

**CODE OF GMP FOR HUMAN BLOOD AND BLOOD COMPONENTS, HUMAN  
TISSUES AND HUMAN CELLULAR THERAPIES  
CONSULTATION SUBMISSION**

**Barwon Health – Bone Bank**

**11/02/2010**

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**Barwon Health, The Geelong Hospital, Geelong Victoria 3220**

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## **Executive Summary**

The Barwon Health Bone Bank is a small human tissue bank located at the Geelong Hospital in Victoria. We exclusively bank femoral heads from live donors having total hip replacement surgery. We provide these as non-irradiated bone for use in orthopaedic procedures, primarily in the Geelong region and occasionally to Bendigo and other areas.

We support the need to provide a safe and reliable tissue service for the Australian public, but we seek to challenge the Therapeutic Goods Committee to review these new regulatory documents with a view to developing a more blood, tissue and cellular therapy specific regulatory vision, rather than a set of manufacturing principles.

We argue, in this submission, that the current model is conceptually and practically flawed and propose a paradigm shift to regulation of blood and tissue banking as a service and not a manufacturing industry. Quality and safety standards should be maintained through “Good *Tissue* Practice” rather than “Good *Manufacturing* Practice.” At minimum, we believe a terminology shift to more appropriate language would be beneficial to the regulation and licensing assessment of the sector.

For the benefit of the Australian public, blood, blood components, human tissue and cellular therapy services must be encouraged to expand and develop with emerging technology, in a safe and controlled manner, with a reasonable balance of justified oversight, but without excessive or undue regulatory burden.

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## **Introduction**

The Barwon Health – Bone Bank (formerly the Douglas Hocking Research Institute – Bone Bank) is a repository for Human Tissue, donated by public and private patients undergoing Total Hip Replacement (THR) surgery in the Geelong region. Although the Bone Bank is operated by Barwon Health – The Geelong Hospital, we rely on the cooperation and support of the local Orthopaedic Surgeons and the theatre staff of the two local private hospitals. The Orthopaedic surgeons and theatre staff are involved in the screening and consent of donors and collection of donations during Total Hip Replacement surgery. They receive no financial remuneration for their contributions to the bone bank, and there is no cost recovery for the institutions that they work for.

The Barwon Health – Bone Bank collects, stores and supplies fresh frozen (non-irradiated) femoral heads for bone graft in orthopaedic surgery. We aim to provide sufficient stock to meet the needs of our local surgeons and, when sufficient stock is available, we often supply bone to surgeons in Bendigo and other areas upon request. The bank is licensed to ‘manufacture’ this ‘product’ by the Therapeutic Goods Administration (TGA) under the current regulatory regime.

Our small bank is maintained by three core staff members who are employed in a part-time capacity for their bone bank duties. Quality control and medical director roles are fulfilled in a predominantly advisory capacity, which is funded directly by Barwon Health, as the approved ‘cost recovery’ rebate currently allowed through section B of the Prosthesis List is not sufficient to meet these costs.

We are one of only 2 or 3 small banks in the country who struggle to routinely supply this non-irradiated ‘product,’ which our local orthopaedic surgeons prefer over the irradiated alternatives produced by other, mostly larger, bone banks.

The Banks Review<sup>1</sup> discusses the need to reduce the “regulatory creep” that results in unintended and unnecessary, “pervasive effects” on small business. “Regulatory creep” in the human tissue sector gravely jeopardises the future of small, localised banks such as ours. We fear that “regulatory creep” will undoubtedly remove our valued, non irradiated tissue resource from the healthcare system. This is not because of any failure of our bank or the precious tissue we supply, which has been in common medical use for many decades, but because the banks that supply these tissue items will become non-viable under the regulatory and ‘cost recovery’ rebate systems. Obviously, this would be an unintended and unnecessary consequence of the “Therapeutic Goods Act.”<sup>2</sup>

Unfortunately, the current post release ‘cost recovery’ system does not effectively compensate or ensure the long term survival of any tissue bank and “regulatory creep” increases the burden on the tissue sector. Our own recent experience with the requirements for microbiological contamination testing stands as an example of the restrictive consequence of a regulatory burden that potentially threatens the survival of the entire sector.

