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**

7 March 2013

Summary of inspection findings

Sunderland Royal Hospital (the establishment) was selected to receive a themed inspection. The themes selected for 2012/13 include quality management, contingency planning and risk management.

Although the HTA found that the establishment had met the majority of the HTA standards, shortfalls were found, particularly in relation to audit, contingency planning and risk assessments. Audits are carried out within the department, but these relate to clinical, rather than regulatory matters. There is no contingency plan in place dealing with on-going storage of raw data and traceability records in the event the establishment ceases to be licensed and, while risk assessments have been carried out as part of the drafting of policy and procedural documents relating to the licensed activity, these have not been documented.

In addition to the standards assessed as part of the themed inspection, the HTA reviewed the establishment's compliance with standard PFE3 as an issue relating to the temperature at which allografts were stored was noted during the traceability audit. As storage of allograft material for longer than a few weeks appears to happen rarely and staff reacted immediately and appropriately on noting the issue, the HTA has taken a proportionate approach and provided advice rather than classifying it as a shortfall.

The HTA previously found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. Their suitability was not re-assessed during this inspection.

The HTA's regulatory requirements

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

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

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

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

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

However, a themed inspection may be carried out on establishments which have been found previously to represent a lower risk. Themes target Standards which the HTA has identified as common shortfalls across the human application sector in 2011. The themes selected for 2012/13 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.

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone **Tendons**				**E**			
Cartilage	**E**						

Background to the establishment and description of inspection activities undertaken

The establishment carries out two distinct activities under the HTA licence: storage and procurement.

It buys in allograft material in the form of femoral heads, bone struts and tendons from another HTA licensed establishment for elective surgery on specific patients. If not used in the operation for which they were intended allografts are stored for use in other procedures. As storage can exceed 48 hours, an HTA licence for storage is required.

Allograft is ordered by a trained member of theatre staff and is delivered to stores, where that trained person checks delivery paperwork, packaging integrity and expiry dates. Hospital porters then transfer the received tissues to the laboratory within the Department of Haematology, where they are placed in a monitored, alarmed, freezer. Details of bone and tendons received are recorded in the 'femoral head log book' with traceability being maintained by reference to each unit's unique identifying number.

There are procedures in place for the release of allograft from storage for use in operations, in order that traceability is maintained, with recipient details again entered into the femoral head log book and unique numbers recorded in the patient's folder and electronically on their operation record.

A consultant surgeon in the Orthopaedic Department procures cartilage from patients for use in Matrix-induced Autologous Chondrocyte Implantation (MACI).

The establishment has a service level agreement with the cartilage cell processor, covering supply of the tissue biopsy kit, transportation of the biopsy and mandatory donor testing. When the cartilage cells have been processed, they form an Advanced Therapy Medicinal Product (ATMP) and fall outside the remit of the HTA. Accordingly, procurement is the only licensable activity carried out by the establishment in relation to MACI.

The MACI process encompasses two stages. In the retrieval stage, the consultant surgeon takes consent from the patient. Consent forms and patient information leaflets supplied by the chondrocyte processing company are used for the MACI aspects of the operation, together with a standard NHS hospital consent form for the surgical procedures and related anaesthetic.

A cartilage biopsy is taken from the patient during a standard arthroscopic procedure, placed in a supplied transport medium (part of a pre-supplied biopsy kit) and transported to the processing company where the cartilage is processed to form an MACI implant. A blood sample is also taken from the patient at this time and sent to the processor's testing laboratory for mandatory testing. Results of mandatory testing are then forwarded to the establishment. The transport of procured cartilage for processing, as well as that of blood samples for mandatory testing, is carried out by the processor, which is a company authorised by the competent authority in Denmark.

Traceability is maintained by the use of unique biopsy kit numbers, which are applied to all documentation relating to the consent, testing, transport and processing of samples, as well as, where appropriate, patient name, date of birth and hospital number.

When the processed cells are ready for implant, which is the second stage of the process, the patient is given an appointment and arrangements are made for delivery of the implant, now an ATMP, on the morning of the operation.

No full MACI procedures had been carried out since the date of the last HTA inspection, as there has been only one procurement, with implantation taking place at another hospital. Accordingly, no audit of the procedures and records relating to MACI has been carried out since the last inspection.

This was a routine, themed inspection. The establishment had previously been inspected in 2011, when two minor shortfalls were identified. These were addressed by the establishment in advance of publication of the final report of that inspection. However, one of those shortfalls, relating to audit, was again identified during this inspection.

The inspection comprised a visual inspection of the bone storage refrigerator, as well as that used for storage of chondrocyte biopsy kits, and discussions with key staff relating to procedures and processes carried out.

In addition, an audit of traceability was carried out:

For the MACI procedure, the records for two patients were reviewed (their operations having pre-dated the last inspection) for presence of signed consent form, biopsy records, testing results and chondrocyte release forms. In addition, the log sheet entries relating to those patients were reviewed. In both cases, traceability had been maintained by use of unique biopsy kit numbers, and patient details, including hospital numbers.

