DRAFT TGO – Standards for banked human musculoskeletal tissue

PAGE	CLAUSE	COMMENTS
2	Interpretation	***aseptic technique*** is this a common definition? I am concerned over 'prevent' – could minimise be substituted? ***banked*** – so quarantined tissues are not banked?
3	Interpretation	The mortuaries in WA will not implement humidity and particulates regulation, nor conduct ongoing monitoring. The occasional cadaveric tissue retrieval is not their core business.
4	Interpretation	***tissue*** – interesting definition. This means that organs are tissue.
6	General Requirements (h)	*exposure to toxic substances ……* This is vague and too open to interpretation. How would it be determined if a toxic substance affects the tissue to be retrieved or how much is a toxic amount? I suggest either substituting with, or adding as an alternative, "had treatment for exposure to toxic substances" because if treatment has been required then the exposure is significant.
7	General Requirements (4) (b)	*Deceased donors of osteochondral……must be between the ages of 15 to 55 years.* The quality of 'soft' MS tissues is dependant on factors such as health and fitness levels of donors in conjunction with age. Hence suitable tissues can be found in donors older than 55 years. I suggest changing 'must' to 'should' and adding 'but may be retrieved from older donors provided their cartilage and menisci are in good condition'.
7	General Requirements (8)	Would applying antibiotic at retrieval be considered part of the preparation of the biological?
8	General Requirements (10) (d)	If the bioburden reduction process has been validated and the tissue sample test was negative prior to irradiation why would you test specimens again post irradiation? Why validate the irradiation process if you aren't going to trust it? How are positive test results for post irradiation specimens to be interpreted when indications are that these are testing laboratory mistakes? Allografts should not be wasted because the testing lab has contaminated their testing process.
8	General Requirements (12)	Does this include validation of shelf life? I don't believe there is any scientific literature to support 5 years. Apart from micro testing any other validation would be extremely difficult and questionable.
9	Schedule Labelling	(a) & (b) Unique identifier on the package and the paperwork is acceptable. But why should I have to throw out the donation because the hospital has forgotten to put one of the other pieces of information on either of these? The decision to accept or reject should be based on risk assessment. E.g. why reject because the jar does not say femoral head? The appearance of a femoral head is obvious.