Our contracted service laboratory ceased providing a TGA licensed microbiological contamination service to us in 2008. The Australian Code of Good Manufacturing Practice for Human Blood and Tissues<sup>3</sup> mandates that this testing be performed in a TGA licensed facility,

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however, there is no other licensed facility in Victoria that is prepared to meet the regulatory requirements for introducing and validating the culture methods required for our sample types. It simply is not cost effective, particularly considering the relatively small number of samples to be cultured for us annually. Our microbiological samples could be reliably cultured using similar culture methods, within a couple of hours of collection, at a local pathology service, but the mandate for TGA licensed facilities has required us, at significant additional cost, to transport microbiological specimens from Geelong to Sydney, overnight, to a TGA licensed microbiology laboratory. The samples are ultimately cultured up to 24 hours after collection.

Even under validated transport conditions, the prolonged, interstate transport time clearly cannot enhance our sample or tissue “quality” in any way, yet has served to double our upfront costs. This is an inevitable consequence of the high regulatory burden that has been applied to the sector. There are currently very few microbiology testing laboratories prepared to undertake the onerous process of TGA licensure and it has been our recent experience that many of those that are not directly linked to a blood or tissue service are questioning the cost implications and rational for continuing to provide licensed services.

The additional impacts of this single regulatory requirement illustrate some examples of the very real financial consequences that threaten the existence of our tissue bank service:

- Although the significant additional cost of transport and the higher service fees for the testing were incurred in mid 2008, we were unable to recover these additional costs until our application for a rebate increase on Part B of the Prosthesis List was approved in February 2009 (Please note that that our approved rebate is at a lower rate than was justified in our application).

Consequently, our budget was stretched for more than 6 months, with additional costs incurred for transport and no guarantee that our rebate increase would be approved. This left our public hospital to absorb the additional costs while we waited for the February 2009 List. The alternative would be to close the bank for collections until the additional cost recovery could be guaranteed. Fortunately for orthopaedic patients in Geelong, our hospital’s Chief Executive Officer elected to support the bank financially rather than lose 6 months worth of potential donations.

- If not for the 180 day donor retesting requirement for live donors, which delays the release of tissue until follow-up serology screening is completed, we would never be able to recoup the additional cost of any tissue released before the February 2009 Prosthesis List was published. Although regulatory and ‘cost recovery’ issues are separate, one cannot be considered without consideration to the implications of the other. The impact of regulatory requirements on the financial viability of tissue banking in this country must be considered by the Therapeutic Goods Committee in the review of these draft documents.

There is no opportunity to recover the cost of discarded or non-conforming product, yet significant cost is still incurred.

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- The change control for this issue alone took more than 6 months for our part-time staff to complete to a standard that will satisfy the regulatory requirements of the TGA. The biggest issues were firstly, finding an appropriately licensed facility that was willing to take our work, then negotiating and validating a transport method to safely deliver the specimens interstate within defined time and temperature limits.
- In the transition period between service contracts, 10% of our donations (and consequently our income) for 2008 was lost, due to an inability to have the specimens cultured. This income loss and 6 months of staff time, diverted from regular duties, will never be recovered or compensated under the current rebate scheme. Thus leaving our local public hospital to absorb the cost.
- To meet transport service requirements for overnight delivery, our specimens must be dispatched by 15:00 hours each day. This prevents collection from surgical cases scheduled in the afternoon. As a result, our collection rate in 2009 has been decimated by 40% as compared to 2008. Therefore, on top of the staff time loss for 2008, our ability to generate income to support the service has also been reduced by 40%.

