Site visit inspection report on compliance with HTA minimum standards

Chapel Allerton Hospital

HTA licensing number 22505

Licensed for the

- **procurement, testing, storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**

25 – 29 June 2012

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Chapel Allerton Hospital (the establishment) was found to have met all HTA standards.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Paragraph 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone Marrow	**E**		**E**		**E**		
Cord blood	**E**				**E**		
Ovarian tissue				**E**			
Bone				**E**			
Cornea				**E**			
Amniotic membrane				**E**			
Heart valves				**E**			

Iliac vessels				**E**	**E**		

Background to the establishment and description of inspection activities undertaken

Chapel Allerton Hospital (hub) is one of four hospital sites where licensable activity takes place. The Leeds General Infirmary, Seacroft Hospital and St James's University Hospital are all satellite sites covered by the licence. All licensed premises are part of the Leeds Teaching Hospitals NHS Trust, which is the Corporate Licence Holder.

Although licensed for procurement, testing, storage and distribution, at Chapel Allerton Hospital there is currently one licensable activity taking place. Bone and occasionally other tissues such as tendons are purchased from another licensed establishment and are stored until allogeneic end use, during orthopaedic surgery.

Chondrocytes were previously procured under the licence. These were sent to another establishment for processing under the authority of a service level agreement (SLA) and cultured cells returned to the establishment for autologous end use. There has been no chondrocyte-related activity in the last year and currently, following changes made to some procedures by the processing company, documentation relating to this procedure is being updated. Once the establishment's documentation has been updated, chondrocyte procurement may take place in the future.

At the Leeds General Infirmary iliac vessels are stored for use in paediatric liver transplants. Iliac vessels are received by the establishment with the donor liver and may be used in transplantation surgery. Any remaining vessels are stored by the establishment following the surgery for use in the same organ recipient should they be needed in further transplant related surgeries. Unsused iliac vessels are stored for possible use in other transplant surgeries.

On rare occasions, the establishment distributes iliac vessels which were not needed during transplant surgery and remained sealed in their original packaging to other centres, in emergencies, for use in transplant surgery. Should this distribution of vessels occur, the establishment has developed an end user form which contains details of the iliac vessels being transferred. The form also informs the receiving centre of its responsibility to maintain traceability data for 30 years following use or disposal of the vessels and its responsibility to report serious adverse event or adverse reactions (SAEARs) to the DI.

In addition to iliac vessel storage, paediatric bone marrow is procured for autologous and allogeneic (related sibling donor) use. Peripheral blood stem cells (PBSCs) are also procured, however, this is undertaken by another licensed establishment under an SLA and is therefore not taking place under the establishment's licence. Bone marrow that has been procured is distributed by the establishment to the other licensed establishment under an SLA where it is processed and stored until being requested back by the establishment for end use. Mandatory testing of donors is undertaken by the establishment, with the testing being carried out at Leeds General Infirmary. Additional mandatory testing is also undertaken by the processing and storage establishment.

Finally, at Leeds General Infirmary, storage of heart valves for use in cardiac surgery takes place. Heart valves are purchased from other licensed establishments (heart valve banks) and are stored by the establishment until allogeneic end use.

At St James's University Hospital storage of amniotic membrane and corneal tissue is undertaken. Tissue is purchased from another licensed establishment and is stored at the establishment until end use in ophthalmic surgery. Again this activity is covered by an SLA which defines each establishment's responsibilities.

Adult iliac vessels are also stored at St James's University Hospital. As with the paediatric service, iliac vessels are received by the establishment with the donor liver and may be used in transplantation surgery. Any remaining vessels are stored by the establishment following the surgery for use in the same organ recipient should they be needed in further transplant related surgeries. Again, unused iliac vessels may be used in other transplant surgeries or transferred to other transplant centres in emergencies and the same end user form as the paediatric service is used.

Additionally at St James's University Hospital, adult bone marrow is procured for antilogous and allogeneic (related sibling donor) use. PBSCs are also procured and in the same way as the paediatric cells, this is done under an SLA with another licensed establishment. Again, as with the paediatric service, bone marrow is processed under the authority of an SLA with another licensed establishment which process and store cells until returning them to the establishment upon request for end use.

