**TGA DRAFT TGO - STANDARD FOR BANKED HUMAN MUSCULOSKELETAL TISSUE**

**New Zealand Blood Service comments - February 2010**

| Clause | Comment |
|---|---|
| **Section 7**<br>General Requirements | |
| 3 (b) (iv)<br>for surgical bone donors, squamous cell carcinoma of the skin which has been fully excised and not recurred for the last 5 years. | Bone donors are frequently elderly and compliance with the requirement "not recurred for the last 5 years" would be difficult. Recommend changing the wording to "shows no evidence of disease" or "is in remission". |
| (9)<br>A biological that is non-irradiated (or any similar bioburden reduction process) banked musculoskeletal tissue must demonstrate no microbial growth when the representative samples or specimens for bioburden from tissues that were collected and processed in accordance with subsection 7(9)(a) and (b) or when additionally processed and sampled in accordance with subsection 7(9)(c), are tested.<br>(a) collected, processed and sampled for bioburden in a operating theatre of an accredited hospital; and<br>(b) maintained at 1°C to 10°C for less than 72 hours prior to freezing;<br>(c) thawed under specified conditions, and further processed in an environment that is at minimum equivalent to Grade B with a background environment which is equivalent to Grade C using aseptic technique, sampled for bioburden using a validated method and refrozen within 24 hours. | This entire clause is too complex and confusing and should be re-worded and simplified. |

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| 10 (a)<br>representative musculoskeletal tissue samples, referred to in subsection 7(10)(b) and (c), sampled prior to a bioburden reduction process, must be tested for bioburden to determine the total viable count to exclude tissue contaminated with specified microorganisms of clinical significance. Specifications for the tissue must include microorganisms that will result in rejection of the tissue. | Determination of total viable count should not be required. Qualitative methods should be acceptable as long there are specifications for the microorganisms that will result in rejection. Bones with non-pathogenic organisms are irradiated before issue making quantitation irrelevant. |
| 10 (d)<br>representative samples of musculoskeletal tissue subject to a terminal bioburden reduction process such as irradiation must demonstrate no microbial growth when tested | It should not be a requirement to retest for microbial growth after irradiation. This involves destructive testing of precious product. The irradiation process can be adequately controlled with the use of spore strips. |
| **Schedule 1** Labelling | |
| (2)<br>At release the final product label on the container and primary pack must include the following minimum information:<br>(a) unique identifying number/alphanumeric linked to donor number;<br>(b) type of tissue;<br>(c) tissue size in metric units for critical measurements e.g. struts, quantity of milled bone;<br>(d) name and address of the supplying tissue establishment;<br>(e) single patient use – symbol;<br>(f) instruction for opening to sterile field;<br>(g) expiry date;<br>(h) storage conditions;<br>(i) sterile (if applicable);<br>(j) antibiotics, if applicable;<br>(k) autologous use only, if applicable;<br>(l) “See package insert” | There should be the option of putting some requirements in the package insert, e.g. (d) for address and (f). |

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| (3)<br>Additional information must be supplied on issue with the released musculoskeletal tissue:<br>(b) tissue size(s) in metric units: millimetres (mm), centimetres (cm), or grams (gm), volumetric (cc), where relevant | Tissue size should go on label as it is variable so can't be defined in the package insert. |
| 3<br>(c) biohazard label and a statement including a warning that the biological could transmit infectious agents | Consistent with the current approach for blood components, it is reasonable to include a warning statement about transmission of infection. However, a Biohazard label should not be required in the package insert. Biohazard labels should be reserved for products with positive infectious disease testing results and should be applied to the product rather than in the insert. |
| 3<br>(g) name and address of the supplying facility; the name of a contact person, a contact phone number. Email and web addresses may also be included. | It should not be a requirement to include the name of a person. This would create the unnecessary expense of reprinting the package insert every time staff change. Phone number of the issuing Tissue Bank should be sufficient. |