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**

12 March 2014

Summary of inspection findings

Addenbrooke's Hospital (the establishment) was subject to a themed site visit inspection. The themes selected for inspections in this sector for 2013 / 2014 include quality management, contingency planning and risk management.

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

Although the establishment had met the majority of the HTA standards, seven minor shortfalls were found with regard to the Governance and Quality Systems (GQS) standards. The shortfalls were in relation to an absence of agreements with other licensed organisations and third parties, an absence of documented procedures for some licensable activities, lack of governance meetings or contingency planning for records and raw data, lack of traceability and the absence of a procedure for reporting serious adverse events and adverse reactions. Advice has also been given relating to the GQS and Disposal (D) standards.

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 (DI), Licence Holder, premises and practices are suitable.

The statutory duties of the DI 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.

However, a themed inspection may be carried out at establishments which have been found previously to represent a lower risk. Themes target standards against which the HTA identified common shortfalls across the human application sector in 2012. The themes selected for 2013/14 are outlined in the table below.

Themes	**HTA Standards**
Quality management	
Standard operating procedures for licensed activity	GQ1(b)
Document control system	GQ1(d)
Quality Management System – continuous and systematic improvement	GQ2(a)-(c)
Internal audit system for licensable activities	
Contingency Planning	
Plan to ensure records of traceability are maintained for 10 or 30 years as required.	GQ4(m)
Risk Management	
Procedures for the identification, reporting, investigation and recording of adverse events and reactions	GQ7
Risk assessments	GQ8
Traceability	GQ6

In addition to the standards listed above, the HTA will follow up on any other issues that have arisen since the establishment's last inspection.

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/cells	-	-	-	**E**	**E**	-	-

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Addenbrooke's Hospital (the establishment). This was the fourth site visit inspection of the establishment since it was issued an HTA human application licence in October 2006. It was a routine 'themed' inspection to assess whether the establishment is continuing to meet the HTA's standards. The previous human application inspection was undertaken in March 2012.

The organisation also holds an organ donation and transplant (ODT) licence (HTA licensing number 40032) for both procurement and transplantation activities involving organs, and was audited under this licence in October 2013.

The organisation carries out kidney, pancreas, liver and small bowel transplants under the ODT licence. It also performs multi-visceral transplants (where a cluster of organs is transplanted, e.g. liver, pancreas and small bowel) and modified multi-visceral transplants (a multi-visceral transplant without the liver). The organisation also carries out organ procurement at several regional hospitals under the ODT licence as part of the National Organ Retrieval Service (NORS). The current inspection did not include activities taking place under the ODT licence.

The activities under the human application licence relate to the storage, distribution and end use of 'donor tissue' ('liver vessels' and, occasionally, abdominal wall grafts) in connection with transplant surgery. The liver vessels are primarily iliac arteries and veins and occasionally other blood vessels (e.g. aorta, carotid vessels). Organ transplantation may occasionally require the use of liver vessels, and multi-visceral and modified multi-visceral transplants may also require abdominal wall grafts. The donor tissue provides additional vasculature which contributes towards the success of the transplant. The donor tissue is procured at the time of organ donation and is transported to the establishment by NHS Blood and Transplant (NHSBT), along with the organs, in validated organ transport boxes. Procurement of the donor tissue and initial donor serology testing is covered by the organisation's ODT licence and the initial testing is carried out by NHSBT. Additionally, two separate donor blood samples for confirmatory testing arrive with the organ. Confirmatory testing is performed for donor tissue which is stored pending transplantation or distribution and is carried out in the laboratories at the Addenbrooke's site, which have Clinical Pathology Accreditation (CPA). Neither the establishment itself nor the Addenbrooke's laboratories are licensed by the HTA for testing although there is a third party agreement (TPA) between the

establishment and these laboratories. The licensing requirements for testing form the basis of ongoing correspondence with the DI and will be resolved after the issuing of the Final Report.

The donor tissue may be used at the time of organ transplant or during an additional revision procedure within the initial days following transplant. Donor tissue surplus to the requirements of the original intended recipient is stored for possible use in similar procedures on a different recipient. Storage is for up to 14 days before disposal. Stored tissue is occasionally transported to other HTA-licensed ODT organisations for use in transplant surgery. There is no TPA with the courier which transports this donor tissue (see 'Compliance with HTA standards', below) and there are no Material Transfer Agreements (MTAs) or Service Level Agreements (SLAs) with any of the receiving HTA-licensed ODT organisations (see 'Compliance with HTA standards', below).

During 2013, the establishment received 124 units of iliac vessels and used 15 of these in transplantation. Three units were distributed to another HTA-licensed establishment for end use.