At Seacroft Hospital, ovarian tissue which may be implanted back into the donor in the future, is being stored under the establishment's licence. The storage of ovarian tissue is the only licensable activity taking place at Seacroft Hospital.

The establishment has been licensed by the Human Tissue Authority since 2008 and this routine inspection was the third site visit. The timetable for the site visit was developed in consideration of the original desk-based assessment of the establishment's licence application, the establishment's recent compliance self-assessment, previous inspection reports and pre-inspection discussions with the DI. During the inspection, a visual inspection of the premises, review of the establishment's documentation and interviews with relevant staff were undertaken.

Traceability audits were undertaken in each area of activity across the establishment's licences. These audits included a review of records held in tissue register books, which are maintained for bone and other orthopaedic tissue, corneas and amniotic membranes, heart valves and both adult and paediatric iliac vessels. In these areas tissue details were also reviewed in selected sets of patient case notes. In both adult and paediatric haematology, records of bone marrow procurement, transplant and PBSC transplant were reviewed in the patient notes. At Seacroft hospital, ovarian tissue logs were reviewed during the visual inspection of the storage vessel.

The review of the tissue register for the paediatric iliac vessels showed that details of which tissue was allocated to a particular transplant patient were recorded. It could not, however, be determined whether the tissue had been used in that patient, or whether it had been stored and disposed of. This issue was resolved prior to the inspection with the introduction of a tissue traceability sheet filed in the patient notes. Although this new system had not been used in paediatric transplant surgery at the time of the inspection, two examples of the new system were reviewed in an audit of adult patient case notes.

Traceability data for bone marrow and PBSCs being used in adult transplants was recorded in patient case notes, however, there was variation between documents being used to provide traceability of cells. Although it was possible to trace cells from donor to recipient via the patient case notes, advice has been given to the DI below regarding a more consistent approach to the completion of records in patient case notes.

In summary, the traceability audits highlighted no anomalies and showed that tissue being used in patient treatment at the establishment is traceable from donor to recipient.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in

accordance with the requirements of the legislation.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practices. Advice has been separately listed below to reflect the advice given to specific areas of activity taking place under the licence.

No.	Standard	Advice
Ophthalmic tissue – St James's University Hospital		
1.	GQ6(b) & GQ6(c)	Traceability details for corneal and amniotic membrane tissues used in ophthalmic surgery are recorded in the establishment's tissue register. During the audit of patient case notes, records of corneal tissue used in surgery were found, however, no details of amniotic membrane used in surgery were found. To facilitate traceability the DI is advised to develop and implement a system to record tissue identifier details for the amniotic membrane used during surgery within the patient case notes. The DI may wish to implement a tissue tracking sheet which can be filed in the patient notes similar to the ones used for tracking heart valves and iliac vessels.
Haematology - St James's University Hospital (adult), Leeds General Infirmary (paediatric)		
2.	C1(e)	During the audit of patient notes for patients who had undergone PBSC procurement and transplant, there were cases where copies of the consent forms covering the donor testing, cell storage and discard of cells were not found. The procurement of PBSCs is taking place under the authority of an SLA with another licensed establishment also seeking consent prior to procurement. The DI is advised to request that copies of these consent forms are filed within the patient case notes, so that clear records of consent for the procurement of cells are maintained and are available for easy reference.
3.	GQ5(b) & GQ5(d)	During the audit of patient case notes for a patient who had undergone PBSC procurement for an allogeneic transplant, testing for anti Hepatitis B core antigen testing by the establishment had not been performed within 30 days of the cell harvest as required by the Directions 003/2010. Anti Hepatitis B core antigen is one of the mandatory markers required to be tested in all donors. The patient was tested by the establishment for this marker outside of the 30 day requirement. PBSC procurement is undertaken under the authority of an SLA with another licensed establishment which also performs mandatory serological testing in accordance with the requirements of Directions 003/2010. Results of these tests however are not always included within patient case notes. The audit of other patient case notes demonstrated that anti Hepatitis B core antigen testing is routinely performed by the establishment and results were present in bone marrow donor case notes reviewed. The DI is advised to develop a system to ensure that serological testing of all donors for all mandatory markers is carried out in accordance with the