This is just one of the regulatory factors that have contributed a doubling in our Prosthesis List approved rebate from \$1,080 to \$2,113 on the February 2009 list. The cost of our service, to both public and private healthcare, has increased 5 fold since the introduction of regulation in 1996. Yet we still test, package, store and supply our bone donations in much the same way and there have been no adverse clinical outcomes reported from cases involving tissue from our bank in that time. In fact, our *“Audit of the Douglas Hocking Research Institute bone bank: ten years of non-irradiated bone graft”*<sup>4</sup> published in 2009, documents that the incidence of deep infection in procedures using our non-irradiated bone, was no greater than the incidence of deep infection for all local joint replacement surgery.

Orthopaedic surgeons, theatre staff, and the healthcare services they work for, receive no compensation for the costs that they incur through their support of the bone bank. Our quality control and medical advisors are likewise unfunded. The true cost of providing human tissue for transplant is not nearly met by the ‘cost recovery’ model, but by the goodwill of healthcare providers who can ill afford the additional expense and individuals who choose to contribute their skills for the greater good of the community.

In this introduction, we have attempted to give the Therapeutic Good Committee an insight into the real implications of the regulatory burden on this, mostly publicly funded, sector. Giving particular focus to the struggle of banks to provide quality tissue items for the community, within the constraints of a ‘not-for-profit,’ ‘cost recovery’ financial system.

We appreciate that the role of the Therapeutic Goods Committee and the Blood and Tissue reference group does not involve the financial considerations of the blood and tissue sector, however, one cannot be considered without the implications to the other. We implore the committee to carefully judge the implications of the additional regulatory requirements that are proposed in these draft documents and to weigh the conundrum of maintaining quality with the reality of continuing to provide a human tissue service.

If the impact of more stringent regulatory standards ultimately reduces our ability to provide tissue services, then it is not the best outcome for the healthcare of Australian citizens?

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## **General Comments**

The introduction of this new draft of the code represents an opportunity to reconsider some of the manufacturing concepts used in relation to the provision of Blood and Blood components, Human tissues and cellular therapies.

We believe there is a fundamental legislative flaw in defining human tissue items as products. The use of terms such as ‘product’ and ‘manufacture’ consequently lock the human tissue banking sector into a regulatory paradigm developed for manufacturers of inanimate objects and pharmaceuticals. These regulations were never established with the complexities and unique properties of human tissue items or the potential of emerging cellular therapies in mind. Human tissue and cellular therapies do not fit well within the manufacturing framework. We have expressed this view in the current round of government reviews into areas that affect tissue banking and Health Technology Assessment<sup>5</sup>. We see this as a timely opportunity to reassess the definitions and regulation of human tissue items.

The greatest obstacle facing human tissue products in the current regulatory model is that they are not considered in their own context. They are consolidated within an existing system, designed for manufacture of pharmaceuticals and devices, a regulatory system in which they simply do not fit, nor belong. Human tissue items, by their very nature, are as unique and variable as the donor from which they come.

Human tissue ‘products’ are regulated as ‘manufactured’ medical devices, which they clearly are not. Many of the manufacturing principles simply don’t apply to something that is procured from a living being, rather than manufactured from defined and controllable raw materials. The simple fact is that human tissue items are neither ‘manufactured,’ nor are they ‘products’.

Our fear is that the spectre of this manufacturing style of regulation and “regulatory creep” will have negative implications in the future for organ transplant activities and will also stifle the development of cellular therapies from the research lab to clinical application in our “not-for-profit,” “cost recovery” legislated service industry.

If tissue and cellular therapies are to develop and proliferate in this country, then we feel there needs to be a reconsideration of the current regulatory model. The American Association of Tissue Banks in the United States has developed a Code of Good ‘Tissue’ Practice to apply to human tissue banking and presumably cellular therapies. If the principles are based on the provision of a tissue service, then this would seem to be a more enlightened approach to the regulation of human tissue and cellular therapies.

