Site visit inspection report on compliance with HTA minimum standards

The Derby Bone Bank

HTA licensing number 11029

Licensed for the

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

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

25-26 March 2019

Summary of inspection findings

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

Although the HTA found that The Derby Bone Bank (the establishment) had met many of the HTA's standards, nine minor shortfalls were found in relation to: the absence of a documented procedure for obtaining consent; the absence of a documented procedure for managing non-conforming tissue; the absence of a documented procedure for managing returned products; the absence of agreements with external testing organisations; incomplete recording of products and material coming into contact with tissues and cells; the absence of a documented procedure for ensuring that the Single European Code (SEC) is recorded in the recipients' medical records; the absence of a documented procedure for managing non-reportable incidents; a lack of awareness of the types of adverse event which should be reported to the HTA and; a lack of availability of risk assessments, for staff, for HTA-licensed activities.

Advice has been given relating to the Governance and Quality, Premises, Facilities and Equipment, and Disposal standards, as well as advice on licence management.

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

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

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

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licenses 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 Category; Tissue Type	Procurement	Testing	Storage
Musculoskeletal, Bone; Bone	**E**	**E**	**E**
Other; Cartilage (ATMP)	**E***	**E***	

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the Derby Bone Bank (the establishment), which was issued an HTA licence in May 2009. This was the sixth HTA site visit inspection of the establishment (the last inspection was in March 2017) and the first since the amended Human Tissue (Quality and Safety for Human Application) Regulations 2007 came into force on 1 April 2018 [Q&S Regulations (as amended)]. The current inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards.

The Derby Bone Bank has been operational since 1994. It is licensed under the Q&S Regulations (as amended) for the procurement, testing and storage of tissues and cells for human application. Licensed activities occur in the pre-admissions clinic, the operating theatre complex, the Bone Bank storage area and the Department of Microbiology.

The establishment is also licensed under the Human Tissue Act 2004 (HT Act) for the storage of relevant material for use for a scheduled purpose but it does not currently store any relevant material for use for a scheduled purpose under this licence (see *Advice*, item 1).

The DI is a Lead Practitioner for Orthopaedic Theatres, the Corporate Licence Holder (CLH) is the University Hospitals of Derby and Burton NHS Foundation Trust, and the CLH Contact (CLHC) is the Surgery Division Nursing Director. There are six Persons Designated (PDs) working under the licence: two Senior Staff Nurses, the Lead Patient Co-ordinator for Bone Donation, a Lead Practitioner in Hand Theatres, the Professional Development Facilitator (Orthopaedic Theatres) and the Microbiology Service Manager - Derbyshire Pathology.

Procurement

The establishment procures femoral heads from patients undergoing elective hip replacement surgery. At a pre-operative assessment visit all patients scheduled for hip replacement are given a bone donation information sheet. If the patient agrees to donate their femoral head, consent for donation and two blood samplings are sought by trained nurses. The pre-assessment nurses also take the patient's medical and social history and blood samples for mandatory serology testing; this takes place up to 30 days before the operation [see shortfall against standard C1(a)]. A copy of the consent form is retained in the patient's hospital notes and a copy is provided to the consented patient.

Following procurement the femoral head is washed with sterile saline and double-potted in validated sterile containers. The outer pot is placed in a clear plastic bag and a unique pot serial number is allocated to each femoral head from the Bone Bank folder along with the donor's addressograph label that is affixed to the outer pot. The femoral head is then taken to the Bone Bank for storage.

A swab of the outer surface of the femoral head is placed in a culture medium bottle and this, along with a chip from the cut end of the procured bone, is sent to the Department of Microbiology for microbiological testing.

Storage

The Bone Bank consists of two locked -80°C freezers which are located in the access-controlled theatre area. Donated bone is stored in the 'quarantine freezer' and paper records of bone receipt and storage are kept in a Bone Bank ledger, along with individual donation records. These are all kept in a locked cabinet next to the freezers. Sample location is indicated in the ledger and on a whiteboard chart.

Once the initial and the 180-day serology, and microbiology test results are reviewed the results are recorded in the Bone Bank ledger. The results are reviewed by the microbiology consultant. If they are negative, the clear plastic bag containing the bone jars is changed on transfer and the donor patient details form is updated along with the date the bone is moved to the 'release freezer'. The move is also recorded on the whiteboard chart and the notes are moved from the quarantine to the release cabinet drawer. Any samples with positive results are confirmed by the reference laboratory. If both sets of results are positive, the femoral heads are disposed of according to the Trust's disposal policy, following a two-person check of the unique jar number and donor addressograph.

The majority of femoral heads stored at the establishment are for allogeneic use. Occasionally, femoral heads are also procured for autologous use and are stored in a separate drawer of the -80°C release freezer until required.

