

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

### **NHSBT Liverpool – The Horder Centre for Arthritis**

#### **HTA licensing number 11018 (Satellite)**

##### **Licensed for the**

- **procurement, storage and distribution 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**

**22 November 2018**

#### **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 Horder Centre for Arthritis (the establishment) had met the majority of the HTA's standards, one minor shortfall was found in relation to the lack of availability of risk assessments, for staff, for HTA-licensed activities.

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

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

## The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual (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.

Tissue Category; Tissue Type	Procurement	Storage	Distribution
Musculoskeletal, Bone; Bone	E	E	E

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

This report refers to the activities carried out by the Horder Centre for Arthritis (the establishment), which was issued an HTA licence in March 2008. This was the second HTA site visit inspection of the establishment (the last inspection was in February 2014) 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 Horder Centre for Arthritis is one of two satellites of NHS Blood and Transplant (NHSBT) Liverpool licensed under the Q&S Regulations (as amended) and is part of NHSBT's live

bone donation programme. It is licensed for the procurement, storage and distribution of tissues and cells for human application (see *Advice*, item 1).

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).

NHSBT Liverpool has entered into Service Level Agreements (SLAs) with each of its satellites ('agreement for the surgical bone donor programme') which detail each party's roles and responsibilities (see *Advice*, item 2). NHSBT Liverpool has appointed an 'authorised responsible person' at each satellite and this individual is also the Person Designated (PD) under the HTA licence.

The DI of NHSBT Liverpool is the Director of Quality, the Corporate Licence Holder (CLH) is NHSBT Liverpool and the CLH Contact (CLHC) is the Interim Chief Executive Officer. The PD working under the licence at this satellite is the Surgical Care Practitioner - Theatre Manager.

## Procurement

The establishment procures femoral heads from patients undergoing elective hip revision and replacement surgery. Pre-operative assessment nurses, trained to seek consent, will identify, approach and consent suitable patients scheduled for a hip operation. Consent is obtained for the procurement of the femoral head and for mandatory serology tests. A copy of the consent form is retained in the patient's hospital notes at the establishment, a copy is provided to the consented patient, a copy is retained by NHSBT and a copy remains with the procured bone and accompanying blood sample for serology testing.

Trained staff at the National Referral Centre (NRC) at NHSBT Liverpool are responsible for taking the patient's detailed medical and social history over the telephone to ensure that the donor is suitable. The 'surgical bone medical questionnaire' is completed by the NRC Specialist Nurse and is reviewed and authorised by the Clinical Support Team. The completed paper document is retained by NHSBT Liverpool.

NHSBT Colindale sends labels containing a unique donor identity number ('G' number) to the establishment. Neither the establishment nor NHSBT Colindale apply the Single European Code (SEC); this is applied at NHSBT Liverpool before distribution to end users.

A pre-operative blood sample for mandatory serology testing is taken on the day of procurement (see *Advice*, item 3). Procurement of femoral heads takes place using bone donation kits supplied by NHSBT Colindale. Each serial-numbered kit contains sterile, tamper-evident pots for storage of the femoral heads, bottles of culture media for sterility testing of bone chips taken from the femoral head and blood draw tubes for serology testing. The kits are stored in a dedicated locked container adjacent to the freezer within a secure area of the hospital. Staff monitor the temperature of the container with a maximum and minimum thermometer daily to ensure that the temperature range for the culture media bottles has not been exceeded. Following removal of the femoral head, two bone chips are taken from the cut end of the procured bone and placed in the culture media bottles for analysis. The bone is placed into an inner container which is placed in a secondary container by the scrub theatre nurse.

## Storage

Once surgery is complete, the paperwork recording details of the procurement are sent to NHSBT Liverpool. Two members of staff place the femoral head containers and the culture media bottles into a locked -40°C freezer for short-term storage together with the centrifuged

blood samples for serology testing. The culture media has been validated for storage at this temperature. The freezer is linked to a continuous temperature monitoring unit which feeds into a wired callout alarm system linked to the hospital switchboard. Temperature excursions outside the set ranges trigger both audible alarms and the callout system, although the system is not tested regularly (see *Advice*, item 4). A work instruction, laminated and applied to the front of the freezer, details the procedures staff must follow to contact the Tissue and Eye Services Duty Manager. There is also a list of relevant staff for the switchboard to contact. The freezer is linked to the hospital's emergency power supply to mitigate the risk of sample loss due to a power outage.

Once a fortnight, staff from the tissue donation team at NHSBT Colindale visit the centre to collect the procured femoral heads, culture media bottles and blood samples, to review temperature logs for the freezer and kit container and to replenish bone donation kit stocks. A risk assessment of the freezer is also performed at this time. Blood samples are sent to NHSBT Manchester for testing; if the volume of blood is less than 10 ml the blood sample is tested at NHSBT Colindale. The culture media bottles are analysed at NHSBT Colindale and the bone is transferred to NHSBT Liverpool for storage and eventual distribution to end users. The establishment does not dispose of any tissue directly and non-conforming consignments are transported to NHSBT Liverpool for disposal.

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 freezer storage area located outside the operating theatre and a roundtable discussion with staff from NHSBT Colindale, who are responsible for overseeing the service. Documentation was also reviewed.

Audits of traceability were carried out:

- Three femoral heads were selected at random from the freezer. Labelling details and the storage location was cross-checked with appropriate records and the donor file was reviewed to ensure that it contained the live bone donor tissue tracking record, the live bone donor consent form and the live bone donor file checklist. 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.

## Compliance with HTA standards

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

#### Governance and Quality

Standard	Inspection findings	Level of shortfall
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 are risk assessments for licensed activities, these are not currently available to staff.	<b>Minor</b>

#### 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 removing the activity of 'Distribution' on the licence held under the Q&S Regulations (as amended) as a licence for distribution is only required when tissues and cells are released for end use.  The DI is also 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.	GQ1(p)	During the inspection, it was noticed that the SLA between NHSBT Liverpool and the establishment refers to the archived HTA Code of Practice on 'Consent (Code 1)' and not the current HTA Code of Practice 'Guiding Principles and the Fundamental Principle of Consent (Code A)'. The DI is advised to consider updating the SLA to reflect current guidance.
3.	GQ5(f)	Although blood samples for donor testing are clearly labelled with a unique donor code, the time of donation and place are not recorded. The DI is advised to ensure that these are recorded on the blood sample label.
4.	PFE3(c)	The DI is advised to consider challenging the temperature alarm callout system on a regular basis to ensure that it is functioning correctly.

#### Concluding comments

During the inspection, areas of good practice were noted:

- NHSBT has implemented a comprehensive and well-constructed programme of staff training to ensure that those involved in the procurement and storage of femoral heads as part of the live bone donation programme are aware of the procedures they must follow and the regulatory requirements associated with such work. Training material has been tailored to match the requirements of specific roles within the programme and staff in key positions such as the PD have the opportunity to attend additional information days organised by NHSBT Liverpool. Annual refresher training

is mandatory for staff at satellite sites.

- The establishment has good follow-up procedures for both internal and independent audits, with actions assigned to appropriate staff and findings distributed throughout the team.
- There are good follow-up procedures for all deviations, quality exception reports and complaints, with regular discussion at Quality Management Team meetings.

One area of practice was identified during the inspection that requires improvement, resulting in a minor shortfall. The HTA has given advice to the DI with respect to the Governance and Quality, and Premises, Facilities and Equipment standards, as well as advice on licence management.

The HTA requires that the DI addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfall identified during the inspection.

**Report sent to DI for factual accuracy: 20 December 2018**

**Report returned from DI: 7 January 2019**

**Final report issued: 15 January 2019**

## Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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

#### Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
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.
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.
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.
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 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.
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.

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**

<b>Standard</b>
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.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 002/2018.
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.
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

<b>Standard</b>
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.

## Human Tissue Act 2004 Standards

Consent standards
<b>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</b>
<p>a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.</p> <p>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.</p> <p>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.</p> <p>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.</p> <p>e) Language translations are available when appropriate.</p> <p>f) Information is available in formats appropriate to the situation.</p>
<b>C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent</b>
<p>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.</p> <p>b) Records demonstrate up-to-date staff training.</p> <p>c) Competency is assessed and maintained.</p>
Governance and quality system standards
<b>GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process</b>
<p>a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.</p> <p>b) There is a document control system.</p> <p>c) There are change control mechanisms for the implementation of new operational procedures.</p> <p>d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.</p> <p>e) There is a system for managing complaints.</p>
<b>GQ2 There is a documented system of audit</b>
<p>a) There is a documented schedule of audits covering licensable activities.</p> <p>b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.</p>

**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.