Donor tissue is stored in a lockable refrigerator within a defined area of the operating theatre suite. Access to this area is subject to coded card security, monitored by CCTV and staffed 24 hours per day. The tissue refrigerator is labelled to indicate that it contains human tissue for transplant and is alarmed, the alarm sounding locally. A back up refrigerator is adjacent to the tissue refrigerator. The refrigerators are connected to separate hospital emergency power supply circuits. The temperature of the tissue refrigerator is monitored once a day and is also recorded continuously using a chart system. The temperature of the back up refrigerator is monitored once a day. If the temperature deviates outside the range as set out in the Standard Operating Procedure (SOP), the refrigerator alarms and trained staff can assess if donor tissue needs to be transferred to the back up refrigerator. At the time of the inspection, the tissue refrigerator and back up refrigerator temperatures were 4°C and 5°C, respectively.

The refrigerators are subject to an annual service and calibration plan.

The donor tissue in its transport packaging (vessel pot and double bagging) is received directly by one of four authorised persons in the department and is placed in the tissue refrigerator after the staff member has followed a procedure to check the quality of the packaging. It is then placed on a 'quarantine' shelf, pending confirmatory testing results. The back up refrigerator is also used as storage for non-conforming consignments (e.g. donor tissue with damaged packaging).

The information on the bag label (type of donor tissue, NHSBT ODT number, HTA A number, donor blood group) is entered into the fridge register, along with the date and time of receipt and expiry date. The sample is then allocated a 'form number' (*see Advice item 7*).

When needed for transplant surgery, trained staff enter the details of date and time of removal, donor tissue type and hospital number of the recipient in the fridge register as a separate entry underneath. If donor tissue is disposed of, or is transferred to another unit, these details are also entered into the fridge register. Tissue is disposed of by incineration and is bagged separately from other clinical waste, although the reason for each disposal is not recorded (*see Advice item 11*). Tissue for transfer is repackaged pending transport by courier. When a patient attends for an operation which may involve donor tissue, that fact is noted as part of the clinical consent process.

The site visit inspection included a visual inspection of the refrigerators and the area where records are kept. Meetings were held with: the DI (Consultant Transplant Surgeon/University Lecturer); the Unit Leader – Main Theatres; the Team Leader – Main Theatres; the Compliance Administrator – Main Theatres; and, the CLH Contact (Risk and Quality Advisor). A document review, review of traceability records [through the NHSBT NHS Electronic

Offering System (EOS)] and vertical and horizontal audits were carried out. Details of the audits are provided below.

Three packages were located within the tissue refrigerator and the records were compared to the details in the fridge register. No discrepancies were noted.

A forward vertical traceability audit was carried out in relation to four sets of vessels that had been procured, stored and then allocated for use in patients. The audit was conducted by tracing the the unique donor NHSBT ODT number on the NHS EOS through to the recipient's unique hospital number in each case. The recipients' notes, tissue register and hospital database were also examined. There were discrepancies for two of the patients, where the recipients' entries in the tissue register did not match the electronic data or the data in the patients' records (see 'Compliance with HTA standards', below).

Inspection findings

The HTA found the DI and the (Corporate) Licence Holder (CLH) to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
N/A	There are no SLAs or MTAs with any of the receiving HTA-licensed ODT organisations. *See Advice item 1.*	**Minor**
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Some procedures still need to be created and developed. *See Advice item 2.*	**Minor**
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	There is no existing regular governance meeting which covers HTA issues for staff working under the licence. *See Advice item 3*.	**Minor**
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.	A courier company transports donor tissue to other HTA-licensed ODT establishments for use in transplant surgery. There is no TPA with the courier company.	**Minor**
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.		

GQ4 There is a systematic and planned approach to the management of records.		
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.	There is no plan, procedure or written agreement with another HTA-licensed establishment to transfer traceability records and raw data in the event of termination of licensable activities.	**Minor**

GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.		
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.	The vertical audit revealed incomplete traceability on two (out of four) selected donor tissue samples. *See Advice item 8.*	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.		
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.	There is no local procedure for identifying and reporting serious adverse events or adverse reactions (SAEARs). *See Advice item 9.*	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI is advised that the SLA/MTA should ensure that: • Responsibilities for SAEAR reporting are delineated between organisations. • Traceability is maintained during transport and there is confirmation of receipt. • Transport conditions required to maintain the properties of the donor tissue are validated and potential associated contamination risks are minimised.
2.	GQ1(b) but also relevant to standards GQ1(h), GQ1(i), GQ7(b) PFE4(b)	The SOPs which need to be specifically created should cover: • management and quarantine of non-conforming consignments (and examples of types of non-conformances). • management and quarantine of consignments with incomplete (or positive) test results. • SAEARs (see below). • Transportation.
3.	GQ1(c)	In other establishments, regular governance meetings have covered items such as: reportable incidents, changes to SOPs, audits and their results, adverse incidents, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). These meetings should be governed by an agenda, and minutes circulated. The minutes should include timelines for

		identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings.
4.	GQ2(a)	Although there are elements in place, the quality management system (QMS) would benefit from further development. The QMS for this sector is described in the document 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment' (paragraph 29): 'The quality management system should include the following documentation: • A quality manual which provides an overview of the quality system. • Standard operating procedures. • Guidelines from relevant professional bodies or advisory committees. • Training and reference manuals. • Reporting form. • Donor records and any records required by the HTA. • Information on the final destination of tissues and cells. • A risk management system. • Non-conformances and incident monitoring and follow-up, including serious adverse event and reaction management. • A mechanism to control changes to ensure these do not adversely affect the quality and safety of the tissues and cells and which allows for the mitigation of risk associated with change'. http://www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf The DI may wish to consider appointing a PD to assist in further development of the QMS.
5.	GQ2(b), GQ4(b)	Some internal audits have been carried out since the last inspection. These include ongoing checks of refrigerator temperatures, refrigerator contents, expiry dates and records completion. The inspection revealed discrepancies between working practices and documented procedures. When compared with the SOP 'Removal, storage and disposal of blood vessels for transplant' the following procedures were not being performed: - A quarterly review of all procedures. - Backing up the refrigerator paper records. - Recording the reason for disposal. The DI is now advised to formalise an audit schedule. Theis should be divided into small increments, carried out by different team members. It should include horizontal audits to ensure that SOPs accurately reflect

		current practices and vertical tissue traceability audits, from records of receipt to end use, disposal or transfer. The results of all audit findings, and actions taken, should be formally recorded to ensure continuing improvement of processes and practices.
6.	GQ2(c)	It is recognised that the audits carried out by members of the local Risk and Patient Safety team are of good quality and are done independently of the theatre team. As a further development of independent audit, the DI is advised to consider the potential for different HTA-licensed teams working at Addenbrookes Hospital to audit each other's work.
7.	GQ4(e)	The DI is advised to consider transferring all details held within the paper records relating to donor tissue onto an electronic spreadsheet/database, which can also act as the back up register. These details would include all the details currently recorded on the fridge register along with date of retrieval, refrigerator temperature at time of sample log in, disposal details, transfer details.
8.	GQ6(c)	The record and audit system needs to be modified. This will ensure that the establishment has procedures in place to ensure that tissues are traceable. The DI should consider the following risks to tissue traceability: - Tissue which is used immediately by the surgeons on arrival at the hospital and which has by-passed the log in system. -Tissue which is requested by the surgeons but which is not used and is disposed of directly from theatre.
9.	GQ7(b), (c)	The DI is advised to include within the local SOP on Serious Adverse Events and Adverse Reactions': • the reporting obligations to the HTA (24 hours). • the dissemination of HTA regulatory alerts. • the identity of personnel who should report SAEARs in the DI's absence. • the submission of a SAEAR follow-up report to the HTA within 90 days. The DI is referred to the HTA's website page for further information: http://www.hta.gov.uk/licensingandinspections/reportingtothehta/adverseeventandreactionreporting.cfm
10.	GQ8(a)	Some general risk assessments (e.g. Risk Assessments 5099, 5100) have been performed on tissue storage/disposal and the premises and facilities. The DI may wish to consider carrying out detailed risk assessments addressing specific parts of the overall process. These could include those surrounding: - Receipt/transfer/disposal (e.g. wrong or missing documentation, sample loss). - Storage (e.g. the capability and capacity of the refrigerator to store

		vessels and abdominal wall grafts covering both negative and positive virology status; the suitability of the tissue and back up refrigerators to store multiple large abdominal wall grafts).
11.	D2(a)	The DI should ensure that the reason for disposal of each tissue sample is recorded.

Concluding comments

Following the site visit inspection of the establishment in 2012, four minor shortfalls were found in relation to: staff training [GQ3(e)]; use of the back up refrigerator [GQ6(b)]; Trust documentation for SAEAR reporting [GQ7(b)]; and, maintenance of the back up refrigerator [PFE5(a)]. All of these were closed following assessment of submitted evidence in 2012. Closure of these shortfalls was confirmed at this current site visit inspection. At the last site visit inspection, eight items of advice were given. The DI had proactively implemented six of these items before this current site visit inspection. The remaining two pieces of advice have been included as Advice items in this report.

During the site visit inspection of Addenbrooke's Hospital areas of good practice were noted:

- There is evidence of effective communication, close working relationships and good teamwork across the different disciplines that make up the theatre team and between the theatre team and the governance team. There is a strong commitment to continuous improvement across the extended team.
- There is evidence of good communication with colleagues within NHSBT to include the sharing of ideas for the continuous improvement of quality systems and procedures.
- The hospital has a number of HTA licences and has in place an effective 'Human Tissue Management Committee' where the DIs for each of these licences meet on a regular basis to share experiences and practices and to discuss common issues.
- There is a well thought out competency assessment framework for all relevant transplant staff members covering all practices and procedures under the licence, including HTA matters.
- The premises are well maintained and the critical equipment, being the storage refrigerator, is subject to good validation (including temperature mapping), maintenance and cleaning regimes.

There are some areas of practice which require improvement, including seven minor shortfalls. The HTA has given advice to the DI with respect to governance and quality systems and disposal.

The HTA requires that the DI addresses the shortfall 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 site visit inspection.

Report sent to DI for factual accuracy: 9 April 2014

Report returned from DI: 22 April 2014

Final report issued: 13 May 2014

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: 20 October 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. Individual standards which are not applicable to this establishment are shown in are highlighted as grey text.

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.