TGA DRAFT TGO – STANDARD FOR BANKED HUMAN SKIN

New Zealand Blood Service comments - February 2010

Section & Clause	Comment
7 General Requirements	
(4) Acceptability criteria for minimum and maximum age of a donor, the body surface area and quality of the skin to be donated to produce a biological must be defined and documented by each manufacturer of skin.	It should not be necessary to specify criteria for age of donor, body surface area and skin quality. Council of Europe Guidelines specifically state "No age limit applies to skin donation. Acceptance criteria depend on an individual's size, skin condition and state of health." This would be covered by a donor assessment and the requirements in clause 3.
(5) Banked human skin must be collected from (b) a deceased donor as soon as possible after death and take place within 24 hours of death provided the body has been refrigerated (1°C to 10°C) within 12 hours of death.	Services not able to procure skin on a Sunday would lose valuable donors as they wouldn't be able to meet the 24hr requirement. CoE Guidelines allow more flexibility for services that are not able to procure skin 7 days a week. They allow the following: *"If the body has been refrigerated within 6 hours of death, procurement should start within 24 hours and not later than 48 hours after death."* NZBS supports this approach.
(6) The collected tissue must be sampled for bioburden determination, using a validated sampling technique, prior to being packaged within at least one moisture impermeable barrier using aseptic technique, maintained and transported at 1°C to 10°C. The maximum time that the skin remains at 1°C to 10°C before either processing or freezing must be no more than 72 hours	Quantitative determination of bioburden should not be required. Qualitative methods should be acceptable as long there are specifications for the microorganisms that will result in rejection.

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Schedule 1 Labelling	**Comment**
(2) The container and primary pack in which each unit of skin is packaged for release for transplant must be labelled with, at minimum, the following: (v) expiry date/manufacture date	Procurement date plus shelf life should be an acceptable alternative to expiry date.
(3) A package insert is to be supplied to the transplant unit with a released biological that is banked skin detailing at least the following information: (b) tissue size(s) in metric units: millimetres (mm), centimetres (cm) relevant to the dimensions	Tissue size should be on the label as specified in 2 (b). It isn't feasible to include it in the package insert as it will be different for each product.
(3) (c) biohazard label and a statement including a warning that the biological could transmit infectious agents	Consistent with the 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 (g) name and address of the suppling facility; the name of a contact person, a contact phone number. Email and web addresses may also be included.	"suppling" should read "supplying". 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.