The establishment also stores cryopreserved menisci and tendons (used in knee revision and reconstructive foot and ankle surgery; see comments under 'Inspection Findings', below). These are purchased from two HTA-licensed suppliers under the terms of service level agreements (SLAs). The suppliers are responsible for donor selection, consent, procurement, serological testing and transportation. These are stored on a separate drawer in the -80°C release freezer and records are maintained in the Bone Bank ledger.

The -80°C freezers are plugged into a power socket but are not hard-wired to the wall. The temperature is monitored by a wheel chart which is reviewed and replaced weekly. The freezers are fitted with audible and visual alarms and are linked to a continuous temperature monitoring unit feeding into a wired callout system which notifies the switchboard. Temperature excursions outside the set ranges, including power failure, trigger both audible alarms and the callout system, but the system is not tested regularly (see *Advice*, item 12).

The freezers are subject to an annual service and calibration under contract.

Patients consent to transplantation approximately four weeks before surgery. When required, the tissue is removed and taken to the operating theatres for thawing before use. The date of removal and patient number of the recipient are entered into the Bone Bank ledger (see *Advice*, item 8).

Disposal

Tissue is disposed of by incineration and is bagged separately from other clinical waste but the method of disposal (incineration) is not included in the local procedure (see *Advice*, item 13). The date of disposal and the reason are documented.

Contingency

The use of two freezers provides for contingency storage. There is an agreement with a HTA-licensed establishment for further contingency storage.

Testing

The Department of Microbiology laboratories are accredited by the United Kingdom Accreditation Service (UKAS) to International Organization for Standardization (ISO) standard 15189: 2012. The last UKAS inspection was in December 2018. Samples are tested using CE-marked diagnostic kits on automated testing equipment according to manufacturers' instructions. Antibody tests for a range of viruses and bacteria are carried out, including HIV-1 and 2, HBsAg, HBc and HCV. *T. pallidum* and HTLV-1 testing take place at separate HTA-licensed establishments [see shortfall against standard GQ1(p)]. Repeat serology testing is performed 180 days post-surgery. Depending upon the marker, confirmatory serology and Nucleic Acid Amplification Technique (NAT) testing takes place either locally or at one of the other HTA-licensed establishments.

The department routinely takes part in external quality assessment schemes for the above tests.

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection report, communications with the HTA since the last inspection and annual activity data. The inspection included a visual inspection of the tissue

procurement and storage areas, area for tissue receipt and the serological testing laboratory. Discussions and interviews were held with key staff and documentation was reviewed. Two discussions were held with the Quality Management Teams and interviews were held with a PD (Donor Patient Co-ordinator), the DI and CLHC.

Audits of traceability were carried out:

1. Two units of bone (procured femoral heads) were selected at random from the quarantine freezer and three units (two procured femoral heads, one purchased tendon) were selected at random form the release freezer. Labelling details, details of order, receipt and storage, and location were checked in the Bone Bank ledgers. There were no discrepancies noted.
2. A total of four donor/recipient files were reviewed to ensure that they contained all relevant documentation, including serology and microbiology results. A further one file was reviewed for tissue which had been disposed. There were discrepancies noted [see shortfall against standard GQ4(j) and *Advice*, item 5].
3. The training records of two representative members of staff who handled the products were checked. There were no discrepancies noted.

Inspection findings

The HTA found the DI and the CLH to be suitable in accordance with the requirements of the legislation.

However, since the last inspection, the establishment has stored menisci on a few occasions. The HTA considers this a breach of the standard condition of the establishment's licence that requires it to seek approval from the HTA prior to it storing a new type of tissue and/or cells.

The HTA will consider the need for regulatory action in relation to this matter separately to the inspection findings reported below.

Compliance with HTA standards

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code 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.	Although there is a wide range of documentation on the consent process, there is no documented procedure on obtaining donor consent. Specifically: • When consent for bone donation and donor serology is taken. • When donor serology samples are taken. • The documentation to be provided. • The staff authorised to take consent.	**Minor**

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.		
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	There is no documented procedure for identifying and managing non-conforming tissue received from suppliers.	**Minor**
k) There is a procedure for handling returned products.	Tissue removed from the freezer that is not subsequently used but is placed back in the freezer is considered a 'returned product'. There is no documented procedure for managing returned products.	**Minor**
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.	During the inspection, the establishment was unable to provide evidence of SLAs with the external testing organisations.	**Minor**

