

THERAPEUTIC GOODS ORDER NO. XX - *Standards for banked human musculoskeletal tissue.*

Reviewer: Stephanie Beeton [Hunter New England Bone Bank]	Date 12/2/10	
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Clause Ref.	Page Ref.	Comment	
7 (3)(b) (iv)	6	Is allowing SCC through consistent with industry practice?	
7 (3)(e)	6	In relation to osteomyelitis being declared cured...what does this entail?	
Schedule 1 (1)(a)(iii)	9	On the labelling of the packaging at retrieval, this can be difficult for non processing Tissue Banks who do reopen the 2 layers applied in theatre. Some of the information is on the documentation that the hospital sends with the bone, and forms part of the acceptance criteria into the Tissue Bank. This is not flexible enough.	
Schedule 1 (2)	9	Some of the requirements like tissue size and instructions to open onto the sterile field, that are expected on the product label are included in the supplied documentation, due to the size that would be required if it all had to go onto the product label. "See supplied documentation" would be useful on the label.	