TGA DRAFT TGO - STANDARD FOR MINIMISING INFECTIOUS DISEASE TRANSMISSION

New Zealand Blood Service comments – February 2010

Section & Clause	Comment
4 Interpretation	
Clause 2 Prion disease – risk of	The definition is very narrow and applies only to vCJD. Inclusion of Classical CJD measures should be considered.
7 General Requirements	
Schedule 4 (3) Blood sampling of a deceased donor must take place prior to cell or tissue collection and no later than 24 hours after death, if a pre-mortem blood sample is not available.	This requirement needs to match the allowed time frame for collection of skin. In our comments on the Standard for Banked Human Skin we have indicated a preference for a 48 hour time frame for skin collection as specified in Council of Europe Guidelines. The allowed time frame for sample collection would therefore also need to be 48 hours.
Schedule 4 (6) The test kits/methodologies used for the mandatory tests for screening must (a) be current technology; and (b) have regulatory approval for the intended use; and (c) be used in accordance with the approved methodology (i.e. in accordance with the test kit instructions); and (d) be validated for the purpose for which it is to be used. In the case of any changes to test methodology, these must also be formally validated and documented.	There are no infectious serology kits available in Australia or NZ that have been validated and approved by the regulators for cadaver testing. This is a significant issue for all tissue banks. Validation of this type of testing is not within the capabilities of tissue banks or blood services. If TGA requires validated test kits to be used they will need to work with the manufacturers of test kits to achieve this.
Schedule 4 (10) Dedicated samples of the serum from deceased or living donors taken at time of donation, and also the samples taken from live donors at 180 days post-donation, must be archived at or below minus 25°C unless the conditions of archive are validated at a different temperature (or as recommended by the test kit manufacturers) for the period from sample collection to a minimum of 2 years after the expiry date of the human blood and blood components, human tissues or human cellular therapies.	First line should state “serum/plasma” as samples may be either.

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Schedule 4 (11) Where screening protocols change during the life of a product in storage, where possible and practicable the donor's archived serum/plasma must be retested with the new screening test protocol prior to release of human blood and blood components, human tissue or human cellular therapy products.	This would potentially create a major logistical issue for large blood services and it is not clear under what circumstances it would be acceptable not to conduct retrospective testing. It may be clearer to say that any decisions about whether to conduct retrospective testing in these circumstances should be made in consultation with the regulator.
Schedule 4 (12) Documentation of the tests performed, test modifications, analyses and any anomalies required to be appended to the donor record in addition to the test results.	While this may be possible for small Tissue Banks that keep paper files on each individual donor, it is not achievable for large blood services with electronic blood management systems. While blood management systems will show the tests performed on each donation, most will not have the functionality to record against each donation any test modifications, analyses or anomalies. These things would normally be recorded elsewhere in the Quality System as deviations or similar and would be traceable back to the affected donations.

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Schedule 5 Table 4 Testing requirements for Blood Components	• Based on the risk profile in this country, HTLV1/2 testing is mandatory in NZ only on a blood donor's first donation. Mandating this test on every donation would have a significant impact on NZBS for a doubtful increase in product safety. • NZBS considers HBcAb testing to be an imprecise tool for reducing the risk of HBV transmission and does not support a mandatory requirement for HBcAb testing on all blood donations. In a study of 10,126 donations we found 8.9% to be reactive for this marker. This would be a significant loss of donations unless HBsAb were also introduced for these donations. 3.1% (314) of the donations in the study were HBcAb reactive with a HBsAb <100 IU/L – still a significant loss of donations. Only one of the 314 HBcAb positive donations was positive for HBV NAAT. NZBS is a medium endemnicity area for HBV which occurs primarily in childhood. HBV NAAT is a more specific indicator for transmissibility of HBV infection. NZBS introduced single donor HBV NAAT testing two years ago. Previously NZBS received between 0 and 2 reports of HBV transmissions per year, some of which were not confirmed. Since the introduction of NAAT there has been 1 report of possible HBV transmission which has been conclusively shown through lookback studies not to be transfusion transmiited. The following article supports NAAT over anti-HBc in high endemnicity countries: Allain J-P. Occult hepatitis B virus infection: implications in transfusion. Vox Sanguinis 2004;86:83-91
Schedule 5 Table 4 Footnote **c:** for a HPC-C unit, the maternal sample may be acceptable if reactive for HBcAb provided it satisfies the criteria given in 2 or if hepatitis B antigen negative when tested by DNA testing (NAAT)	Delete the word "antigen". NAAT is not antigen testing.

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Schedule 5 Clause 1(c) A physical examination must be conducted by a competent person to ascertain the suitability of a donor to donate cells or tissues and must take place	Living donors of blood and tissues such as bone should not be required to undergo physical examination. The only requirement should be an interview covering medical, travel and behavioural history. A physical examination would be an unnecessary and unwelcome intrusion for a blood donor and may deter many from donating.
Schedule 5 Clause 4 Examination for microbiological contamination of donor cell or tissue specimens must be performed using a validated method.	Should add “or be performed by a NATA accredited microbiology laboratory”.
Schedule 5 Clause 5 (5) For blood and blood components, human tissues and human cellular therapies required to be manufactured in a facility with an approved quality system, the bioburden of the cell or tissue specimens must be determined and the results recorded. Specifications for the human blood and blood components, human tissues or human cellular therapy must be in accordance with (a) those set in the respective product specific Orders, or (b) those set based on established and clinically acceptable numbers and types of organisms for the indication of use and should include (i) a limit for Total Viable Count (aerobic and anaerobic microorganisms); and (ii) absence of specified microorganisms of clinical significance.	The rationale for the requirement for quantitative determination of bioburden is not clear. While this may be applicable in the pharmaceutical industry it is not necessary nor practicable to implement for these products. We know of no other international standards that require it for these products, unless a claim of sterility is being made. Blood services typically undertake qualitative or, at most, semi-quantitative bacterial monitoring of blood components by testing a percentage of platelet products only. This clause is implying that bioburden must be determined on every product produced and it specifies the need for acceptance criteria, implying it is a release criterion for product. While it is standard practice to conduct microbial surveillance (not bioburden estimation) of all tissue products as a release criterion, it would be impossible to implement for blood because of the short time frames available for release of blood components. Typically, any biological products that are found to have positive microbial cultures are either discarded, irradiated or, in certain clinical situations, administered with antibiotic cover. Therefore the need for quantitation is of questionable value.