GQ4 There is a systematic and planned approach to the management of records.		
j) Records are kept of products and material coming into contact with the tissues and / or cells.	During the inspection, the establishment was unable to provide evidence that batch records for microbiological swabs and saline are recorded on a consistent basis.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	There is no documented procedure for ensuring that the Single European Code (SEC) on tissue provide by external suppliers is recorded in the recipients' medical records to ensure full traceability from receipt to end use.	**Minor**
GQ7 There are systems to ensure that all adverse events 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.	The establishment has a documented procedure for recording and managing serious adverse events and reactions (SAEARs) but there is no comparable procedure for the management of non-reportable incidents.	**Minor**
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.	During the inspection, it was found that one potential SAE had not been reported to the HTA. Although there is a documented procedure for managing SAEARs there is no description of the types of events which constitute a SAEAR and there is no indication that staff are aware of these types of event.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
c) Staff can access risk assessments and are made aware of local hazards at training.	Although there is a detailed suite of risk assessments there is no evidence that these are readily available to staff.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI is advised to consider revoking the licence held under the HT Act from the establishment's portfolio of HTA licences as this licence is not being used.
2.	N/A	DI is advised to remove the activities of cartilage (ATMP) procurement and testing from the licence held under the Q&S Regulations (as amended) as the establishment is not currently carrying out these activities.
3.	GQ1(b)	The DI is advised to consider introducing a documented procedure for acquisition of Rh (negative) tissue for mothers of child-bearing age.
4.	GQ1(c)	The Trust is the CLH on two HTA licences. There are currently no meetings between DIs and individuals named on these two licences. The DI and CLHCs are advised to consider setting up joint governance meetings involving staff on all of these licences as an opportunity for shared learning.
5.	GQ2(b)	The establishment currently carries out detailed procedural audits but few horizontal or vertical audits of stored material and associated records. The DI is advised to consider adding further horizontal and vertical audits to the establishment's audit schedule. This is especially important since it was identified during the HTA traceability audit that one record had an incorrect expiry date for the bone and two records did not have pot serial numbers.
6.	GQ3(f)	The DI is advised to consider incorporating the relevant parts of the 'Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment' as part of the establishment's current regulatory training programme. In addition, the DI is advised to consider including examples of SAEARs and the requirement to report SAEARs to the HTA within 24 hours of discovery.
7.	GQ4(e)	The DI is advised to consider using a two-person check for tissue placement into storage, retrieval from storage, confirmation of identity prior to thawing and confirmation of identity prior to disposal.
8.	GQ4(e)	The DI is advised to consider adding the following to the Bone Bank ledger: • The time from release by the supplier to deposit in the freezer. • The time of removal of the tissue for transplantation.
9.	GQ7(f)	There is no documented procedure to cover a recall initiated by tissue suppliers in terms of who should respond and how this should be carried out.
10.	GQ8(a)	The establishment has a risk assessment for tissue storage. The DI is advised to consider expanding this to cover the frequency of freezer

		cleaning and decontamination.
11.	PFE1(a)	The DI is advised to consider expanding the Derby Bone Bank risk assessment of the premises to cover the procurement and testing areas.
12.	PFE3(c)	The DI is advised to consider challenging the audible temperature alarms and temperature alarm callout system on a regular basis to ensure that it is functioning correctly.
13.	D2(a)	The DI is advised to consider adding the method of disposal to the local procedure on disposal.

Concluding comments

During the inspection, areas of strength and good practice were noted:

- The Bone Bank is managed by a very experienced and dedicated team.
- There is a detailed consent training programme and refresher consent training is delivered annually with an assessment by an orthopaedic surgeon.
- There is a detailed and thorough independent audit conducted by the DI of another bone bank
- Bone Bank staff have developed a detailed competency training matrix for theatre personnel.

There are a number of areas of practice that require improvement, including nine minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality, Premises, Facilities and Equipment, and Disposal standards, as well as advice on licence management.

The HTA requires that the DI 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: 16 April 2019

Report returned from DI: 29 April 2019

Final report issued: 28 May 2019

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: 6 February 2020

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 002/2018 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 002/2018 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.
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.
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 002/2018.
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.
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.
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 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
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 002/2018 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.
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 002/2018.
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 002/2018.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
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.
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.
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.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that

have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
d) Records are kept of transportation and delivery.
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.

Human Tissue Act 2004 Standards

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.
c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.
e) Language translations are available when appropriate.
f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.
b) Records demonstrate up-to-date staff training.
c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records. b) There are provisions for back-up / recovery in the event of loss of records. c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems. b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. b) Risk assessments are reviewed regularly.

c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it. b) A register of donated material, and the associated products where relevant, is maintained. c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom. d) A system is in place to ensure that traceability of relevant material is maintained during transport. e) Records of transportation and delivery are kept. f) Records of any agreements with courier or transport companies are kept. g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice. b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity. b) Where relevant, storage arrangements ensure the dignity of the deceased. c) Storage conditions are monitored, recorded and acted on when required. d) There are documented contingency plans in place in case of failure in storage area.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. b) Users have access to instructions for equipment and are aware of how to report an equipment problem. c) Staff are provided with suitable personal protective equipment.

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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to 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 represents a systemic failure and therefore is 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 straight away.

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 the proposed action plan the establishment will be notified of the follow-up approach the HTA will take.