**Site visit inspection report on compliance with HTA minimum standards**

**Glenfield Hospital**

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

**25-29 September 2017**

## 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.

Glenfield Hospital (the establishment) where the Leicester Bone Bank is located was found to have met all HTA standards. Since the previous inspection in September 2015, there has been a change in the HTA Designated Individual.

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.

'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 | Testing | Storage | Distribution |
|---|---|---|---|---|
| **Bones** | **E** | **TPA** | **E** | **E/TPA** |
| **Tendons and Menisci** | | | **E** | |
| **Cardiac tissue, heart valves** | | | **E** | |

**Background to the establishment and description of inspection activities undertaken**

Glenfield Hospital (the establishment) is where the Leicester Bone Bank is based. It was set up in 1991 and supplies bone for transplants to hospitals throughout the UK. The Bone Bank has been licensed by the HTA since 2008 when the Quality and Safety for Human Application Regulations came into force. The hub site at the Glenfield Hospital is licensed for procurement, donor testing, storage and distribution of tissues and cells for human application. The licence holder is the University Hospitals of Leicester NHS Trust and the licence holder contact is the Director of Clinical Quality.

Staff based at the hub site oversee licensable activities undertaken at eleven satellite sites where storage (s) and/or procurement (p) or distribution (d) take place - Airedale Hospital (s), Barlborough NHS Treatment Centre (p, s), Bradford Royal Infirmary (s), Broomfield Hospital (s), Calderdale Royal Hospital (s), Lincoln County Hospital (s), Leicester General Hospital (p, s), Leicester Spire Hospital (p, s), Norfolk and Norwich University Hospital (s, d), Nuffield Orthopaedic Centre Oxford (s) and Pilgrim Hospital Boston (s). Glenfield Hospital also stores

and uses heart valves and cardiac patches supplied by another HTA licenced establishment which are used in paediatric surgery. Cardiac tissue is stored in a locked -80$^0$C freezer near theatres.

This was the sixth routine site visit inspection of Leicester Bone Bank and included a visual inspection of the hub site and the following satellite sites where storage (s) or procurement (p) take place - Barlborough NHS Treatment Centre (p), Calderdale Royal Hospital (s), Nuffield Orthopaedic Centre Oxford (s). The inspection also included a visit to Leicester Royal Infirmary where mandatory donor serology testing and product testing of bone procured at Leicester General Hospital and Spire Hospital takes place. The inspection team also visited the microbiology laboratory at Kings Mill Hospital where swabs and bone chips from bone procured at Barlborough NHS Treatment Centre are tested.

Interviews were held with the DI (Medical Lead for Bone Bank and Consultant Orthopaedic Surgeon) and the Head of Service. Discussions were also held with the Assistant Head of Service, the Site Supervisor (satellites in the Leicester area) and persons designated (PD) based at the satellite sites visited by the inspection team.

Consent for bone donation is sought from potential donors who are provided with information about bone donation. Trained staff undertake medical assessment of donors and seek consent before bone is procured. Donors who undergo hip surgery at Leicester General Hospital are consented over the telephone; these discussions are recorded and stored. Donors who undergo surgery at Barlborough NHS Treatment Centre and Leicester Spire Hospital have face to face meetings with trained staff who undertake donor assessment and seek consent which is recorded in writing and documented within the donor's notes. Consent forms are sent to the hub site.

Femoral heads are procured during elective hip replacement surgery. Trained theatre staff take a bone chip from the neck of the femoral head to detect any systemic infection. The procured femoral head is washed with saline and swabbed just before it is placed in a sterile tamper evident screw capped pot which is in turn placed in a second sterile tamper evident screw capped pot. The swab is tested to detect any contamination which may have occurred during procurement or handling of the bone. The pots are labelled with the donor details and the date of the procurement. Theatre staff then place the bone in a quarantine freezer.

Donor testing is undertaken on bloods samples collected on the day of donation. The blood samples are collected in serum-separating tubes and used for mandatory testing including serology and nucleic acid testing (NAT). The blood sample is stored at -20$^0$C until it is ready to be tested. Serology testing takes place under a third party agreement with Leicester Royal Infirmary which has Clinical Pathology Accreditation. NAT testing takes place under a Service Level Agreement with another HTA licensed establishment. All donors are tested for HTLV - I/II; repeat testing after 180 days will only take place if indicated following a risk assessment.

