Site visit inspection report on compliance with HTA minimum standards

Sunderland Royal Hospital

HTA licensing number 22610

Licensed for the

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

21 February 2017

Summary of inspection findings

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 HTA found that Sunderland Royal Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found in the governance and quality standards relating to documented procedures, independent audit and incident reporting. The HTA has also given advice to the Designated Individual with respect to audit, record retention and risk assessments.

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.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'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
Chondrocytes	**E***						
Bone				**E**			
Tendon				**E**			

Background to the establishment and description of inspection activities undertaken

The establishment is licensed for the procurement and storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations).

The establishment has been licensed by the HTA since December 2010 and this was the fourth routine site visit inspection to assess whether or not the establishment continues to meet the HTA standards. The timetable was developed in consideration of the previous inspection report and pre-inspection discussions with the DI. During the inspection, the fridge within the blood laboratory where storage takes place was visited. Reviews of the establishment's documentation were undertaken and interviews were held with the DI, staff who order tissue and theatre staff.

In the past, the establishment has undertaken two clinical activities under its licence. Firstly, the establishment procured chondrocytes from donors diagnosed with cartilage defects. The procured chondral cells were collected by another tissue establishment, transported to their laboratory and cultured to expand the number of cells before being returned to the originating establishment for autologous implant to correct the donor's cartilage defect. During the inspection it was learned that no procurement of chondrocytes has taken place since the previous inspection in February 2015 with the last procurement taking place in 2014. From discussions with the DI it was learned that there are currently no planned chondrocyte procurement procedures in the future. In addition, the tissue establishment which provided the chondral cell expansion no longer provides the service so should activity in this area re-commence, a different provider would need to be identified. It was agreed with the DI that although still licensed for procurement, this activity is currently on hold (see advice item 7).

As there has not been any chondrocyte procurement activity since 2014, prior to the previous HTA inspection, no review of donor clinical notes was undertaken during this inspection. If this activity was to re-start in the future, a new tissue establishment providing a chondral cell expansion service would need to be identified meaning that current procedures for consenting donors, procuring and packaging cells, associated procedural documentation and donor information would require amending to reflect the new provider's systems. Since the existing procedures and documentation would require amending prior to any re-commencing of chondrocyte procurement activity, no procedures or documentation were assessed during this inspection.

The second clinical activity taking place under the licence is the storage of allograft orthopaedic tissues, typically femoral heads, tendons and strut grafts, for use in various surgeries. This activity continues at the establishment and was the focus of the inspection visit to which this report relates. Allograft material is ordered from another HTA-licensed establishment by a member of theatre staff. Tissue is ordered for use in specific surgeries. When ordering tissue, details of the tissue that has been ordered, the details of the intended recipient and the order number is recorded in the establishment's tissue register. Tissue is delivered directly to the establishment's theatres were the member of staff who placed the order undertakes various checks on the shipment. These checks include checks on the integrity of the outer packaging and checks on the accompanying paperwork which is used to verify that the shipment details match the order and order number recorded in the tissue register.

Once satisfied that the correct order has been received and it has not been damaged during transit, the delivery is opened and the dry ice levels within the shipping container are checked to ensure that there is sufficient remaining to maintain the integrity of the frozen tissue. The tissue containers are then checked for any sign of damage in addition to verifying that each tissue's unique identifier and expiry date matches the details on the accompanying paperwork. Expiry dates are allocated by the organisation supplying the tissue and are based upon the establishment's storage freezer's operating temperature. Following verification against the paperwork, tissue identifiers, expiry dates and date of receipt are recorded against the appropriate tissue order details within the tissue register.

Once all of the checks have been completed and the details recorded within the tissue register, a porter is called to take the tissue from theatres to the blood laboratory where the

tissue will be stored within a -30ºC freezer. Transfer of the tissue by the porter is recorded within a 'porter transfer' record book which includes the porter's signature, the time the tissue was collected in addition to arrival at the laboratory and signature of the person receiving the tissue and placing it into the freezer. If the received tissue is not required during the surgery of the intended recipient and has not been removed from the storage freezer, tissue continues to be stored for use in other elective or trauma-related orthopaedic surgeries involving different recipients.