		requirements of Directions 003/2010. The DI is additionally advised to request copies of mandatory serological testing results performed by the other licensed establishment that undertakes PBSC procurement, so that they may be filed in the patient case notes.
4.	GQ6(a), GQ6(b) & GQ6(c)	Although traceability of cells from donor to recipient was demonstrated in all sets of patient case notes reviewed, different documents were used in each case to provide traceability information. For example, in one case final analysis records from the cell harvest were used to locate the unique cell identifier; in another set of notes the unique identifier was found by reviewing the cell return request form. From the review of patient case notes it was evident that the establishment does not have a standardised approach to the completion of records relating to the harvest, processing and transplant of cells within the patient case notes. The DI is advised to develop a system to standardise which documents relating to the cell harvest and transplant should be completed within the patient case notes. These may include but are not limited to: consent forms, donor testing results, cell harvest records, analysis records from processed cells, cell return request forms, transport and delivery documents and cell transplant records.
5.	PFE3(a)	Additive free heparin used during the procurement of bone marrow is currently stored in the establishment's oncology theatre suite. Although the theatre's environment is maintained at a defined temperature, there is no temperature monitoring of the area where the heparin is stored. The DI is advised to undertake temperature monitoring of the storage area where heparin is stored, to assure himself that the storage temperature has not deviated from the defined storage temperature range. During the inspection, the consultant haematologist suggested that heparin could be used on a prescription basis and would therefore be stored until needed in the establishment's pharmacy department, where storage temperatures of stored drugs and consumables are monitored. The DI may wish to adopt this suggestion and discontinue heparin storage within the theatre suite. This approach would be similar to that of the paediatric service, which issues heparin on a prescription basis.
Ovarian Tissue Storage – Seacroft Hospital		
6.	GQ3(f)	The establishment has developed an HTA specific induction program which will be rolled out to all staff when activity other than storage involving ovarian tissue commences. The induction program includes aspects of the Human Tissue Act 2004 (HT Act) and associated codes of practice. The induction did not however include details of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations), which is the legislation under which the ovarian tissue is being stored. The DI is advised to amend the induction program so that it also includes relevant aspects of the Regulations, to help assure himself that staff working under the licence are fully aware of the relevant regulatory context.
Cardiac Tissue Storage – Leeds General Infirmary		
7.	GQ7(e) & GQ7(f)	While the unit would follow instructions from its provider on recall arrangements, the establishment does not have a documented procedure to follow in case they receive a tissue recall from one of the licensed heart valve banks, from which tissue is purchased. The DI is advised to develop and document a tissue recall procedure, including

		steps taken to quarantine any tissue that is currently in storage, to ensure it is not used for patient treatment.
8.	PFE3(b) & PFE5(k)	The establishment currently does not have a contingency plan covering storage freezer failure. Although it was indicated during the inspection that heart valves by an adverse event such as a freezer failure would be discarded, it is possible that a freezer failure was detected before the temperature rose above acceptable limits. In this instance heart valves may be transferred to another suitable freezer as part of a 'rescue' contingency procedure. The DI is advised to develop a contingency plan covering the failure of the heart valve storage freezer. This contingency plan should include what action to take in the event of a freezer failure. In producing the plan, the DI is also advised to identify suitable alternative storage facilities for heart valves if they have not been subjected to a temperature deviation which would render them unsuitable.
Chondrocyte Tissue Procurement and Distribution – Chapel Allerton Hospital		
9.	GQ1(p), GQ1(q), GQ1(r) & GQ1(s)	The establishment has an SLA in place with an establishment that is licensed by its own European Union member state. This has been in place since January 2009. Although the SLA does not specify an end date, the DI is advised to continue with his review of the SLA to assure himself that it continues to reflect the planned activity that may take place and that it remains in force.
10.	GQ5(b)	The patient information leaflet associated with chondrocyte procurement and re-implantation, references the serological testing of all donors for mandatory markers including HIV, Hepatitis B, Hepatitis C and syphilis. The leaflet however does not refer to HTLV-1 testing which is mandatory for donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas. Donor testing is carried out under the SLA by the establishment which is undertaking the processing of the cells. The DI is advised to ensure that HTLV-1 testing is carried out on all relevant donors and that the patient information leaflets for affected donors reflect the appropriate serological tests.
11.	PFE3(a)	The establishment has learned that a change in process now means that the storage medium for procured chondrocytes during transport to the other licensed establishment for processing has a defined storage timeframe. Documentation supplied with the storage medium is currently not written in English, meaning that the establishment cannot determine the point at which the defined time period begins. The DI is advised to seek clarification regarding this time period with the processing establishment and to arrange to have relevant documentation supplied in English, or with a clear indication of how long medium can be stored. Once determined, the changes to the establishment's existing procedures should be updated to reflect the new procedure and requirements.
Orthopaedic Tissue Storage - Chapel Allerton Hospital		
12.	GQ6(b) & GQ6(c)	Tissue used in orthopaedic surgery at the establishment is traceable from donor to recipient via the orthopaedic tissue register which records unique tissue identifiers and recipient details. A recent internal audit however has indicated that tissue identifiers are not being consistently recorded in the patient case notes as required by the establishment's SOP.