We recommend a brave leap to the use of more appropriate terminology and a refreshed code and standards that reflect the realities and unique nature of the provision of human blood and blood components, human tissues and cellular therapies.

Firstly, it is our view that the provision of human blood and blood components, human tissues and cellular therapies is a ‘service’ industry and not a ‘manufacturing’ industry. We collect altruistic ‘donations’ and ‘process’, not ‘manufacture,’ these as a ‘not-for-profit’ service to provide a therapeutic benefit.

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We would like to recommend that the Therapeutic Goods Committee consider a change in the terminology of the code from “products” to “human blood and tissue items” and from “manufacture” to more appropriate term such as “processing” or “preparation”, where relevant.

As any additional requirements in this new draft of the code have significant implications for smaller banks such as us, we urge the Therapeutic Goods Committee to identify the additional requirements and to consider the “real” added quality value versus the potential additional cost of implementation. We hope the committee understands the fragility of the altruistic tissue services and appreciates that additional regulatory requirements directly increase the cost of providing human blood and tissue items, which will ultimately increase the cost of healthcare.

### **Specific Comments**

<b>Clause</b>	<b>Page</b>	<b>Comment</b>
		<b>Section 1 QUALITY MANAGEMENT</b>
103	5	We are concerned with the implications of the inclusion of the word ‘efficacy’ in this clause. Because of their biological source and use, it is difficult to both define and measure the efficacy of many human tissue items, particularly femoral heads in our case. Our bank releases whole femoral heads, which may be utilised by surgeons for a number of different types of procedures. The bone may be cut or shaped to fill a bone deficit in a trauma procedure. It may be milled and mixed with cement in the revision of an artificial joint replacement or repair of a fracture malunion or even utilised in the immobilisation of a deformed or injured joint.
104	5	The First dot point makes reference to Good Laboratory Practice. Is this to be interpreted as the OECD principles of Good Laboratory Practice? If so, it is not included in the references. Will auditors be auditing for compliance with the requirements of the OECD principles of Good Laboratory Practice also? If so, this is a new specific requirement in this draft code and we would request clarification of this?

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104	5	Dot point 8. We believe the words “ <b>and subsequently handled</b> ” should be removed. This suggests a requirement to ensure tissue product quality is maintained in post distribution handling. (i.e. handling by the utilising surgeon/hospital.) This will be interpreted by manufacturing assessors to mean that the tissue bank is responsible for post distribution storage and handling of tissue. This falls outside the scope of tissue ‘manufacturing’ (or supply of human tissue items) and represents an unreasonable and unmanageable expectation. Other than ensuring safe transport of the tissue to its destination and providing handling and storage instruction, human tissue banks cannot be expected to be responsible for maintaining tissue, post release, when end users are outside the control and scope of the bank.
106	6	This clause makes specific reference to a ‘quality unit’. We suggest that thought be given to rewording this clause and any other that refers to a ‘quality unit’ or ‘quality department.’ The reality is that we, like most other small tissue banks, do not have more than one individual responsible for quality and this situation must be allowed for.
113	7	This is a new specific requirement that could represent an additional level of regulatory burden, particularly on smaller banks such as ourselves. We currently review most of the cited points at regular quality meetings or as part of internal audits. If this requirement is intended as additional to internal audits/self inspections, then it could represent significant additional work, especially for smaller banks with only a part-time quality role.
115	7	This is also a new specific requirement that could represent an additional level of regulatory burden. Again, if this is intended as additional to internal audits/self inspections, then it could represent significant additional work, especially for smaller banks with only part-time management.
		<b>Section 2 PERSONNEL AND TRAINING</b>
201	9	It is difficult to find personnel with the necessary qualifications and practical experience in this specialised field, making it difficult for smaller, specialised banks to comply with this clause. Some scope must be allowed for new staff if services are to continue.

