Site visit inspection report on compliance with HTA minimum standards

NHSBT

HTA licensing number 11018

Licensed for the

- **procurement, processing, testing, storage, distribution and import/export 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**

16 – 18 September 2014

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.

University Hospital of Hartlepool, Wansbeck Hospital and Northumbria Healthcare NHS Foundation Trust's Hexham General Hospital, which for the purposes of HTA licensing are satellite sites of NHSBT Liverpool, were found to have met all applicable HTA standards. In addition to these satellite sites, Cumberland Royal Infirmary was also visited during this inspection. Cumberland Royal Infirmary is currently licensed as a satellite site for the procurement, storage and distribution of tissue however, procurement activity has now ceased and the establishment is not undertaking any activity under the satellite licence.

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, Licence Holder, premises and practices are suitable.

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

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

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

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

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

University Hospital of Hartlepool

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Femoral heads (Bone) from living donors	**E**			**E**	**E**		

Wansbeck Hospital

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Femoral heads (Bone) from living donors	E			E	E*		

Hexham General Hospital

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Femoral heads (Bone) from living donors	E			E	E*		

Cumberland Royal Infirmary

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Femoral heads (Bone) from living donors	E*			E*	E*		

Background to the establishment and description of inspection activities undertaken

University Hospital of Hartlepool, Wansbeck Hospital and Northumbria Healthcare NHS Foundation Trust's Hexham General Hospital are three of 37 satellite sites of NHSBT Liverpool (the hub). The hospitals have been licensed as satellite sites since September 2007, September 2007 and April 2009 respectively. The satellite licences cover the procurement and storage of femoral heads as part of a live bone donation programme. Although licensed for distribution, Wansbeck Hospital and Hexham General Hospital do not distribute tissue. Collection of procured femoral heads and distribution to the hub premises take place under the hub licence and are the responsibility of NHSBT. NHSBT has entered into an agreement ('Agreement for the surgical bone donor programme') with the hospitals which details each party's roles and responsibilities. NHSBT has appointed an "authorised responsible person" who is the Person Designated under the HTA licence and acts as a key contact for each of the hospitals.

Patients who are scheduled for hip replacement surgery at the satellite sites are offered the chance to donate femoral heads, which are collected and held on behalf of NHSBT Tissue Services. Pre-operative nurses at the hospital who have been trained by NHSBT to seek consent provide information to patients, who are then given time to consider the donation before choosing to give their consent. At the University Hospital of Hartlepool and Hexham General Hospital, a NHSBT consent form and 'Surgical Bone Medical Questionnaire' form is used by the nursing staff seeking consent to obtain and record the patient's medical and social history in order to ensure that the potential donor is suitable for bone donation. At Wansbeck Hospital, nursing staff seek the consent of the potential tissue donor; however, the

nurse does not collect the medical and social history's of potential donors. The collection of the medical and social history is collected over the telephone by staff operating from the NHSBT hub premises. Patients who are assessed as suitable at this stage indicate their consent by signing a bone donation consent form, which is also witnessed by the pre-assessment nurse. One copy of the consent form is provided to the patient, one copy is returned to NHSBT, and two copies are attached to the front cover of the donor's notes (with ISBT 128 barcodes attached) which alerts theatre staff that the patient has provided consent for bone donation. Additionally, the anaesthetist is also alerted to the patient being a bone donor and will then take a blood sample for mandatory serology testing by NHSBT.

NHSBT supplies, to the hospitals, kits which are used to collect the femoral heads. These kits include containers for the procured bone, a blood draw tube for serology testing and microbiology testing reagents. Once alerted to a potential donor, a kit is retrieved from a temperature monitored storage location and taken to theatres in preparation for the collection of the femoral head. Following removal of the femoral head, and once the orthopaedic surgeon is sure that the patient's own femoral head will not be required during their surgery, bone chips are taken from the procured femoral head and placed in the microbiology testing broth for analysis by NHSBT. The procured femoral head is placed into an inner container and then a secondary container by the scrub theatre person.

Once surgery is complete, the paperwork recording details of the procurement, the serology blood samples and a copy of the consent are returned to NHSBT. The pot containing the femoral head and the microbiological testing broth containing the bone chips are placed into a -40^{o}C freezer to be stored while awaiting collection by NHSBT staff. At each of the hospitals, staff monitor and record the temperature of the storage freezers each working day (Monday to Friday). Additionally, maximum and minimum temperatures are recorded daily (Monday to Friday) and each freezer is monitored by a temperature data logger. The data loggers are collected by NHSBT staff when the procured bone is collected and are taken back to the hub site so that the temperature records can be downloaded and reviewed. The data loggers act as the main source of temperature records during the storage of the procured bone prior to collection by NHSBT.

Procured bone and microbiology samples are collected from the hospitals by NHSBT staff on a regular basis. The bone and associated samples are then transferred to the hub site for storage and provided it meets the required quality and safety standards, eventual distribution to end users.

In addition to the procurement programme, the University Hospital of Hartlepool also stores tissue for end use under the satellite licence agreement. Under this agreement, NHSBT supplies a consignment stock of tissue which is stored in a separate 'end use' freezer located in a separate part of the hospital for the site to access. NHSBT staff visit the end use freezers on a regular basis to replace used tissue with new stock. In addition, tissue traceability forms are collected by NHSBT staff and are returned to the hub site to help maintain traceability during end use. Records of tissue used during surgery is also recorded in the recipient patient's clinical notes and electronic theatre records.

During the inspection it was learned that the University Hospital of Hartlepool was also distributing bone for end use to another hospital within the same Trust. Although there was some procedural documentation covering this licensable activity, some documents lack sufficient detail to ensure that distribution takes place as expected. No end user information which instructs the end user hospital on how to record traceability information, how long the tissue can be stored prior to use and how to report serious adverse events and reactions was in place. Additionally, defining an appropriate temperature for transportation and validation of the transport container used for transport to ensure that it maintains this temperature had not been undertaken. Following the inspection NHSBT informed the HTA that the distribution of bone between hospital sites activity had been stopped. Advice has been given below to the

Designated Individual (DI) should he wish to re-commence this distribution activity in the future.

This site visit inspection of the University Hospital of Hartlepool, Wansbeck Hospital and Northumbria Healthcare NHS Foundation Trust's Hexham General Hospital was the first inspection of these satellite sites and included interviews with the persons designated for the satellite sites, pre-operative assessment nurses who seek donor consent and NHSBT staff (satellite co-ordinator, quality and governance representative and the regional tissue donation manager).

A document review was carried out at each of the hospital sites during the inspection. Documents reviewed included (list not exhaustive): the agreement between NHSBT and Friarage Hospital, policies and procedures, audit schedules, audit reports and corrective actions, incident reports, risk assessments, temperature monitoring records, consent records, procurement records and training records. Records of consent and donation that are stored in the donor's clinical notes were also reviewed at the Wansbeck Hospital site. Donor clinical notes were not available at the University Hospital of Hartlepool and Hexham General Hospital sites.

A traceability audit was undertaken as part of the inspection. At the University Hospital of Hartlepool and Hexham General Hospital sites, an audit of a procured femoral head in storage awaiting collection by NHSBT against the procurement records was undertaken. At Wansbeck Hospital, no procured bone was stored in the freezer at the time of the inspection; however, an audit of historical records of three procured femoral heads was undertaken. No traceability anomalies were identified during these audits. However, at Wansbeck Hospital, three examples of consent forms which had not been fully completed were found. On these forms, the question regarding use of procured bone for research, should it not be suitable for use in recipient surgery, had not been completed.

At the University Hospital of Hartlepool, an audit of consignment stock tissue used in recipient surgery was also undertaken. Unfortunately, recipient clinical notes were not provided for review; however, the establishment indicated that there was a record of allogeneic tissue being used in surgery entered into the recipient's clinical notes in addition to the NHSBT unique tissue identifying number. Both of these records are entered into the clinical notes as part of the operation notes section. Additionally, the establishment indicated that the NHSBT unique identifier is also entered onto the establishment's electronic theatre records system.

As clinical notes were not provided, an audit of a femoral head used in a recent surgery was cross-checked against the NHSBT record of use sheets and the theatre's electronic records. A discrepancy was found in this audit with the last digit of the unique identifier not having been transcribed onto the electronic records. Traceability was however still maintained through the NHSBT end use record sheets. Advice had been given below regarding expanding the scope of audits to include the end use consignment tissue so that the DI can assure himself that the full unique identifier is entered into both patient notes and electronic theatre records as expected.

Inspection findings

The HTA found the premises and practices 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.	GQ1(b) PFE4(i) PFE4(j)	The DI is advised that, should distribution of tissue from the Hartlepool Hospital site to the other hospital within the same Trust re-commence, the SOP relating to the transport of tissue to the other hospital within the same Trust should be updated. The update should include more detail of the transport procedure and associated processes regarding transport. The SOP should contain details including but not limited to : • The container which should be used to transport the tissue • The correct tissue packaging • The paperwork which should be included with the transported tissue • The labelling requirments for the transport container • The arrangements for transport of the tissue • Cleaning of the transport container after use.
2.	GQ1(b)	The DI is advised that, should distribution of tissue from the Hartlepool Hospital site to the other hospital within the same Trust re-commence, all other local SOPs relating to the transport of tissue should be reviewed. This review should include the appending of the standardised forms to record shipping and end use to the relevant SOP so that it is clear when reviewing SOPs, which data fields on the forms require completion.
3.	GQ7(g)	The DI is advised that, should distribution of tissue from the Hartlepool Hospital site to the other hospital within the same Trust re-commence, end user agreements should be put in place to help ensure appropriate use and record keeping with regards to the use of tissue. The end user agreement should include as a minimum : • Details on how long tissue can be stored and how to store the received tissue • The receiving establishment's responsibilities with regards to recording and maintaining use and traceability information • The receiving establishment's responsibilities to report serious adverse events or serious adverse reactions to the supplying establishment.

4.	PFE4(g)	The DI is advised that, should distribution of tissue from the Hartlepool Hospital site to the other hospital within the same Trust re-commence, the transport conditions required to maintain the integrity of the tissue during transportation should be defined and documented within the establishment's governance documentation.
5.	PFE4(h)	The DI is advised that, should distribution of tissue from the Hartlepool Hospital site to the other hospital within the same Trust re-commence, the shipping containers used to transport the tissue should be validated. This validation should ensure that the shipping containers can maintain the conditions required to ensure that the tissue's integrity during transport are maintained.
6.	C3(a)	Potential tissue donors, when attending pre-surgical assessment visits during which establishment staff seek consent, often bring other family members such as their spouse, partner or child to the visit. During the consent seeking process, when a medical history is taken from the potential donor, sensitive lifestyle questions are asked. The establishment has already identified that there are potential difficulties for a donor in answering these lifestyle questions with another family member being present during these meetings where consent is sought. The DI is advised to consider updating the annual refresher training given to establishment staff seeking consent. These updates may include further specific guidance to establishment staff who seek consent regarding the lifestyle questionnaire and the questions asked during the consent seeking process. The DI may wish to include advice regarding undertaking one-on-one meetings with potential tissue donors who attend consent seeking meetings during the taking of the donor's lifestyle so that the donor is able to freely discuss any sensitive issues with the consent seeker.
7.	C1(d)	During the audit of donor records, two examples of donor consent forms were seen where the question regarding the use of tissue not used in recipient surgery in research had not been completed. The establishment has already identified variable compliance with the completion of this question, which currently requires the consent seeker to delete part of a statement regarding the use of tissue for research. The DI is advised to continue with plans, which are already in place, to amend the format of the question regarding the use of unused tissue for research purposes so that it becomes a stand alone yes/no question. This change may help reduce the risk of a consent seeker missing or not responding to the question regarding research.
8.	GQ4(i)	During the inspection, the establishment indicated that when end use consignment tissue is used as part of patient treatment, records of its use including tissue identifiers are recorded in the recipient's clinical notes. Although tissue traceability is maintained via other tissue usage records, the DI is advised to consider ensuring that clinical notes for patients who have received allograft tissue are kept for 30 years from the date of use of the tissue so that an additional traceability record is maintained.
9.	GQ8(a)	During the inspection, an example of a risk assessment that had been undertaken at Wansbeck Hospital and Hexham General Hospital, relating to the procurement of tissue, was reviewed. The risk assessment was clear and the risks associated with procuring tissue had been adequately determined and measures to mitigate against these risks identified. However, two of the risks and associated mitigating measures identified related to end use of tissue and

		had been included in the risk assessment in error. The DI is advised to amend the risk assessment to remove references to end use of tissue.

Concluding comments

During the inspection, staff at all satellite sites demonstrated an awareness of the legislative requirements relating to the licensable activities that they are undertaking.

Examples of the establishment reviewing procedures and updating them to make them more effective were reviewed during the inspection. These examples included the updating of the consent form so that all sensitive questions regarding donor lifestyle have been moved within the consent form so that they appear in a discrete lifestyle question section. Another example relates to the changing of the type of freezer temperature datalogger being used to monitor storage freezer temperatures. A new type of datalogger which operates at lower temperatures, allowing the storage freezer temperatures to be reduced, is now being used. This lower temperature will provide a longer period for which the storage temperature would remain appropriate in the event of a freezer failure, giving the establishment greater time to safely relocate any stored tissue.

The HTA has given advice to the Designated Individual with respect to the distribution of end use consignment tissue, aspects relating to seeking consent and risk assessments.

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

Report sent to DI for factual accuracy: 17 October 2014

Report returned from DI: 20 October 2014

Final report issued: 11 November 2014

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
• Consent forms comply with the HTA's Code of Practice • Consent forms are in records and are made accessible to those using or releasing relevant material for a scheduled purpose • If the establishment obtains consent, a process is in place for acquiring consent in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Where applicable, there are agreements with third parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice • Consent procedures have been ethically approved
C2 Information about the consent process is provided and in a variety of formats
• Standard operating procedures (SOPs) detail the procedure for providing information on consent • Agreements with third parties contain appropriate information • Independent interpreters are available when appropriate • Information is available in suitable formats, appropriate to the situation • Consent procedures have been ethically approved
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• Standard operating procedures (SOPs) detail the consent process • Evidence of suitable training of staff involved in seeking consent • Records demonstrate up-to-date staff training • Competency is assessed and maintained

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Policies and procedures are in place, covering all activities related to the storage of relevant material for research in connection with disorders, or the functioning, of the human body • Appropriate risk management systems are in place • Regular governance meetings are held; for example, health and safety and risk management committees, agendas and minutes • Complaints system

GQ2 There is a documented system of quality management and audit
• A document control system, covering all documented policies and standard operating procedures (SOPs). • Schedule of audits • Change control mechanisms for the implementation of new operational procedures
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
• Qualifications of staff and training are recorded, records showing attendance at training • Orientation and induction programmes • Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training • Training and reference manuals • Staff appraisal / review records and personal development plans are in place
GQ4 There is a systematic and planned approach to the management of records
• Documented procedures for the creation, amendment, retention and destruction of records • Regular audit of record content to check for completeness, legibility and accuracy • Back-up / recovery facility in the event of loss of records • Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)
GQ5 There are documented procedures for distribution of body parts, tissues or cells
• A process is in place to review the release of relevant material to other organisations • An agreement is in place between the establishment and the organisation to whom relevant material is supplied regarding the tracking and use of material and eventual disposal or return
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail
• There is an identification system which assigns a unique code to each donation and to each of the products associated with it • An audit trail is maintained, which includes details of when and where the relevant material was acquired, the consent obtained, the uses to which the material was put, when the material was transferred and to whom
GQ7 There are systems to ensure that all adverse events are investigated promptly
• Corrective and preventive actions are taken where necessary and improvements in practice are made • System to receive and distribute national and local information (e.g. HTA communications)

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- Documented risk assessments for all practices and processes
- Risk assessments are reviewed when appropriate
- Staff can access risk assessments and are made aware of local hazards at training

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- A risk assessment has been carried out of the premises to ensure that they are appropriate for the purpose
- Policies in place to review and maintain the safety of staff, authorised visitors and students
- The premises have sufficient space for procedures to be carried out safely and efficiently
- Policies are in place to ensure that the premises are secure and confidentiality is maintained

PFE 2 Environmental controls are in place to avoid potential contamination

- Documented cleaning and decontamination procedures
- Staff are provided with appropriate protective equipment and facilities that minimise risks from contamination
- Appropriate health and safety controls are in place

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- Relevant material, consumables and records are stored in suitable secure environments and precautions are taken to minimise risk of damage, theft or contamination
- Contingency plans are in place in case of failure in storage area
- Critical storage conditions are monitored and recorded
- System to deal with emergencies on 24 hour basis
- Records indicating where the material is stored in the premises

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- Documented policies and procedures for the appropriate transport of relevant material, including a risk assessment of transportation
- A system is in place to ensure that traceability of relevant material is maintained during transport
- Records of transportation and delivery
- Records are kept of any agreements with recipients of relevant material

- Records are kept of any agreements with courier or transport companies

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Records of calibration, validation and maintenance, including any agreements with maintenance companies
- Users have access to instructions for equipment and receive training in use and maintenance where appropriate
- Staff aware of how to report an equipment problem
- Contingency plan for equipment failure

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- Documented disposal policy
- Policy is made available to the public
- Compliance with health and safety recommendations

D2 The reason for disposal and the methods used are carefully documented

- Standard operating procedures (SOPs) for tracking the disposal of relevant material detail the method and reason for disposal
- Where applicable, disposal arrangements reflect specified wishes

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.