		To facilitate traceability the DI is advised to develop and implement a system to record tissue identifier details for the tissue used during orthopaedic surgery within the patient case notes. The DI may wish to implement a tissue tracking sheet which can be filled in the patient notes similar to the ones used for tracking heart valves and iliac vessels.
Establishment wide advice (all tissue users)		
13.	GQ1(c)	The DI holds governance meetings which include all areas of licensable activity. These meetings are usually only held once a year and are not always attended by all staff working under the licence, due to difficulties in finding a suitable meeting time for all tissue users.. All staff, however, that were spoken to are in regular contact with either the DI or the human tissue manager and are aware of their responsibilities under the licence. During the inspection it was suggested that setting up a human tissue sub group, similar to those set up under different licenses held by the establishment may help improve flexibility of meetings and therefore make meeting easier to attend by more staff. The DI is advised to develop a human application sub group which will involve the human tissue manager and as many of the establishment's Persons Designate who can attend, to meet more frequently and with a reduced agenda. These governance meetings will provide a forum for staff to raise issues and to share good practice across all areas of the licence.
14.	GQ7(b)	Throughout the inspection, various adverse event reporting SOPs were reviewed as part of the general review of the establishment's documents. There was variation in what each procedure included and in some areas the SOP did not define what constitutes a serious adverse event or adverse reaction (SAEAR) that would be reportable to the HTA and what action to take if one occurred. All staff however, that were spoken to, were clear about the need to contact the DI or the human tissue manager in the event of a SAEAR who would then initiate the investigation and inform the HTA. The human tissue manager indicated during the inspection that a central licence wide SAEAR procedure will be produced, which will include details of what constitutes a SAEAR, who should report it to the HTA and within what timeframe. The DI is advised to implement the licence wide SAEAR procedure as planned across all areas of licensable activity at the establishment.
15.	GQ7(b)	During the inspection it was learned that a possible adverse incident may have occurred within the orthopaedic tissue area. A routine internal audit identified a femoral head which had no records of disposal and did not appear to have been used in patient treatment. Although initial thoughts were that this tissue was removed from storage, not used in surgery and disposed of, the records were incomplete and could not provide a guarantee. This represents a potential loss of traceability for this femoral head, which may have been used in patient treatment. This event was discovered only a matter of days prior to the inspection and it was not clear at that stage what had happened with the tissue. Although this incident does not represent a reportable serious adverse event, the DI is advised to continue his investigations to establish any root causes for the incident and identify any possible actions which may mitigate the risk of a similar even re-occurring.

Concluding comments

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

The establishment demonstrated compliance with all HTA standards. The establishment also

has a proactive approach to meeting the HTA standards with some work being done during the inspection to act on advice immediately.

The establishment's licensable activity is diverse and covers multiple hospital sites and multiple tissue types. During the inspection all staff demonstrated a strong awareness of their responsibilities under the legislation. The establishment also benefits from a full time human tissue manager who works with the DI to coordinate activity taking place under the licence and provide guidance to staff working under the licence.

Report sent to DI for factual accuracy: 25 July 2012

Report returned from DI: 18 August 2012

Final report issued: 20 August 2012

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.

s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.

e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured,

processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.

d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.

i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.