When required for use in surgery, a porter is requested to collect a specific tissue from the storage freezer with collection time, delivery time and porter details being recorded within the porter transfer record book. Details of the recipient and date of use are recorded against the appropriate entry in the tissue register. If tissue is requested in theatres but subsequently not used in surgery, it is not returned to the freezer irrespective of the length of time is has been out of storage. Instead, tissue is disposed of as clinical waste in line with the establishment's Trust disposal policy. Disposal of the tissue is also recorded in the tissue register.

The establishment's documented procedure states that use of allograft tissue is recorded in the recipient's clinical notes, the tissue register and the electronic theatre records relating to that surgery.

During the inspection, several audits of tissue use were undertaken. The clinical notes from three patients who had each received two allograft femoral heads as part of their surgery within the last twelve months were reviewed. In all three cases, recipient details, surgery date, individual tissue identifier and tissue expiry dates were taken from the establishment's tissue register. The porter transfer records were also reviewed to ensure that transfer to and from the storage freezer had been recorded. Tissue identifiers and tissue expiry dates were then sought within the relevant clinical notes and in the electronic surgical records.

In all three cases, no tissue identifiers or expiry dates were recorded within the clinical notes although reference to allograft being used was present within the surgeon's operating notes. A review of the electronic surgical record showed that for all three patients, records of the tissue identifiers were recorded. However, in only one patient's case had the tissue's expiry date been recorded. In all three patient's cases however, a review of the surgical procedure date and expiry date of the tissue that had been recorded in the tissue register by establishment staff, showed that tissue had been used within its expiry date, six months from receipt of tissue. In one patient's case, the final digit of the tissue identifier had been omitted in the electronic surgical record which is thought to have been as a result of an inputting error during manual data entry. In all three cases, records of transfer of tissue to and from storage by the porters were recorded as expected.

Although traceability from receipt of tissue at the establishment to end use of the tissue in patients was maintained in all of the three cases reviewed, no record of tissue identifiers or expiry dates were contained within the relevant clinical notes. Traceability is maintained by virtue of the tissue register and electronic surgical records. This is contrary to the establishment's standard operating procedure (SOP 6) which describes receipt, storage and use of allograft tissue and states that records of allograft use should also be maintained within the recipient's clinical notes (see advice item 5).

A further review of the establishment's tissue register including details of allograft tissue received and either used or disposed of between the date of the inspection and the start of 2015 was also undertaken. An example of a patella tendon which was received, not used in patient treatment and disposed of was seen and dates of receipt, storage and disposal were recorded as expected. However, this review identified five examples where tissue had been supplied to the establishment with expiry dates longer than those which were expected ie. six months. In three of these five cases, the allograft tissue was used in patient treatment within six months from receipt of the tissue. In the remaining two cases, the tissue had been used

within the expiry period stated on the product, but following a period of more than six months in storage at the establishment.

The DI was informed that this should be reported to the HTA as a serious adverse event, investigated and corrective actions to ensure that in future, tissue with unexpectedly long expiry dates will be identified and followed up with the tissue supplier. In addition, the DI was informed that the use of the tissue outside of the usual six month period should be notified to the tissue supplier.

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
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.	The establishment's main SOP detailing the procedures around receipt, storage and use of tissue (SOP6) does not fully describe the procedures being undertaken at the establishment. The SOP should describe the procedures performed when receiving tissue, storing tissue and releasing tissue for use, for example, checks performed on the tissue identifiers and packaging upon receipt of tissue are not included within the current procedure. Additionally, the procedure detailing the operation of the storage freezer and its alarm system was not available on request'. Staff thought that this would be within the laboratory where the freezer is located however, it was not available for review during the inspection.	**Major (Cumulative)**

g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	Checks such as condition of the outer transport container, order number, individual identifiers and condition of the individual tissue containers are not included within the establishment's main SOP detailing the procedures around receipt, storage and storage of tissue (SOP6). In addition, although tissue expiry dates are cross-checked between the tissue container and the accompanying delivery paperwork, these checks do not include a check that the expiry date is the expected six month period. Such checks may have helped to identify the five items of tissue supplied to the establishment during 2016 which had been given longer than expected expiry dates.	
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.	There is no procedure detailing the fate of any tissue being stored at the establishment should the establishment cease undertaking licensable activity.	
GQ2 There is a documented system of quality management and audit.		
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.	The establishment undertakes an annual audit of activity where each allograft and the associated records for tissue used in patient treatment or disposed of are reviewed. These are carried out by the DI and his staff. However, there is no system for audits to be carried out in an independent manner that covers both the use of tissue and the establishment's compliance with HTA standards. Although this was also identified during the previous inspection in 2015, no independent audit has been undertaken.	**Major**