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Clause	Page	Comment
205	9	As above, it is difficult to find personnel with the necessary qualifications and practical experience in this specialised field. One of the realities in the human tissue sector is that it is especially difficult to find personnel with <b>'practical experience, at management level'</b> in the field to replace an outgoing quality or production nominee? Scope must be allowed for suitable experience in other disciplines. We would also like to see 'quality management' added to the bracketed list of qualification examples.
		<b>Section 3 PREMISES AND EQUIPMENT</b>
		<b>General Comment:</b> In this section and throughout the document, use of the terms 'premises' and 'facilities' are often interchanged. We believe that the terms should be defined for the purpose of the code and used in a consistent manner, especially because most tissue banks are part of much larger institutions with shared facilities and premises.
300 and 301	12	The inclusion of the word 'designed', in these and other clauses, concerns us because many facilities, such as our own, were not originally designed specifically for their current use. We believe that any move to require redesign or design assessments in the sector, represents an additional unnecessary regulatory burden. It should be sufficient that premises are suitable, adapted and maintained appropriately for their intended use. Additionally, the requirements of human tissue collection would not have been specified in the design of tissue collection sites such as mortuaries and operating theatres. Any requirement for justification or design assessment of these areas will undoubtedly pose a significant challenge for the sector, with no measurable improvement to the quality of tissue collected.
302	12	We suggest careful consideration with regard to the intent of the phrase <b>"...to afford maximum protection"</b> with regard to entry of insects or other animals. "Maximum protection" against insect entry could be interpreted to require extreme measures such as vacuum sealing of wall cavities and requiring air-lock entry to processing areas.



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305	13	We are concerned that this clause, as written, will be interpreted to require ranges to be set for lighting, humidity, air quality and ventilation even when these factors will not adversely affect our tissue donations, which are sealed at collection in an operating theatre and never opened until after release. Validation and monitoring of conditions that are not critical to the tissue should not be required.
306	13	Again, we are concerned with the use of the term “specifically designed” in relation to premises. Is this term really necessary? Not all tissue banks have specifically designed premises and what about future advances and emerging technologies? The term ‘mix-up’ also seems simplistic. If this clause is necessary, then we suggest a change to <b>“Premises should be appropriate for the tissue item processed and they should be used so as to avoid the risk of errors or contamination.”</b>
317	14	<b>“Product storage facilities should not be used for any other purpose.”</b> Please define and standardise the use of the terms facility and premises. As written, this statement can be interpreted to mean that labelling, preparation of documentation or packaging for dispatch cannot be performed in the same building or institution as product is stored. If the intent of the statement is in regard to storage equipment then it should be stated as such. We see no reason why other activities cannot be performed in the same room as secured tissue storage freezers are housed.
318	14	We are concerned with the use of the word “designed” here too. Tissue banks are not in the business of equipment design. Prefer the term <b>“suitable for its intended purpose”</b> as stated in the current code.
319	14	Although the principle of this section refers to formal qualification of premises, facilities and equipment which is critical to the control of processing, we would like to see this particular clause specifically restricted to equipment <b>“which is critical to the control of manufacture”</b> or processing, as in the current code. We are concerned that this clause, if read in isolation as currently written, could be interpreted to require IQ and OQ for any equipment at all, including photocopiers and fax machines, etc.

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321	14	Again, we are unhappy with the use of the word “designed” here. Tissue banks are not in the business of equipment “design”. We would prefer a reference to consideration of cleaning requirements in the selection process for equipment.
327	15	This clause should also be restricted as critical to processing.
328	15	This clause needs to specifically exclude transport of tissue that is released for transplant. It would be an unnecessary and unmanageable burden on the sector to require recording and review of temperature data for every tissue released. Validated transport container and controlled conditions should be sufficient for released tissue.

