Draft AUSTRALIAN CODE OF GOOD MANUFACTURING PRACTICE HUMAN BLOOD AND BLOOD COMPONENTS, HUMAN TISSUES AND HUMAN CELLULAR THERAPIES		
Reviewer: Stephanie Beeton [Hunter New England Bone Bank]	Date 11/2/10	

Clause Ref.	**Page Ref.**	**Comment**	
Introduction	2	Technical Standards files are not mentioned in any other document and not even in the Biologicals Framework implementation paper dated 4 December 2009. A standardized template would be beneficial to Tissue Banks.	
101	5	":….resources at all levels…" leaves interpretation open to the auditor, especially when the Tissue Bank is within the hospital and Area Health Service environment.	
103	5	Demonstrating efficacy for class 2 products is often not able to be done. Therefore, remove the word efficacy.	
104	5	Good Laboratory Practice is mentioned. Should there be reference to the TGA licensed laboratory that the TGA licensed Tissue Bank is using, that it is a requirement of the Laboratories licensing to adhere to this document, not the Tissue Bank directly?	
305	13	To avoid implementing expensive monitoring systems that the manufacturers of critical materials do not require, I suggest the following wording. "For critical materials, records should demonstrate that manufacturer stipulated storage conditions are being met'. (eg light, temperature.)	
306	13	Suggest, "Premises should be appropriate for the tissue products manufactured and be used so as to avoid errors or contamination."	
318	14	Remove the word "designed". Prefer the term "suitable for its intended purpose".	
328	15	…"there should be an alarm to indicate that a temp control system has failed" This is expected for storage containers like freezers, but for eskies sending tissue out to hospitals, this is very restrictive in	

		what type of monitoring device can be utilised by the Tissue Bank. An alarm does not need to be audible.	
700	22	Rather than stating…"for all contingencies…", use the word "reasonable contingencies".	
805	23	Instead of stating "statutory information", can the word "consent" be used. There will be instances where medical information can be gained post donation, and should not be ruled out.	
806	23	Please clarify "authorised person".	
819	25	References to Physical Examination of the donor prior to collection of Tissue does not work for living donors of surgical bone. What is the TGA expectation here? Is this simply the surgeon visually accepting the donor?	
917	30	This is a useful clause for autologous skull flap donors. However, the clause itself does not include tissue, it only mentions blood and cellular therapies.	