The log sheet relating to the one procurement carried out since the last inspection was also reviewed.

In relation to the storage of allografts, the only unit being stored at the time of the inspection was located and details of its unique number and expiry date were recorded. The unique number was used to trace the record of receipt of the femoral head in the femoral head log book.

Three recipient patient files were examined for records of femoral head or tendon use in operations. The details of the unique identifiers were compared with corresponding entries in the femoral head log book. In one case, the unique identifier for a patellar tendon had not been entered into the patient's operation record. As no other errors in traceability were found, the use of an allograft had been recorded in the patient notes, though not the unique number,

and the records in the femoral head log book were complete, the HTA has provided advice rather than recording it as a shortfall.

In the course of the audit of traceability, the HTA noted that the allograft storage freezer, which is also used for some blood products, was maintained consistently at -33°C rather than below -40°C, which has the effect of shortening the expiry date of bone products to six months from donation. Accordingly, as the shortened expiry date for the unit in storage had been exceeded, hospital staff reported this as an incident on the Trust reporting system and arrangements were made for the stored bone to be disposed of. Advice has been provided regarding this, under standard PFE3c and d.

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.		
b) There is an internal audit system for all licensable activities.	There has been only one MACI procurement since the last inspection and therefore no audit of procedures or records has taken place. It is not certain whether any further MACI procedures will be carried out (see Advice point 4). With regard to the receipt, storage and use of allograft material, while the supplier periodically requests recipient details as an audit of traceability, there is no internal audit schedule or procedure covering the procedures or records relating to this activity. By putting in place such a schedule of audits, and ensuring that they are carried out in an independent manner, the DI will identify any systemic issues which could affect traceability, including any failure to record details within patient notes or issues relating to storage of allograft material, thus helping to minimise risk to quality and safety of tissues stored and also helping to ensure patient safety.	**Minor**
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.		

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.	With regard to traceability records pertaining to the MACI activity, this standard is met as the relevant records are held by the cell processor, which is authorised by another EU competent authority. However records of raw data relating to storage of MACI biopsy kits and allograft are kept only at the establishment, as are allograft traceability records, and there is no contingency plan covering on-going storage in the event the establishment ceases to be licensed. By agreeing and documenting contingency arrangements, the DI will ensure traceability and raw data records are maintained, aiding the tracing of recipients or donors in the event of a subsequent serious adverse event or reaction.	**Minor**
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.	While risk assessments are carried out within the operating theatre department, these relate to matters of clinical care and are not specific to the licensed activity or regulatory risk. Risks relating specifically to the licensed activity have been assessed and taken into account in the drafting of Standard Operating Procedures (SOP), but have not been formally documented. As a result, they have not been subject to review and are not accessible to staff. By documenting risk assessments of all aspects of the licensed activity, including delivery delays, failure of storage facilities and loss of traceability, the DI will be able to identify potential risks to the maintenance of traceability, the quality and safety of tissues and cells and the safety of donors or recipients and consider steps to mitigate these. Risk assessment will also help to inform review of processes and related documented policies and procedures.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1b PFE3c,d	The DI is advised to review the SOP and related documentation relating to allograft storage to ensure the change to acceptable expiry dates, necessary as a result of the storage temperature being higher than -40°C, is reflected in them.
2.	GQ1d	The DI is advised to ensure that all procedural documentation relating to the licensed activity, including the Autologous Chondrocyte Implantation pathway document, falls within the document control system, perhaps by being incorporated as an annex or appendix to the controlled SOPs.
3.	GQ1d	As the SOPs relating to the MACI procedure refer staff to the cell processor's guidance on procedures and on labelling of biopsy and blood test kits, the DI is advised to incorporate these as annexes to the SOPs, in order to facilitate their use by staff.
4.	GQ2b	In the event that it is decided to continue with MACI activity, the DI is advised to ensure that audits related to the process and related documentation are scheduled, carried out and recorded.
5.	GQ6b	The DI is advised to consider using the same log book format for traceability of MACI implants, as that used for allografts. As the same staff member is responsible for both records, uniformity of format may aid in minimising the risk of any transcription error in recording traceability details.
6.	GQ6b	The DI is advised to remind all theatre staff of the importance of recording allograft identification details within the patient notes of recipients. While records are maintained in the femoral head log book, having traceability details in recipient patient operation notes further aids traceability.
7.	GQ7a	While the SOPs relating to the MACI procedure and storage and use of allograft material provide for the need to report Serious Adverse Events and Reactions (SAEARS) to the HTA, the process is not covered in detail and thus most suited to staff very familiar with the system. The DI is advised to consider preparing more detailed guidance for staff on how to report SAEARs to the HTA, perhaps in the form of a specific SOP, particularly as changes to the reporting system mean any staff associated with the licence can now report SAEARs. Any SOP should detail what categories of event or reaction are reportable and the method and timescales for doing so.

Concluding comments

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the Designated Individual with respect to documented procedures and further development of the serious adverse event or reaction reporting procedure.

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: 21 March 2013

Report returned from DI: No comments received from DI

Final report issued: 15 April 2013

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: 13 August 2013

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.