Product testing *i.e.*microbiology testing of swabs and bone chips from procured femoral heads is undertaken at Leicester Royal Infirmary and King's Mill Hospital, Nottinghamshire. The establishment disposes of donated bone if the swabs or bone chips test positive for microbial contamination.

The hub stores all donor records, a central stock list and the location of stored bone at the hub site and satellite sites. Satellite sites are provided with a site file, which contains contact details of staff at the hub, relevant standard operating procedures (SOPs), and freezer log sheets used to log the storage and removal of bone from each freezer.

Staff from the hub site visit the satellite sites on a regular basis to collect and transfer procured bone to the hub site. Each femoral head is assigned a unique ID number which includes the year and consecutive donation number, is weighed and is stored in designated quarantine freezers until being authorised for use. Staff use validated containers containing

dry ice or freezer packs to transport bone between the hub and satellite sites. The DI, Head of Service and the Assistant Head of Service review consent forms, donor assessment records, donor test results and microbiology test results in order to decide whether or not to authorise the use of each donated femoral head for transplantation. Authorised bone is transferred to the designated 'ready to be transplanted' freezers for long term storage; the expiry date is five years after the date of procurement. All donor identifiers are removed from the pots before they are distributed for transplantation.

The hub site and satellite sites store bone in -80$^0$C chest/ or upright freezers. The hub site has five chest freezers - three quarantine, one 'ready to be transplanted' freezer and one contingency freezer. All freezers are continuously temperature monitored using probes, and an independent proprietary wireless monitoring system which sends a text when the temperature deviates from the specified limits (minimum -90$^0$C and maximum -60$^0$C). The temperature of each freezer can be checked remotely. Satellite sites where procurement takes place are provided with two freezers - one quarantine freezer for freshly procured femoral heads and the second freezer for bone which is ready to be used for transplantation. Freezers are plugged into sockets on an emergency power supply line in the event that the power supply is interrupted. The hub is responsible for maintaining and calibrating the freezers and checking the alarm system.

Staff at the hub site provide training to pre-assessment nurses, consent seekers and theatre practitioners at the hub and satellite sites as appropriate. Training includes information about the HTA standards and role play is used to embed learning. Refresher training is provided every three years. Training is also provided to theatre staff at satellite sites where storage for enduse takes place. Staff from the hub site collect paperwork, check freezer logs, review stock levels, replenish stock and collect procured bone, as appropriate.

Hospitals order bone by completing a 'Femoral Head Order Form' which includes the name of the hospital, surgeon, patient details, blood group, date of surgery and size of femoral head requested. The bone bank takes care to ensure that bone from Rhesus negative donors is allocated to Rhesus negative women of child bearing age. Staff at the hub site arrange for a designated courier service working under a third party agreement to transport bone to other endusers. The pot containing bone is packaged in dry ice and the container is sealed with adhesive tape which is in turn covered with a large self sticking Bone Bank label. The use of the large label enables staff to determine if the package has been tampered with or opened after it was dispatched from the Bone Bank. Bone once dispatched cannot usually be returned. If surgery is to take place at a satellite site where bone is currently stored, staff at the hub site allocate a femoral head in storage at that site for use in surgery.

The HTA team was informed that there were no tissue samples being stored for the scheduled purpose of research. The HTA understands that all samples which were previously stored on site had been transferred to another organisation where they are to be used for a research project.This inspection did not review traceability or transport of these samples. The inspection team was also informed that the establishment no longer stores tendons and menisci imported by another HTA licensed establishment.

Staff attend regular meetings with the DI. Guidance relating to new and emerging infections issued by JPAC (Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee) are discussed along with operational issues. Regular audits take place and actions are taken to address non-conformances. Incidents are reported and investigated and risk assessments are undertaken as appropriate.

A document review was undertaken. The quality manual, SOPs covering donor selection, rationale for medical history/lifestyle questions for femoral head donors, the procedure used to interview and assess potential femoral head donors, the telephone script used to interview and consent potential donors, procedure for retrieval of femoral heads, checks undertaken

during site visits, agreements with endusers and instructions to endusers who receive bone for implantation were reviewed. The agreements included the requirement to report serious adverse events and reactions to the hub site within 24 hours of discovery.

The SLA and TPA agreements as appropriate, between the Bone Bank and providers of the following services were reviewed – microbiology laboratory at Leicester Royal Infirmary for donor testing; provider of NAT testing services, provision of wireless temperature monitoring service; provision of freezer maintenance and probe calibration service; courier service for transport of tissues. Agreements between University Hospitals Leicester NHS Trust and Trusts or organisations where the satellite sites are located were also reviewed.