GQ7 There are systems to ensure that all adverse events 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.	The establishment does not have a documented procedure relating to the reporting of serious adverse events or adverse reactions (SAEARs) to the HTA which includes: • what constitutes and serious adverse event; • what constitutes a serious adverse reaction; • who should report these to the HTA and who reports in their absence; • how to report SAEARs to the HTA; and • instructions that all SAEARs are reported within 24 hours of discovery Although this was identified during the previous inspection in 2015 and the DI understood that it had been addressed, no procedure relating to the reporting of SAEARs is in place.	**Major**

Advice

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

No.	Standard	Advice
1.	GQ1(b)	The establishment's SOP detailing the procedure for undertaking internal audits states that audits are undertaken on a four-monthly basis. The DI has, however, recently extended the audit period with annual audits taking place which include a review of all tissues received at the establishment. The DI is advised to update the establishment's audit SOP to reflect these changes. Additionally, the DI is advised to include a review of the storage freezer's temperature data as part of the annual audit.
2.	GQ2(b)	The establishment undertakes an annual audit where each allograft and the associated records for tissue used in patient treatment or disposed of are reviewed. Although the DI discussed the findings and follow up actions, these had not been documented. The DI is advised to fully document all audit findings and any actions taken as a result of them so that audit reports are available to share with relevant staff for learning purposes.
3.	GQ4(d)	The establishment records ordering, receipt and use or disposal of allograft

		tissue in the tissue register. The DI is advised to periodically scan or photocopy this register and keep these duplicates so that should the original become damaged or be misplaced, tissue traceability records would not be lost.
4.	GQ4(h)	The laboratory where the tissue storage freezer is located has recently changed the monitoring and alarm system. The DI is advised to seek assurance from the laboratory that the new system's temperature records will be maintained for the required ten-year period. In addition, the DI should verify that the previous temperature monitoring system's data continues to be retained and will be available for the required time period.
5.	GQ6(b) GQ2(b)	Traceability from receipt of tissue to use in patient treatment or disposal was demonstrated by virtue of various records including the tissue register and electronic theatre records. The DI is advised to remind all users of allograft to record tissue identifiers and expiry dates within the patient's clinical notes as described in the establishment's receipt, storage and use of tissue SOP (SOP6). Reviews of tissue details in recipient's clinical notes should also be included within the establishment's annual audit to help assure the DI that surgeons are recording tissue use in the clinical notes.
6.	GQ8(a)	The establishment has risk assessments in place that relate to the quality and safety of the tissue and cells being received, stored and used at the establishment. These include risks relating to failure of the storage freezer, use of incorrect material and loss of traceability. The DI is advised to review and build upon these risk assessments to assure himself that they remain appropriate. Examples of areas to review include, but are not limited to, the effect of changing the freezer temperature monitoring equipment and the receipt and use of out of date tissues. In addition, the DI is advised to document control indicators on the documented risk assessments such as issue and review dates so that staff can be assured that they are using and referring to the most up to date version.
7.	General	During the inspection it was learned that no procurement of chondrocytes has taken place since the previous inspection in February 2015 with the last procurement taking place in 2014. From discussions with the DI it was learned that there are currently no planned chondrocyte procurement procedures in the future. In addition, the tissue establishment which provided the chondral cell expansion no longer provides the service so should activity in this area re-commence, a different provider would need to be identified. The DI is advised that prior to any chondrocyte procurement activity re-starting that he should inform the HTA of the re-commencement and also develop a suite of procedural documents to describe the processes used by the new service provider.

Concluding comments

Although shortfalls were identified during the inspection, the establishment demonstrated an open approach to the inspection and close working relationships between various staff involved in undertaking the licensable activity.

The procedure that has been put in place to record the transfer of tissue from receipt to storage and vice versa by the porters was seen to be good practice and helped the DI to assure himself that transport times remain acceptable and are taking place as expected.

There are a number of areas of practice that require improvement, including three major shortfalls. The HTA has given advice to the Designated Individual with respect to audit, record retention and risk assessments.

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: 20 March 2017

Report returned from DI: 24 March 2017

Final report issued: 27 April 2017

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: 17 June 2019

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.