		<b>Section 6 SUBCONTRACTING</b>
		We are concerned that this section has been incorrectly titled as the use of the terms subcontracting and subcontractor would likely be intended to mean contracting and contractor. Please review the use of this terminology. Additionally, we feel that it should not be necessary to establish contracts or service agreements with various departments of ones own organisation.
		<b>Section 7 COMPLAINTS AND RECALLS</b>

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Clause	Page	Comment
702	22	<p>The introduction of this new draft of the code represents an opportunity to consider some of the manufacturing concepts and how they are used in relation to the provision of Blood and Blood components, Human tissues and Cellular therapies. The recall concept is a good example of another of these misused concepts that should be reconsidered and improved to better represent the issues in our sector.</p> <p>With the possible exception of blood and blood component products, other human tissue items are collected, processed and most importantly released on an individual basis for a particular use in an individual procedure for an individual patient. Most often, they remain in the banks control until they are shipped, no more than one day prior to the scheduled procedure. The manufacturing concept of recall of product from the mass market place is not a general consideration for the tissue sector. The structure of this section should reflect this reality of the tissue sector and not be aligned with a manufacturing concept for the sake of convenience.</p> <p>If a quality issue came to light after a tissue has been released and implanted, the terminology should reflect the reality that the tissue would not be 'recalled', but that the surgeon and recipient should be alerted to the issue and any potential hazard with a 'Tissue Hazard Alert' or similarly defined process. Because there are risks to be considered with intervention, it is unlikely that a 'recalled' tissue would ever be removed from a recipient and returned.</p> <p>Corrective action regarding any quality issue posing a risk to tissue which has been released from quarantine, but not yet dispatched from the tissue bank, or for any in-house materials or equipment would be enforced within the bank and not require a 'recall', as such, from the market place.</p> <p>Our bank has experienced conflicting information regarding the requirements for 'recall' of tissue that was not yet released from our quarantine stock in recent years. We would be happy to share the details of this experience with the reviewers of this submission if further information is requested.</p> <p>We would like to encourage the reviewers to recommend a more tissue specific approach to the principles of this section with a provision for 'Hazard Alert' and follow-up that reflects the reality of the sector using tissue appropriate language.</p>

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<b>Section 8 COLLECTION AND PROCESSING</b>		
806	23	This clause requires the definition of an acceptable timeframes for donor assessment, yet the accompanying draft Therapeutic Goods Order entitled <i>Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies</i> , Schedule 3 (2), specifically mandates timeframes. Suggest either removing the requirement from this clause, as the TGO makes it redundant, or make reference to the TGO requirement.
815	24	With due respect to the intent of this clause and it's relevance for sites of multiple collection, such as blood collection centres, the clause is less relevant and difficult to control for tissue donation from individual donors. It is not possible to impose control of the organisation of collection areas for our tissue collections and for many other tissue collection instances. Our donations are collected as part of an individual surgical procedure. Our bank and the TGA have no specific jurisdiction over medical procedures, including how a surgeon chooses to best organise the operating theatre to perform surgery on a patient. We are limited in the requirements we can stipulate in this area and we require the cooperation and good will of professional medical staff to make live donor tissue donation possible. Such a specific requirement will be difficult to comply with and the risk of a labelling or records error in an individual procedure is minimal. We suggest a review of the wording of this clause.

