

Point 4 “Interpretation”

- ***allogeneic*** means material for administration to an individual that is obtained, or derived, from a genetically different individual

XXXXXX Comment: This definition does not include provisions for identical twin, hence description should state “from an individual other than the recipient” in preference to “genetically different individual”.

- ***banked*** means maintenance, under appropriate controlled conditions, in an inventory, of a finished product that has been determined suitable for supply;

XXXXXX Comment: Donated bone in bone banks is quarantined under appropriate controlled conditions for over 6 months **prior** to being a finished product ie determined “suitable to supply”. Does this definition therefore mean that such bone will not be considered to be “Banked”? The term banked should include any tissue/cellular material retrieved for purpose of transplantation – whether or not it is cleared for use.

- ***bioburden*** means the quantity and characteristics of microorganisms present in the goods or to which the goods may be exposed in a manufacturing environment;

XXXXXX Comment: What is meant by “*the goods*”? Does this mean product or materials or both? Clarification is required.

- ***physical examination*** means a clinical based inspection of a living or deceased potential donor to determine suitability of theetc

XXXXXX Comment: should state “to identify risk factors” rather than “to determine suitability of the person to be a donor” as suitability implies further medical checks are not required.

Schedule 1

XXXXXX Comment: This table is not user friendly. Suggest reworking.

Schedule 2 Clause 1a

XXXXXX Comment: Schedule 1, table 1 –refers to “Autologous”. “Compliance with requirements set out in schedule 2” is “All requirements except 1b)”
For autologous tissue, 1a should also be an exclusion.

Schedule 2 clause 1b

XXXXXX Comment: This statement is very poorly structured and open to confusion.

Schedule 3 Clause 2

“face to face interview with the donor or guardian/next of kin”

XXXXXX comment: For living donors, it is not appropriate to conduct the medical & social history interview with a guardian/next of kin due to the personal nature of the lifestyle questions. The requirement should be to interview only the actual donor.

Schedule 3 Clause 2a

XXXXXX Comment:

- For living Femoral Head donors, the concept of obtaining medical/social history on the day of surgery (ie donation) is undesirable. Donor may feel under duress immediately prior to surgery, and may have been prescribed a sedative or been given anaesthetic premedication.

Submission from XXXXXX

TGO Standards for minimising disease transmission

- XXXXXX questions the requirement for face-to-face interviews to occur within 7 days prior to donation. This clause assumes patients are seen in the surgeon's rooms or a pre-admission clinic in the week prior to surgery, or that patients have time to schedule a visit to the tissue bank. The reality is that patients may have their pre operative visits up to a month prior to the date of surgery.
- Completion of a face-to-face interview 7 days post donation is no less comprehensive and provides no less a degree of safety than one conducted prior. The real risk inherent in this clause is that there will be fewer eligible donors because patients often do not have time prior to surgery to fit in this interview and patients are stressed and more likely to forget critical information. Post donation they do have the time for the interview. Allowing the interview post donation, provided a comprehensive documentation of verbal history has been undertaken prior to donation, should be acceptable.
- XXXXXX questions the need for "Face to face" interviews – Interviews for deceased donors within the coronial system in NSW/ACT may be conducted by telephone. Why is there to be a double standard if enforcing face to face interviews for living donors? Skilled interviewers can get all information required via telephone.

Schedule 3 Clause 2d

XXXXXX Comments: The XXXXXX questions the need for history to be confirmed in writing by the donor no more than 7 days prior to the donation. As in the dot point above, this seems a double standard in relation to deceased donor information which can be captured in a telephone interview. There would be no decrease in safety if the history was confirmed in the period after donation when tissue is in quarantine.

Schedule 3 clause 3

XXXXXX Comment: This clause reads poorly – as though tissue banks have the ability to predict death 7 days in advance. Suggest rewording to clarify intent.

Table 2a and 2c

XXXXXX Comment: No mention is made of body piercing using sterile single use equipment. There seems to be little justification in the requirement to exclude a donor who has had body piercing performed in the previous 6 months if it can be established that the piercing was made using sterile single use equipment, when compared with 2c, where a person who had a needle stick injury is only excluded if the injury was thought to be at high risk of carrying hep B etc. It is not clear why body piercing using sterile equipment is considered more of a risk than a needle stick injury, especially in light of "standard precautions" where all blood and bodily fluid is considered to be infectious.

Table 2t

XXXXXX Comment: Clarification is required re "Recipients of Allogeneic blood, blood components or blood products that do not meet the requirements of this order." Are tissue banks able to accept donors who have had ARCBS blood and blood products?
Does this clause mean that 12 months exclusion is required when the blood was sourced o/seas and no exclusion is required when the blood was sourced in Australia?

Schedule 4 clause 11

Submission from XXXXXX
TGO Standards for minimising disease transmission

XXXXXX Comment: It is requested that “possible and practicable” be defined in relation to the expectations of this clause.

Schedule 5 clause 1 and 1c

XXXXXX Comment: The stated requirement for “Physical Examination for every donor” should relate to cadaveric donors only. The requirement for physical examination is particular to cadaveric donors who are (obviously) not able to participate in a medical and social history interview per schedule 3 clause 2. Living donors should be excluded from the requirement for physical examination.

Additional Comments:

The XXXXXX (XXXXXX) participated in the Australian Tissue Biotherapeutics Forum (ATBF) workshop to discuss the ATBF response to the draft code and standards. The XXXXXX supports the ATBF submission to the TGA.