Site visit inspection report on compliance with HTA minimum standards

Leicester Bone Bank

HTA licensing number 11011

Licensed for the

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

- **storage of relevant material which has come from a human body for use for a scheduled purpose under the Human Tissue Act 2004**

27-29 August 2013

Summary of inspection findings

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

Although the HTA found that Leicester Bone Bank (the establishment) had met the majority of the HTA standards, a minor shortfall was found in relation to Governance and Quality Management Systems.

Since the last inspection, the establishment has increased the number of satellite licences from nine to eleven and has undertaken the storage and distribution of tendons for human application. The establishment has also increased the level of licensable activity that it carries out, with respect to the storage of relevant material, for the scheduled purpose of research, under the Human Tissue Act 2004. These changes in activity were addressed as part of this site visit inspection.

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

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in 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.

Tissue type	Procurement	Testing	Storage	Distribution
Bones	**E**	**E**	**E**	**E**
Tendons			**E**	**E**
Chondrocytes	**E***			
Heart Valves			**E**	

Background to the establishment and description of inspection activities undertaken

Leicester Bone and Tissue Bank (the establishment) is a non-profit making organisation involved in the procurement, storage and distribution of human tissue for clinical use and the storage of human tissue for research. All licensable activity is co-ordinated through the hub site, based at Glenfield Hospital, Leicester, where long term storage of the establishment's tissue stocks takes place. The establishment also has 11 satellite sites; femoral heads for allogeneic use are procured (p), or stored for transplantation (t) at 10 of these: Leicester General Hospital (p, t), Leicester Nuffield Hospital (p), Spire Leicester (p), Nuffield Orthopaedic Centre Oxford (t), Milton Keynes General (t), Lincoln County Hospital (t), Pilgrim Hospital Boston (p, t), Barlborough NHS Treatment Centre (p), Broomfield Hospital (t) and Airedale Hospital (t). A further satellite site, Bristol Nuffield St Mary's, is licensed for the procurement of chondrocytes for the use in Matrix Induced Chondrocyte Implantation (MACI).

At the time of the inspection, the Boston site was not actively procuring bone and the Bristol satellite was not undertaking any licensable activity.

Consent, for femoral head donation, is currently obtained by trained staff in pre-operative assessment clinics, who are based at the sites which procure bone. Each donor signs two copies of a consent form; one is filed with their patient notes and the other is held by the hub site as a record of donor consent.

Femoral heads are procured in an operating theatre, using aseptic techniques and under the control of an orthopaedic surgeon. Microbiology screening is performed on each femoral head at the time of donation and at the point of implantation into the recipient. Results of all microbiological testing is reported to the hub site. Femoral heads that are procured at the satellite sites are stored in a designated -80 freezer, until they are transferred to the hub site for long term storage.

All tissue is assigned a unique identifier upon receipt at the bone bank. Femoral heads are weighed and then stored in a quarantine freezer until all serology testing has been completed. For all femoral heads that are currently procured, a blood sample for serology testing is obtained at the point of donation. Serology testing is conducted by two other licensed establishments, under the terms of a service level agreement (SLA). Procured bone is held in quarantine until all serology testing results, along with other relevant donor information, have been reviewed by the responsible member of staff at the hub site. The establishment uses a colour coding system for all freezers and bone pots, which allows quarantined tissue to be easily distinguished from tissue that has been cleared for clinical use.

All of the establishment's freezers across the hub and satellite sites are alarmed and monitored and based in a secure location. Maintenance, servicing and calibration of each freezer is provided by the hub site.

A freezer log provides a paper record of material that is procured or held at each site. This information is transferred to an electronic database at the hub site. Satellite sites are visited on a regular basis by a staff member from the hub site, who collects procured bone and accompanying records, delivers stocks of bone for end use and ensures that freezer inventories and temperatures are accurately recorded. Where satellite sites are storing bone for end use, this is not retrieved from the freezer until it has been allocated by a member of staff at the hub site, for use in a specific patient.

The hub site also supplies femoral heads directly to end users on an ad hoc basis. In these instances, tissue is sent by courier under the terms of a third party agreement in validated shipping containers.

In addition to procuring femoral heads, the establishment purchases heart valves from other HTA licensed establishments within the UK. These are stored for end use by cardiac surgeons at Glenfield Hospital. Tendons are also stored and distributed for end use by the establishment.These are imported from outside the EU, by another HTA licensed establishment, and delivered to the Leicester Bone Bank for storage. Leicester Bone Bank then distributes the tendons, when notified to do so by the other licensed establishment. The storage and distribution of tendons is governed by a SLA between the other licenced establishment importing the tissue and the Leicester Bone Bank. Both heart valves and tendons are held within the bone bank, in designated baskets within the -80 freezer, where tissue released for clinical use is stored

The establishment also stores relevant material, obtained with appropriate consent, from deceased donors. This may be supplied to other establishments for research purposes. Frozen samples are stored separately to tissue intended for human application, in a

designated -80 freezer within the bone bank. The establishment also holds blocks and slides of relevant material, from the same donors.

This routine inspection was the establishment's fourth site visit. The visit to the hub site, at Glenfield Hospital, included a visual inspection of the storage facilities, interviews with the DI, bone bank staff and the Corporate Licence Holder and a review of the establishment's policies, training and procedural documentation. In addition to a review of all licensable activities undertaken and co-ordinated by the hub site, the inspection included visits to four of the satellite sites: Airedale Hospital, Barlborough NHS Treatment Centre, Lincoln County Hospital and Pilgrim Hospital Boston. The visits to the satellite sites included meetings with staff involved in storage of bone and obtaining consent, a review of each satellite's site file and freezer logs and a visual inspection of the facilities.