Audit trails were undertaken on seven femoral heads which were transplanted, five femoral heads in storage at the hub site (three in quarantine freezer and two in the 'ready to be transplanted' freezer) and four femoral heads stored at the satellite sites. Records of consent, medical questionnaires, information recorded on the 'Femoral Head Donor Data sheet', microbiology test results for the bone chip and the swab, donor serology test results, nucleic acid test results and authorisation of bone for transplant by the Head of Service and Deputy Head of Service, records in the recipient's clinical notes, as appropriate, were reviewed. There were no discrepancies. The HTA team also listened to a recording of an interview and consent conversation with a potential donor.

Additional medical history/lifestyle assessments undertaken for a selection of donors in order to address a non-conformance were evidenced during the audit trail.

Records relating to a pulmonary patch stored near the theatres, including the unique number, supplier of the tissue and transport were checked. There were no discrepancies.

The establishment uses an electronic database to store information on donor/recipient traceability. Another database is used for management purposes to track movement of bone from one freezer to another. A third database which can combine the functions of the other two databases is currently in development and was not reviewed during this inspection.

### 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

All applicable HTA standards have been assessed as fully met.

### Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | GQ1k | The DI is advised to expand the statement in SOP 7.7/01 'tissues cannot usually be returned once dispatched' to clarify the exceptional circumstances when tissues once dispatched, can be returned. For example the Bone Bank will not accept tissues if the transport box has been opened, or if several hours have elapsed since the bone was dispatched. |
| 2. | GQ1s | The DI is advised to include a statement in the TPA with the courier which states that the establishment will be informed if there has been any transport related incidents including mishandling, in addition to delays in delivery. |

| | | |
|---|---|---|
| 3. | PFE4e | The DI is advised to amend SOP 7.9/02 – Dispatch arrangements for femoral heads' to include step by step instructions for sealing the box and covering the seal with the large Bone Bank label so that there would be clear evidence of tampering, should any tampering take place. |
| 4. | NA | The DI is advised to review and update sections in the Quality Manual which state the role and responsibilities of the DI and Corporate Licence holder contact and remove the statement on page 23, which is not followed by the Bone Bank and appears to suggest that the expiry date of bone can be increased to five years if it is transferred to below -40$^0$C after being stored at -20$^0$C. |

*Following the inspection the HTA was informed that the Quality Manual, SOP 7.7/01 and SOP 7.9/02 were updated to reflect advice items 1,3 and 4 above.*

**Concluding comments**

There were many areas of good practice. The establishment has experienced, committed, long-serving staff who work together to ensure that a robust system of governance is in place to cover the hub site and satellite sites. Staff based at the hub site undertake weekly visits to satellite sites where procurement takes place to meet staff and collect procured bone. Staff also undertake regular visits to sites where bone is stored to deliver bone, undertake audits of bone and tendons in freezers, test freezer alarms and provide training, if required. There is an effective system to monitor training of staff at satellite sites which ensures that all members of staff at those sites who undertake licensable activities undertake induction training and refresher training as appropriate.

There are regular quality meetings where the DI and staff discuss non-conformances, audits, training needs and any changes to procedures. There are robust systems in place for monitoring the temperature of freezers used to store bone and heart valves, testing of alarm systems and taking action in the event of freezer failures.

The HTA has given advice to the Designated Individual with respect to reviewing and updating documents to reflect current practice and updating the TPA with the courier responsible for transporting bone to endusers. Following the inspection, the HTA was informed that the establishment acted on the advice provided by the HTA.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

**Report sent to DI for factual accuracy: 30 October 2017**

**Report returned from DI: 13 November 2017**

**Final report issued: 23 November 2017**

## 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. |

**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.<br>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.<br>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.<br>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.<br>e) Language translations are available when appropriate.<br>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.<br>b) Records demonstrate up-to-date staff training.<br>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.<br>b) There is a document control system.<br>c) There are change control mechanisms for the implementation of new operational procedures.<br>d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.<br>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.<br>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.<br>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.<br>b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.<br>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.<br>b) Where relevant, storage arrangements ensure the dignity of the deceased.<br>c) Storage conditions are monitored, recorded and acted on when required.<br>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.<br>b) Users have access to instructions for equipment and are aware of how to report an equipment problem.<br>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 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 shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

*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 breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

*or*

A shortfall which indicates a failure to carry out satisfactory procedures 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.

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.