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818	25	<p>The inclusion of the specific statement, “<b>Equipment used should be sterile.</b>” will undoubtedly impose a manufacturing compliance expectation, by auditors, that banks take action to control or audit the instrument preparation practices of the operating theatres and sterilisation units of every accredited hospital where tissue donations are collected. This will undoubtedly impose significant additional burden and expense on the sector to investigate practices that are already accredited and audited through alternative methods. The demonstration of appropriate accreditation to perform surgery at any hospital should be sufficient.</p> <p>Although there is no specific implication for our bank in relation to retrieval for cellular therapies and the word ‘should’ is used in this clause, we caution the reviewers of this submission to consider the implications for emerging cellular therapies, that could conceivably require specific collection methods, containers, media or matrixes that may be rendered inactive by true sterilisation processes.</p> <p>With regard to these implications, we suggest careful consideration of the wording of this clause.</p>
821	25	<p>As written, this clause excludes the production of commonly pooled items such as blood components for platelet preparation, pooled plasma for fractionation and the practice of pooling milled bone.</p> <p>Additionally, it would have implications preventing some possible cellular therapies (e.g. Stem cells that are grown on a feeder layer of fibroblasts or any cells grown on a tissue derived intracellular matrix, provided by another donor, such as skin.)</p> <p>We suggest use of a phrase such as “<b>to prevent unintended contact or cross contamination</b>” to allow for intended or required mixing of donor tissue.</p>
825	26	<p>“Sterilisation” should be replaced with “bioburden reduction” or another example.</p>
830	26	<p>We don’t believe that the code should define the type of sterilisation indicator (Radiation-sensitive colour indicators) that should be used, even if it is currently the most common or appropriate. It potentially restricts the use of improved technology if it becomes available.</p>

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Clause	Page	Comment
		<b>Section 10 COMPUTERS</b>
		The addition of this specific section creates additional requirements and regulatory burden on the sector
1000	31	The principle of this section should specifically limit the scope and application of the clauses to computer systems that effect steps in tissue processing. To apply this section to general e-mail, data and document systems, for instance, would create an unnecessary additional burden, particularly when a paper based permanent record is available. For example, as a small bank, we maintain all records on paper, but enter donor and recipient details on a computerised database for the purpose of statistical analysis and quick reference. All permanent records are maintained in hardcopy format and the database is not utilised as a processing tool or reference for the purpose of tissue release. Applying this section of the code to such a system would create an unnecessary burden with no net quality benefit.
1014	33	<b>“Stored data should be checked for accessibility, durability and accuracy.”</b> This clause potentially creates a very burdensome requirement. How often should accessibility be checked for archived records? How long data must be maintained? Indefinitely? Systems and software become outdated and newer versions aren’t always completely back compatible. Is this necessary if paper records exist as the primary permanent record?
1016	33	Our bank is part of a larger hospital and public health network. Does this clause interpret the Computer services department of our hospital network as an outside agency? If so, we object to the regulatory burden of establishing and maintaining service specific agreements between departments of one organisation.

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Thank-you for the opportunity to make this submission. Further information or confidential examples can be obtained by contacting us directly.

<p><b>Gavin Van Der Meer</b> BSc. Production Scientist, Barwon Health - Bone Bank Laboratory Manger, Barwon Biomedical Research Barwon Health The Geelong Hospital PO Box 281 Geelong, Victoria 3220</p> <p>gavinv@barwonhealth.org.au Ph: (03) 5226 7047 Fax: (03) 5260 3129</p>	<p><b>Assoc. Prof. Mark Kirkland</b> MBBS, PhD, FRCPA Medical Director, Barwon Health - Bone Bank Laboratory Director, Barwon Biomedical Research Barwon Health The Geelong Hospital PO Box 281 Geelong, Victoria 3220</p> <p>markkl@barwonhealth.org.au Ph: (03) 5226 7549 Fax: (03) 5260 3129</p>
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1. *“Rethinking Regulation – Report of the Taskforce on Reducing Regulatory Burdens on Business, January 2006”* (the Banks Review)
2. *Therapeutic Goods Act, 1989*
3. *Australian Code of Good Manufacturing Practice - Human Blood and Tissues, August 2000.*
4. *“Audit of the Douglas Hocking Research Institute bone bank: ten years of non-irradiated bone graft”* [Love D, Pritchard M, Burgess T, Van Der Meer G, Page R, Williams S. ANZ J Surg. 2009 Jan-Feb;79\(1-2\):55-61.](#)
5. *Review of Health Technology Assessment in Australia* (the HTA Review)