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

Organisation: Perth Bone & Tissue 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.

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

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: ***Perth Bone & Tissue Bank***

Reference	Issue	Comment
8 (4)	Typo	"…prior to donation ~~are~~ as set out in…"
Table 3	Requirement for Syphilis and HTLV-1/2 testing at donation for living donor that is retested at 180 days	Syphilis and HTLV-1/2 both have window periods. The alternative to perform these tests at 180 days should be allowed, provided the donated tissue is not handled prior to receipt of retest results.
Table 1 (h) & (i)	As this TGO has introduced criteria not previously required, *Not in accordance with the requirements of this Order* may exclude donors who received **tissues** from TGA licensed banks prior to June 2011. (e.g. NAT testing was not required prior to Jan 2009 so a potential donor who had cadaveric bone in 2006, would be excluded) Is this the intent?	Suggest substituting *Not in accordance with the requirements of this Order* with *Not obtained from a TGA approved Tissue Bank.* However organ recipients should always be excluded.
Table 1 (q)	Does not acknowledge the 6 months retest period for a living donor. Why are (iii) and (iv) not given an 'escape clause' similar to (v) in relation to the use of sterile single use needles?	A period of 6 months is required from the time of exposure to collecting blood for screening for HIV, HCV, HBV, or for …… Add *unless performed using sterile single use needles* to iii and iv
Table 1 (s)	Particular' requires definition. This is very open ended to auditor interpretation, making it difficult to state that any particular piece of tissue 'is in accordance with the requirements of this Order'.	1. Delete, or 2. Issue alerts for an epidemiological situation that is of concern.

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

Reference	Issue	Comment
9 (6)	In the following clause, how and who determines most appropriate? · *Serology test kits / methodology must be the most **appropriate** for the sample being tested **and*** · *either approved by TGA **or** performed in a TGA approved facility*	Is it correct that we can now use a non-TGA licensed lab for the mandatory screening, and confirmatory micro and virological provided the lab meets cGMP requirements 905 and 909? cGMP 905 requires a competent laboratory unless legislation requires otherwise. We have not found this requirement in the Act. Is this TGO the only relevant legislation for this requirement?
9 (9)	Does not address an archived sample being unsuitable for testing. In this event would tissue in process have to be rejected because the donor serum cannot be tested as per the new screening protocol?	Include 'where practicable and' after …*prior to the release of the product* 'where practicable, and'
10 (2) (a)	Physical assessment of living donor – what does this mean? As this stands, a patient undergoing hip replacement has to be physically assessed 'at the time of donation'. What is the intent of this? Certainly the donor is being assessed by the surgeon and anaesthetist but not for evidence of risk factors or suitability to donate. The surgeon and anaesthetist are not going to sign a record of assessment.	For a living donor, the MS Tissue standard should say it is not required or specify what is required.
10 (3)(a)i	*… the test must demonstrate that the samples tested are non-reactive.* Results other than non-reactive that are assessed as being clinically negative but the donors must be failed. Tests for living donors retested at 180 days may be clearly non-reactive, but under this clause they would be failed.	cGMP 911 and 912 allows for retesting. If the initial test results are *mildly reactive* and the retest results are *non-reactive* allow the donor to be accepted? i.e. make 'clinically negative' acceptable.

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

10 (2) (a) Physical examination of a living donor who is retested at 180 days will be an unnecessary use of limited resources and will realise no measurable advantage. What is the perceived advantage of this? Leaving this in because it is assumed that surgeons will undertake this is a falsehood. Furthermore, the auditors will have a very long list of requirements that demonstrate compliance.

Other general comments:

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:

Standards for human musculoskeletal tissue

SUBMITTING ORGANISATION: ***Perth Bone & Tissue Bank***

Reference	Issue	Comment
7 (1)	Are MS tissues included in the term *critical materials?* *Defining design and composition of human tissues will be problematic.*	In the definition for critical materials include 'does not included MS tissues'.
7 (4)	Does this clause make post irradiation sampling mandatory?	Provided the irradiation process has been validated and conducted to requirements post irradiation sampling should not be required.
7 (6) (c)	Is the intent of this clause to allow tissue with a positive micro test result to be released provided a sample tested post terminal bioburden reduction is negative?	The addition of 'These samples may be representative of pre and / or post bioburden reduced tissue' will avoid auditors interpreting that testing is required both pre and post terminal bioburden reduction for tissue with a negative pre bioburden reduction test result.
7 (8) Clause (b)	Requirement to establish storage conditions even though meeting TGO specified storage conditions. No date from which shelf life is measured. "Frozen and cryopreserved …" could be interpreted that a cryoprotectorant is required when tissues are frozen at less than minus 40°C.	The 'must be established' should apply where implementing conditions other than those stated. As this is about storage conditions it the commencement date should be specified as being from date of retrieval. 1. Substitute "or" for "and", or 2. Remove "cryopreserved"

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

Other general comments:

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:

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:

General requirements for the labelling of biologicals

SUBMITTING ORGANISATION: ***Perth Bone & Tissue Bank***

Reference	Issue	Comment
6 (3) (e)	Requirement that the date and time of collection is written on the jar in which the FH is contained. The omission by nurses to do this will result in tissue failures. This should not be critical especially as the time and date is written on accompanying paperwork.	Why is this critical
6 (5) *Label on the container* ***and*** *primary pack*	The requirement for a label on the *cover that immediately covers the goods* will have a significant negative impact. As the packaging supplied to hospitals for FH collection is obtained sterile (ARTG listed) from a third party, having the third party put these details onto the container (usually a plastic bag) is not practical. This requirement would prohibit the provision of non-irradiated and whole FHs and put an end to the non-processing FH collection banks.	Limit this requirement to the primary pack.

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

As stated above, the requirement for a label on the *cover that immediately covers the goods* will have a significant negative impact. This can only be achieved if the tissue is opened at the bank. Many FHs are supplied in the packaging in which they were placed at collection. It would no longer be possible to provide these FHs. A long history free of any incidents to support this requirement indicates that the measurable risk will result from enforcing this.

Other general comments: