Site visit inspection report on compliance with HTA minimum standards

Addenbrooke's Hospital

HTA licensing number 11072

Licensed for the

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

8 March 2016

Summary of inspection findings

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

Although the HTA found that Addenbrooke's Hospital (the establishment) had met the majority of the HTA standards, one major shortfall and four minor shortfalls were found with regard to the Governance and Quality Systems (GQS) standards. The shortfalls were in relation to traceability, audits, record keeping and distribution of vessels to other establishments.

Particular examples of 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 Section 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.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Iliac vessels				**E**	**E**		
Other tissues and cells				**E**	**E**		

Background to the establishment and description of inspection activities undertaken

Addenbrooke's Hospital (the establishment) has been licensed by the HTA since October 2006. The licence was re-issued in 2007 when the Quality and Safety for Human Application Regulations came into force.

The establishment is licensed for the storage and distribution of tissues and cells for human application. Cambridge University Hospitals NHS Foundation Trust is the corporate licence holder and the corporate licence holder contact is the Quality Advisor to the Trust. Addenbrooke's Hospital also holds a second human application licence (HTA licence 11066), which covers licensable activities relating to therapeutic stem cells.

The establishment receives blood vessels (iliac veins, iliac arteries, carotid vessels, aorta) and occasionally abdominal wall grafts, which have been retrieved from deceased donors. Vessels are retrieved alongside abdominal organs such as pancreas and liver and used as conduits for vascular reconstruction during organ transplantation, in order to provide additional vessel length if required. NHSBT (NHS Blood and Transplant) holds an HTA Organ Donation and Transplantation (ODT) licence and is responsible for retrieval as it

commissions the National Organ Retrieval Service (NORS) teams which retrieve organs and vessels in accordance with agreed standards.

Specialist nurses – organ donation (SNODs), who work under the licence held by NHSBT, are responsible for seeking consent, donor testing and donor evaluation. Following retrieval, the vessels are placed in a sterile plastic pot and immersed in University of Wisconsin solution containing gentamicin (8mg/litre). The pot is double bagged and secured with cable ties, before it is transported along with the organs in transport boxes containing ice. The packing of organs is in accordance with the NORS guidelines. Transport is undertaken by couriers who work under the ODT licence held by Addenbrooke's Hospital (HTA licence number 40032).

Transplant co-ordinators based at Addenbrooke's Hospital receive donor information from NHSBT through the electronic offering system (EOS). The information includes test results for HIV, Hep B, Hep C, HTLV-1 and Syphilis.

In October 2014, Addenbrooke's Hospital started using a proprietary electronic patient information system to record all clinical information. Records are linked to hospital MRN numbers, which act as patient identifiers. The Transplant Co-ordinator based at Addenbrooke's Hospital is responsible for generating an MRN number for each deceased donor and uploading donor information onto the electronic patient information system. The system links the NHSBT donor number, donor test results and other donor information made available on EOS and the core donor data form provided by NHSBT, to the MRN number of the deceased donor. Two donor blood samples which arrive with the organs are sent to the testing laboratory located at Addenbrooke's Hospital for confirmatory testing. Recipients of organs and vessels are traceable by name, MRN number and date of birth.

Vessels which arrive along with organs remain in the organ transport box for the duration of the organ transplant, so that they can be used if required. Vessels which are not used to support organ transplantation for the designated recipient are placed in a lockable fridge located just outside the theatres. These vessels are placed in the quarantine shelf in the fridge and stored between 3-5^{0}C. The fridge is alarmed and staff can respond to the alarm as the theatre suites are manned 24 hours each day. Theatre staff record the temperature of the fridge on the 'Transplant vessel fridge daily audit form'.

Once the confirmatory donor testing has been completed and found to be satisfactory, the vessels are moved from the quarantine shelf to another shelf. These vessels can be used to support organ transplantation into another recipient at Addenbrooke's Hospital, or sent to other transplant centres (in validated containers supplied by NHSBT). Vessels are stored for fourteen days and are disposed of if they are not used within this timeframe.

The 'Transplant organ tissue and vessels register' is used to record all organs and vessels received by the establishment. This register is also used to record any organs and vessels which are sent away to other centres.

Details of vessels which are transferred to the fridge are recorded in the 'Vessel Fridge Register'. The NHSBT ODT number; type of tissue; donor's blood group; HTA 'A' form number (form which providing information about the retreival); date and time vessels are placed in the fridge; date due for disposal; and name of the person placing it in storage are entered into this vessel register. Records of vessels removed from the fridge and used in a transplant within Addenbrooke's Hospital, disposed of, or transferred to another centre are also recorded in the vessel register to ensure traceability. The HTA team was informed that the transport fluid surrounding organs and vessels (University of Wisconsin solution) is sampled each time an organ or vessel is used in a transplant. The fluid is sent to the microbiology laboratory for analysis in order to detect any microbiological contamination which could impact on the recipient.

In 2015, the establishment received 124 vessels, of which eight were used within the hospital, three sent away to other centres and 111 disposed of. Details of tissue used are also recorded in the proprietary electronic patient information system used in theatres and saved as part of the recipient's electronic patient records.

The Theatre Lead provides comprehensive training and undertakes competency assessments of theatre staff. Surgeons attend weekly meetings to discuss transplant outcomes, training and incidents.

This was the fifth routine site visit inspection of the establishment and included a visual inspection of the theatre area where the fridge is located and a visit to the microbiology laboratory. Discussions were held with the DI who is a consultant transplant surgeon, the corporate licence holder contact who is the Trust's Quality Advisor, the Compliance Manager and the Team Leader (Staff Nurse).

A document review was undertaken. SOPs covering licensable activities, staff training records, risk assessments, meeting minutes and fridge temperature records were reviewed.

Audit trails were undertaken: paper records relating to two vessels stored in the fridge were traced to the 'Transplant organ tissue and vessels register' and 'Vessel fridge register'. Paper records relating to three vessels, one of which had been disposed of, were also reviewed.

The HTA team had several concerns about the change control procedures in place when the proprietary electronic patient information system used by the establishment was implemented – see shortfalls listed under HTA standards GQ4 and GQ6 below:

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
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.	The transport solution in which the vessels are immersed is sampled and analysed to detect microbial contamination. However in many cases, staff do not request the appropriate test *i.e.* 'organ transplant fluid culture', on the proprietary electronic patient information system when samples are sent to the microbiology laboratory for testing. This means that staff are not aware if the vessels are contaminated during procurement or during storage in the vessel fridge and are not able to assure themselves of the quality of the vessels used for transplantation. In the event that a recipient develops an infection, it would not be possible to determine whether or not the vessels were the source of the microbial contamination. Furthermore, the results from the tests are uploaded onto the electronic patient information system under the designated recipient's, MRN number and not linked to the MRN number of the deceased donor (see advice item 3 below).	**Minor**

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.	Clinicians access patient details using the MRN number which is a patient identifier. However, the electronic patient information system does not prevent staff from registering more than one MRN number for each donor and recipient (patient). Clinicians may not be aware that information about a patient or donor may be listed under more than one MRN number. As a result, there is the risk that clinical care will be provided without the clinician accessing all information relating to the relevant donor and recipient (patient). Organs received at the establishment are accompanied by blood samples from the donor. These blood samples are sent to the laboratory for confirmatory testing - mandatory virology tests and testing for CMV. The test results are uploaded onto the electronic patient information system under the designated recipient's MRN number. This creates confusion in the event that the vessels which accompany the organ are stored and used for other recipients. The transplant surgeon who uses these vessels may not be made aware that confirmatory donor testing was undertaken by the establishment. Furthermore, these test results will not be made available to other centres when vessels are sent away from the establishment. The current settings in the electronic patient record system do not allow the transplant surgeon to view details of vessels used during the transplant or update records. The system is configured to allow Theatre Nurses to view details and update records. Hence surgeons do not have direct access to all information relating to vessels when they undertake a transplant.	**Major**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and 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.		
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.		

GQ4 There is a systematic and planned approach to the management 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.	The establishment does not have a regular system of audits which covers records stored in the electronic patient information system. Audits should include records relating to MRN numbers and associated donor tests, tests of the transport fluid, operating room records, implantation of vessels and entries made in the vessel fridge register.	**Minor**
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
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.	The establishment undertakes confirmatory donor testing on blood samples which are received along with organs and vessels. Such testing has to take place in a testing laboratory which is licensed by the HTA (see advice item 6 below).	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.	The establishment supplies vessels to other centres. There is no procedure or checklist which covers information which must be provided to other centres when vessels are dispatched. Also the establishment does not receive confirmation when the vessels reach the other centre (see advice item 5 below).	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
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.		

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	NA	Shortly after the inspection, the HTA was informed that the CLH contact had left the Trust. The DI is advised to inform the HTA of the name of the new

		Corporate Licence Holder contact as soon as possible. The DI is reminded that for the CLH contact to be suitable, he/she must be sufficiently senior and in a position to replace the DI if required. The DI is advised to appoint key members of staff, such as the Theatre Lead, as Persons Designated (PD) under the HTA licence and to provide their contact details to the HTA.
2.	GQ1c	The DI is advised to establish formal links with key members of staff in the microbiology department to ensure that he is kept informed of changes to testing methods or incidents relating to testing which may have implications for the quality and safety of the vessels.
3.	GQ1h	In addressing the shortfall relating to HTA standard GQ2, the DI is advised to amend the SOP which covers the storage and use of vessels to include the requirement for staff to take a sample of the organ transport fluid and send it for analysis to the microbiology laboratory. The DI is advised to ensure that the test results are reported under the donor's MRN in addition to being recorded under the recipient's MRN number as is currently the case.
4.	GQ3e	The DI is advised to increase awareness of incidents which are reportable to the HTA (SAEARs) by providing information about SAEARs during training provided to staff, including persons designated and surgeons involved with licensed activities.
5.	GQ4k and GQ7g &h	In addressing the above shortfall relating to standards GQ4k and GQ7g &h, the DI should consider a checklist which includes the Core Donor Data Form provided by NHSBT, confirmatory donor test results, the expiry date relating to the vessels (14 days from retrieval) and an End-user agreement requiring the receiving centre to maintain records of traceability and report any serious adverse events and reactions to the DI.
6.	GQ5b	The DI is advised to consider putting in place an agreement with the DI responsible for the HTA licence- 11066 held by Addenbrooke's Hospital under the Quality and Safety for Human Application Regulations 2007. HTA licence 11066 covers donor testing in addition to other activities. Such an agreement will ensure that confirmatory donor testing takes place in accordance with the requirements of HTA Directions 003/2010. The DI is advised to establish formal links with the DI of HTA licence 11066 to ensure that he has have sufficient knowledge of any incidents relating to the licensable activity of testing.
7.	PFE3c	The vessel fridge has a local alarm and staff are aware of the procedure to follow when the alarm is triggered. The DI is advised to ensure that the local alarm is tested at regular intervals and that these tests are recorded.
8.	PFE5e	The DI is advised to review the agreement with the company which supplies and maintains the fridges to ensure that they provide prompt and efficient service to the establishment. The HTA inspection team noted that the chart recorder on the fridge was not in working order and the company had not responded to requests to repair or remove the fridge which had previously been designated as a contingency fridge, even though it had not been working for several months.
9.	PFE5k	Staff are aware of the need to move vessels to the contingency fridge in the event of a fridge failure. The DI is advised to document the location of the contingency fridge in the SOP and display the location of the contingency

		fridge on the vessel fridge so that staff have immediate access to the information in the event of a fridge failure.

Concluding comments

There were areas of good practice observed during the inspection. Licensable activities are undertaken by committed staff, who engaged with the inspection team in order to determine where improvements to procedures could be made. There are good systems in place to train theatre staff, including detailed competence training and regulatory training which covers transplantation of organs and vessels. Theatre staff are well supported by the Lead Nurse who works under the licence. There are robust systems in place for written records which cover the receipt, use, transfer and disposal of vessels. There is a Human Tissues Committee, which includes DIs supervising activities under all six licences held by Cambridge University Hospitals, who meet regularly to discuss licensing matters.

There are a number of areas of practice that require improvement, including a major shortfall relating to the proprietary electronic patient information system and four minor shortfalls. In addition, the HTA has given advice to the Designated Individual on a range of matters.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 01 April 2016

Report returned from DI: 15 April 2016

Final report issued 06 May 2016

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 24 November 2017

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

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.
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.
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.
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.
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.