A number of tissue audits were undertaken during the inspection. A minor transcription error was identified for one record in the electronic database; however all femoral heads were traceable from donor to the bone bank and from the bone bank to the recipient. No other anomalies were found.

Four femoral heads, which were being stored for end use, were selected from the freezers at satellite sites. For each of these, the unique number assigned to the femoral head was listed on the local paper log sheet and could be traced to the electronic database at the hub site. Donor records were checked for each of these, including a signed consent form and results from serology and microbiology tests. One case, where a femoral head had been transplanted into a recipient at the Airedale site, was selected. In this instance, the use of the tissue was correctly recorded, alongside the unique donation number, on the freezer log. Recipient details were also held by the hub site, alongside a complete donor record.

Four cases, where bone had been procured, were selected from the freezer logs at satellite sites. In three cases, these femoral heads had been assigned a unique identifier and could be located in the long term storage freezers at the hub site. In the fourth case, the femoral head was unsuitable for clinical use and had been disposed of by the bone bank. This was appropriately recorded by the establishment.

The identification number for a heart valve held in storage was also cross-checked against the electronic and paper records that are held for these items. No discrepancies were found. The establishment records the receipt of the tendons and the centre to which they are distributed and a review of these records was undertaken. No discrepancies were found. However, a review of the SLA in place for the storage and distribution of tendons showed that it did not accurately record the agreed responsibilities of Leicester Bone Bank and the other licensed establishment importing the tissue. Further details of this are described in the inspection findings.

An audit of samples held in storage for research use was also performed. Consent forms for two donors were reviewed and these could be linked to the electronic database, which held the sample inventory. Records for both donors were found to appropriately reflect the storage locations and distribution records for each sample taken.

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.	Although the establishment had an SOP in place for the registration of tendons in the establishment's tissue database, there was no documented procedure in place for the receipt and dispatch of tendons. Furthermore, the Service Level Agreement in place for the storage and distribution of tendons, did not accurately record the agreed responsibilities of Leicester Bone Bank with regard to the dispatch of end user agreements and the maintenance of traceability records.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.		
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.		
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.		

Advice

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

No.	Standard	Advice
1.	GQ1b	As the establishment has made a number of changes to their procedures, the DI is advised to conduct a review of the establishments SOPs, to ensure that they reflect current practices. Suggested amendments include: removing historical references to the irradiation of bone; updating SOPs for end users of bone to reflect the change in bone pots; documenting a maximum storage time for femoral heads when they are supplied on dry ice; and, clarifying the statement regarding retrieval of bone for autologous use in SOP 6/08 .
2.	GQ1b	The DI is advised to implement an SOP which details the process for completing the freezer logs, or to ensure that this process is fully documented within existing documents, such as SOP 9.1/04.
3.	GQ4h/j	The DI is advised to review the procedures, at satellite sites which procure bone, for recording the products and materials that come into contact with the tissues and cells. This is to ensure that, for consumables that are not supplied by the hub site, an audit trail is maintained for each donation.
4.	GQ1p	The DI is advised to consider implementing a condensed format of the end user agreement that is currently supplied for ad hoc users of bone.
5.	PFE2a	Although the tissues stored for research and human application are stored in separate, designated freezers, the same labelling system is used for quarantined tissue and tissue stored for research purposes. The DI is advised to amend the labelling on the designated research -80 freezer to reflect that samples stored in this freezer are not intended for use for human application.
6.	GQ5 (HT Act 2004)	When the agreement for the supply of research tissue is next reviewed, the DI is advised to amend this document so that the appropriate references to the legislation and HTA Codes of Practice are included.
7.	-	The DI is advised to conduct a regular review of all records pertaining to the activities carried out across satellite sites. As part of this, it is the responsibility of the DI to ensure that, in accordance with HTA Licence Annex B - Standard Conditions, that the HTA is informed of changes to licensable activities and nominated personnel, across all sites on the licence.

Concluding comments

A number of areas of good practice were observed over the course of the three day inspection.

Procedures for obtaining consent are well defined; a documented training programme is in place and the establishment staff are committed to continuous evaluation and improvement of their processes.

Tissue governance within the establishment is well managed. Each femoral head that is procured under the establishment’s licence is assigned a unique reference number and tissue that has been released for clinical use is clearly segregated and marked as such.

Leicester Bone Bank provides a high level of support to its satellite sites and to the end users of bone that it supplies. Each satellite site is visited on a regular basis and the site files, held at each satellite, ensure procedural consistency across all sites. Staff training requirements for each satellite are also reviewed and updated, as needed. The frequent site visits and regular checks, that are undertaken by staff from the hub site, are all recorded to provide an audit trail for these activities.

There are some areas of practice that require improvement, including a minor shortfall relating to the procedures and agreements in place for the storage and distribution of tendons. The HTA has given advice to the Designated Individual with respect to SOPs, end user agreements, labelling of designated research freezers and licence management.

The HTA requires that the Designated Individual 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 18 September 2013

Report returned from DI: 01 October 2013

Final report issued: 14 October 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: 15 November 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.