment.
- 'Comments' may include a position including justification or an alternative position.
- Additional general comments are also invited on the impact of these standards, as indicated below each table.

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Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products

SUBMITTING ORGANISATION: NSW Bone Bank

Reference	Issue	Comment
9(1)	Aseptic blood collection	The blood collected for testing from cadaveric donors is used for serology and NA Testing. Any contaminants from non aseptic collection will only have the effect of possible false positive results (not false negatives). Any tissue bank that did not use aseptic techniques would only increase the risk that they would not be able to use the tissue for transplantation. There would not be an increased risk to tissue recipients. As there have been times where the NSW Bone Bank has had to use blood samples collected during the autopsy using non sterile receptacles when the donation has occurred post autopsy, could there be a clause in the tissue specific TGO that blood collection for testing cadaveric donors is not required to be aseptic.
11 (2) a and b	Tissue retrieval within 24 hrs of death	For a musculoskeletal tissue retrieval to be completed within 24 hrs of asystole will mean a dramatic reduction in the number of donors for the NSW Bone Bank. Currently the policy for the NSW Bone Bank is to have 'Knife to skin' (i.e. making the first incision) within 24 hours of asystole if the body was refrigerated within 12hours of death or within 15hours of asystole if the body was not refrigerated. Whilst keeping in mind that a full retrieval can take up to 10 hours (especially if the technicians are in training) but that there should also be a time limit we suggest that the statement be adjusted to 'that retrieval must commence within 24 hours of asystole if the body is refrigerated within 12 hours or commence within 15 hours of asystole if the body is not refrigerated and that all tissue must be retrieved within 32 hours of asystole'.

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What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

Any other concerns have been addressed in the submission made by the ATBF.

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Standards for human cardiovascular tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

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Standards for human musculoskeletal tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

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Standards for human ocular tissue

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

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Standards for human skin

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments:

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General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: _____

Reference	Issue	Comment

What is the perceived impact, if any, of implementing these requirements in your organisation?

Other general comments: