



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

### **Birmingham and Midland Eye Centre**

**HTA licensing number 11061**

#### **Licensed for the**

- **procurement, processing, testing, storage, distribution and import 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 October 2013**

#### **Summary of inspection findings**

The HTA found the Licence Holder, and the premises to be suitable in accordance with the requirements of the legislation. During the inspection it was found that, subsequent to taking on a new role within the Trust, the Designated Individual (DI) no longer has sufficient time to commit to the role of DI and appropriately oversee the licensable activity. The current DI will remain in post in the short term; however, the establishment has identified a replacement who, if approved by the HTA, will take over the DI role during early 2014.

Although the HTA found that the Birmingham and Midland Eye Centre (the establishment) had met the majority of the HTA standards. Two shortfalls were found under the Governance and Quality System standards and, in particular, traceability.

## 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	Processing	Testing	Storage	Distribution	Import	Export
Amniotic Membrane				E	E		
Sclera				E	E		
Cornea				E	E		
Procera				E	E	E	

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

The establishment is licensed for the storage, distribution and import of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the storage of relevant material which has come from a

human body for use for a scheduled purpose other than transplantation under the Human Tissue Act 2004.

Amniotic membrane, corneal tissue, Tutoplast acellular tissue product and sclera tissue are purchased by the establishment and used in patient treatment. The establishment routinely stores only amniotic membrane for more than 48 hours, other tissues being purchased and delivered the day before they are needed in surgery. However, on rare occasions, tissues other than amniotic membrane are purchased and stored over weekends or holidays for use in subsequent surgery and in these cases the establishment stores these tissues for longer than 48 hours.

Tissue is purchased from multiple suppliers some of which are UK based and are licensed by the HTA under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Tissue is also received from suppliers in the United States. The establishment has a range of agreements in place with both UK and US suppliers for the supply of tissue. Since the last inspection some agreements with tissue suppliers have lapsed; however, the establishment confirmed that tissue is not currently being purchased from these suppliers.

The establishment continues to occasionally distribute tissue to another hospital for use in emergency surgery. The establishment has maintained an end user agreement with the hospital covering the tissue distribution.

The establishment has been licensed by the Human Tissue Authority since August 2006 and this routine inspection was the fourth site visit of the establishment. The timetable for the site visit was developed in consideration of the original desk-based assessment of the establishment's licence application, previous inspection reports and pre-inspection discussions with the DI. During the inspection, a visual inspection of the premises, review of the establishment's documentation and interviews with establishment staff were undertaken.

During the inspection it was learned that some traceability record errors have recently been identified by the establishment staff. Following a detailed discussion around these traceability errors it was decided that, a detailed audit of tissue stored at and used by the establishment should be undertaken during the inspection. This was to enable the HTA to assure itself that suitable traceability records are being kept which allow the tracing of tissue from receipt at the establishment through to use in patient treatments.

In summary, the establishment's traceability records are paper based and consist of :-

1. Tissue is received and recorded in a 'Tissue Day Book'. The establishment has a separate Tissue Day book for each tissue type.
2. Tissue is allocated to a specific recipient and their details recorded in the Tissue Day book.
3. Establishment staff create an "in house" label with relevant tissue and intended recipient details. This label is used to then label the tissue pack. Spare labels are created for recording tissue use in other tracking documents and recipient notes.
4. 'HTA Tissue Tracking Pathway' form used to record tissue use (including in house label) and recipient details.
5. Records of tissue being removed from the freezer are also maintained in a freezer tissue register.
6. In house label put into patient notes as part of operation records.

As part of the audit of unused stored tissue, details were taken from two amniotic membrane, one sclera and one Tutoplast tissue packs. Details from the tissue packs were cross checked

against the Tissue Day books and the HTA Tissue Tracking Pathways. No anomalies were found.

An additional traceability audit was also undertaken that included a review of records for tissue that had been used. Details of one sclera and one cornea were reviewed in the Tissue Day books, HTA Tissue Tracking Pathway forms and the recipient patient's clinical notes. No anomalies were found with all tissue identifiers, recipient patient identifiers and tissue details being correctly recorded and tissues used within their expiry dates.

An audit of an amniotic membrane patch was undertaken. In this case, although allocated to a recipient, the tissue was not needed during the surgery. The tissue was disposed of and details of the disposal were correctly recorded on all relevant traceability records.

During the audit of amniotic membrane tissue, two instances where amniotic tissue had been used by theatre staff during an emergency surgery over a weekend were reviewed in detail. Two packs of tissue were used but the relevant tissue tracking forms had not been fully completed nor had the tissue been assigned to a particular recipient and therefore the Tissue Day book had no recipient details recorded in it. These issues had not been followed up by establishment staff during the week following the surgery and the traceability records had therefore been left incomplete. Surgical staff at the establishment are trained to record the use of tissue using the establishment's tracking systems. Although not fully completed, the partially completed records facilitated the identification of the surgery and therefore the recipient. The surgical staff had recorded details of the tissue in the recipient's clinical notes and therefore tissue traceability had not been lost. Traceability was not lost because tissue identifiers are recorded in several records and ultimately within the recipient's clinical notes. If the establishment relied upon a single record of use such as the tissue Day book then traceability may have been compromised.

A unit of Tutoplast acellular tissue was also audited. During this traceability audit it was found that the tissue identifier in the Tutoplast Tissue Day book was different to the tissue identifier on the in house produced tissue labels. A review of the tissue recipient's clinical notes included a review of the recipient's operation record in which the surgical staff had attached a tissue identifying label from the Tutoplast product pack which was provided by the tissue supplier. The tissue identifier on the manufacturers label matched the identifier in the Tissue Day book and showed that the tissue identifier had been mis-transcribed onto the in house tissue labels created by the establishment.

Finally, during the audit, the establishment explained that five corneas that had been purchased and used for surgical training purposes had not been recorded in any of the establishment's traceability systems meaning that the traceability of these tissues has been lost. Using tissue for training and education relating to human health is a scheduled purpose under the Human Tissue Act 2004 which requires relevant material to be traceable from donation through to use or disposal.

### **Inspection findings**

The HTA found the Licence Holder to be suitable in accordance with the requirements of the legislation. During the inspection it was found that subsequent to taking on a new role within the Trust that the Designated Individual (DI) no longer has sufficient time to fully commit to the role of DI and appropriately oversee the licensable activity. The DI's new role is in another part of the Trust and, although the DI has been visiting the eye centre periodically, this has not afforded sufficient time to appropriately oversee all aspects of the establishment's activity. The current DI will remain in post in the short term; however, the establishment has identified a replacement who, if approved by the HTA, will take over the DI role. Following discussions with the establishment's Corporate Licence Holder Contact the HTA understands that the newly proposed DI will apply for the role of DI at the start of 2014 when they take up a substantive post at the establishment. It is expected by the HTA that the establishment will

have a new DI in place by March 2014 at the latest to help ensure appropriate oversight of the licensable activity.

## Compliance with HTA standards

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

#### Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
<p>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.</p> <p>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.</p>	<p>During the traceability audit, three issues were identified with regards to tissue used in patient treatment. Firstly there was an example where two packs of amniotic membrane had been used in surgery however the establishment's procedures for recording tissue use had not been followed. This resulted in incomplete traceability records.</p> <p>Secondly, a transcription error relating to a Tutoplast tissue identifier between the Tissue Day book and the in house printed tissue traceability label was found.</p> <p>Thirdly, the in house sequential tissue identifying number given to tissue received at the establishment had been mis-recorded in two separate Tissue Day books.</p> <p>Although two of these issues were identified by the establishment during preparation for the HTA inspection, these incidents show both that the establishment's traceability systems had not been followed and that the establishment's audit processes had not identified them earlier.</p> <p>Advice to the DI on potential action to take is also given below.</p>	<b>Major</b>

## Human Tissue Act 2004 Standards

### Consent

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The establishment has purchased and used five corneal grafts for surgical training purposes which had not been recorded in any of the establishment's traceability systems meaning that traceability of these tissues has been lost. Using tissue for training and education relating to human health is a scheduled purpose under the Human Tissue Act 2004 which requires relevant material to be traceable from donation through to use and/or disposal	<b>Major</b>

### Advice

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

No.	Standard	Advice
1.	The Regulations GQ6(b) GQ6(c) GQ4(b)	With regards to the shortfall under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 standards GQ6(b) and GQ6(c), the DI is advised to implement a more detailed and more frequent internal audit of tissue received at the establishment.  In order to assure himself that the establishment's traceability data recording systems are being followed as expected, the DI is advised to undertake monthly vertical audits similar to those conducted during the HTA inspection on a suitable number of units of each tissue type used at the establishment.
2.	HT Act GQ6	The DI is advised to develop separate systems for the recording of traceability information relating to tissue being purchased and used in scheduled purposes under the Human Tissue Act 2004 such as training and education relating to human health.  Currently, the establishment's procedure is to record traceability information relating to training tissue in the same Tissue Day book used for the same type of tissue that has been purchased for patient treatment. During the traceability audit it was found that these systems however had not been followed resulting in a loss of traceability for tissues. Recording details of training tissue in separate systems will help to minimise the risk of training tissue mistakenly being used in patient treatment.
3.	The Regulations GQ1(b)	The DI is advised to amend the tissue receipt SOP to include more details of the checks that are carried out by establishment staff when receiving tissue at the establishment. The SOP currently reflects the checks that are made on the tissue by the surgeon prior to surgery however it does not include the full details of the checks made on the shipping packaging and paperwork when tissue arrives.  Additionally, it was learned that the establishment's SOPs will be reviewed in early 2014. The DI is also advised to, as part of the review of SOPs, to

		determine if any other SOPs would benefit from the addition of further detail.
4.	The Regulations GQ2(c)	<p>Since the last inspection the establishment has organised for a member of the Trust's clinical governance team to undertake an independent audit of the establishment's practices. This audit included reviews of the establishment's practices however it did not include a review of the establishment's compliance with the HTA standards.</p> <p>The DI is advised to amend the independent audit procedure to include a review of compliance with the HTA standards.</p>
5.	The Regulations GQ4(a) GQ4(c)	<p>During the traceability audit, examples where corrections to the establishment's in house sequential unique identifying numbers had been made following the discovery of a recording error. These numbers had been amended with the use of correction fluid.</p> <p>The DI is advised to prohibit the use of correction fluid on all of the establishment's records. As an alternative to the use of correction fluid the error should be struck through with a single line so that the original entry is still readable in case it is required for audit or further data error investigations.</p>

### Concluding comments

During the inspection it was found that subsequent to taking on a new role within the Trust that the Designated Individual (DI) no longer has sufficient time to fully commit to the role of DI and oversee the licensable activity. The current DI will remain in post in the short term; however, the establishment has identified a replacement who, if approved by the HTA, will take over the DI role. It is expected by the HTA that the establishment will have a new DI in place by March 2014 at the latest to help ensure appropriate oversight of the licensable activity.

There are a number of areas of practice that require improvement, including two major shortfalls. The HTA has also given advice to the Designated Individual with respect to improving the robustness and frequency of the establishment's internal audits, improvements to some SOPs and changes to the independent audit processes.

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

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

**Report sent to DI for factual accuracy: 13 November 2013**

**Report returned from DI: No comments received**

**Final report issued: 18 December 2013**

### **Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

**Date: 25 April 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.
<b>GQ7</b> 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.
<b>GQ8</b> 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>
<b>PFE1</b> 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



<b>GQ2 There is a documented system of quality management and audit</b>
<ul style="list-style-type: none"> <li>• A document control system, covering all documented policies and standard operating procedures (SOPs).</li> <li>• Schedule of audits</li> <li>• Change control mechanisms for the implementation of new operational procedures</li> </ul>
<b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</b>
<ul style="list-style-type: none"> <li>• Qualifications of staff and training are recorded, records showing attendance at training</li> <li>• Orientation and induction programmes</li> <li>• Documented training programme, (e.g. health and safety, fire, risk management, infection control), including developmental training</li> <li>• Training and reference manuals</li> <li>• Staff appraisal / review records and personal development plans are in place</li> </ul>
<b>GQ4 There is a systematic and planned approach to the management of records</b>
<ul style="list-style-type: none"> <li>• Documented procedures for the creation, amendment, retention and destruction of records</li> <li>• Regular audit of record content to check for completeness, legibility and accuracy</li> <li>• Back-up / recovery facility in the event of loss of records</li> <li>• Systems ensure data protection, confidentiality and public disclosure (whistle-blowing)</li> </ul>
<b>GQ5 There are documented procedures for distribution of body parts, tissues or cells</b>
<ul style="list-style-type: none"> <li>• A process is in place to review the release of relevant material to other organisations</li> <li>• 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</li> </ul>
<b>GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail</b>
<ul style="list-style-type: none"> <li>• There is an identification system which assigns a unique code to each donation and to each of the products associated with it</li> <li>• 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</li> </ul>
<b>GQ7 There are systems to ensure that all adverse events are investigated promptly</b>
<ul style="list-style-type: none"> <li>• Corrective and preventive actions are taken where necessary and improvements in practice are made</li> <li>• System to receive and distribute national and local information (e.g. HTA communications)</li> </ul>

**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.