Site visit inspection report on compliance with HTA minimum standards

Chelsea and Westminster Burns Unit

HTA licensing number 11146

Licensed for the

- **storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**

13 November 2014

Summary of inspection findings

Chelsea and Westminster Burns Unit (the establishment) was selected to receive a themed site visit inspection. The themes selected for 2014/15 include quality management, risk management, procurement of tissues and cells and storage of tissues and cells for end use

Although the HTA found that the establishment had met the majority of the HTA standards, shortfalls were found, particularly with regard to quality management. The shortfall was in relation to an absence of governance meetings.

In addition, the HTA reviewed the establishment's compliance with the staff qualification and training standards. The establishment did not meet the standards relating to: (i) staff competence training and recording; and, (ii) staffing levels.

The HTA previously found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. Their suitability was not re-assessed during this inspection.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual (DI), Licence Holder (LH), premises and practices are suitable.

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

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

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

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

However, a themed inspection may be carried out on establishments which have been found previously to represent a lower risk. Themes target standards which the HTA has identified as common shortfalls across the human application sector. The themes selected for 2014/15 are outlined in the table below.

Themes	HTA Standards
Quality management	
Standard operating procedures for licensed activity	GQ1(b)
Document control system	GQ1(d)
Quality Management System – continuous and systematic improvement	GQ1(c) GQ2(a)-(c)
Internal audit system for licensable activities	
Risk Management	
Procedures for the identification, reporting, investigation and recording of adverse events and reactions	GQ7(a),(f)
Risk assessments of processes and premises	GQ8(a)-(d) PFE1(a)
Traceability	GQ4(e),(h),(i) GQ6(a)-(c) PFE4(d) D2(a)

Themes	HTA Standards
Storage for end use	
Storage equipment is suitable for use, maintained and monitored	PFE2(a) PFE3(a)-(d) PFE5(a)-(f) PFE5(h)-(k)

In addition to the standards listed above, the HTA will follow up on any other issues that have arisen since the establishment's last site visit inspection.

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

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

Licensable activities carried out by the establishment

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Amniotic membrane	**-**	**-**	**-**	**E**	**-**	**-**	**-**
Bone	**-**	**-**	**-**	**E**	**-**	**-**	**-**
Skin	**-**	**-**	**-**	**E**	**-**	**-**	**-**

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Chelsea and Westminster Burns Unit (the establishment). This was the fourth site visit inspection of the establishment since it was issued an HTA licence in October 2006 (the last inspection was in November 2012). It was a routine 'themed' site visit inspection to assess whether the establishment is continuing to meet the HTA's standards.

Skin

Chelsea and Westminster Burns Unit is a large referral centre for both adult and paediatric patients. The establishment stores packaged, fresh-frozen, irradiated cadaveric whole skin for use in burns surgery. The tissue is purchased from NHS Blood and Transplant (NHSBT). In 2013, the establishment received and stored 515 units of fresh-frozen whole skin.

Donor selection, consent to donation, procurement and serological testing of donors is undertaken by NHSBT. NHSBT also arranges the transportation of tissue to the establishment in validated, temperature-controlled containers. There is a service level agreement (SLA) in place with NHSBT (*see Advice item 2*).

The skin, in its transport packaging, is delivered directly to the unit. There, one of eight authorised persons from the Burns Unit takes delivery of the package and places it into the skin freezer after having followed a procedure to check the quality of the packaging, the donor

identity number (the “G-number”) and the individual pack number (*see Advice item 6*). The G-number, date and time of receipt, and expiry date are entered into the skin log book and the date and time of receipt, together with freezer temperature, are noted on the dispatch sheet which has accompanied the package, this being stored separately. There is no current backup system for the skin log book (*see Advice item 8*).

The skin is stored in a data logged freezer at -80°C and there is a remote temperature monitoring system linked to the Blood Transfusion Unit. The details from the data logger are retained electronically. If the temperature deviates outside the set range, the freezer alarms locally and within the Blood Transfusion Unit, which is staffed at all times, allowing for round the clock cover. This procedure ensures that the relevant Burns Unit staff are notified.

The freezer is subject to a six monthly service and calibration plan (*see Advice item 10*). Separate contingency freezer storage is available in a separate part of the building.

When needed for surgery, the details of date of removal from the freezer are entered into the skin log book as a separate entry. The patient number of the recipient is also added to the log book. These details are transferred onto the electronic database. Expiry dates are noted when selecting material for use and this ensures that stock is rotated and that material is used before the date of expiry. Skin which has been thawed but not used is stored in a data logged 4°C refrigerator, which is linked to the Blood Transfusion Unit. Skin is stored for a maximum of 14 days in the refrigerator before re-use or disposal.

Disposal of tissue is recorded in both the paper and electronic records. Tissue is disposed of by incineration and it is bagged separately from other clinical waste.

When a patient attends for an operation which may involve allograft skin, that fact is noted as part of the clinical consent. The G number is entered onto the care plan within the patient notes.

Other tissues

Since 2013, the establishment has also stored packaged, fresh-frozen femoral heads for use in elective hip revision surgery (15 units received and stored in 2013) and amniotic membrane (approximately 10 units received and stored in 2014) for use in ocular surgery for burns.

These tissues are stored in the same -80°C freezer as the skin. Several different staff members from the orthopaedic and ophthalmology departments are placing received skin and amniotic membrane into the freezer. Although the DI has demonstrated informally the skin governance system to a senior orthopaedic nurse, there has been no similar demonstration to ophthalmology nurses.

The establishment also stores irradiated ground bone and demineralised bone matrix (for end use) but this is not covered by the licence.

The present site visit inspection included a visual inspection of the -80°C freezer located outside the burns operating theatre, the laboratory where storage temperature data are monitored electronically, and the area where records are kept.

Meetings were held with the DI (Clinical Nurse Lead – Burns, Plastics and Pain), a Senior Sister (Theatres) and a Senior Nurse (Orthopaedics). A document review and horizontal and vertical audits were carried out. Details of the audit are provided below.

One package of whole skin was selected at random from the freezer and the records were compared to the skin log book. No discrepancies were noted.

Two sets of burns patient notes and two sets of notes for orthopaedic patients were examined for presence of the G number within the records of the operation. The consent forms were also checked to ensure that the patients had been appropriately consented for the allograft. The

paper records were also traced back to the skin log book and the stored dispatch notes. There were no discrepancies.

Inspection findings

The HTA previously found the DI and the (Corporate) LH (CLH) to be suitable in accordance with the requirements of the legislation. Their suitability was not re-assessed during this inspection.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	There is no existing regular governance meeting, which covers HTA issues, for staff working under the licence. Since there are new users of human tissue, such regular meetings (with appropriate Persons Designated, PDs) will be especially important. *See Advice item 4*.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Although there is detailed, recorded competency training for staff working in the burns unit, there is no such training for orthopaedics and ophthalmology staff using the freezer. *See Advice item 8*.	**Minor**
k) The establishment is sufficiently staffed to carry out its activities.	There are now several members of staff, from different departments, who are placing different tissue types within the freezer. The HTA requests the DI to nominate, and inform the HTA, appropriate PDs based within the orthopaedic and ophthalmology departments to oversee the activities taking place under the licence. Appointing such PDs will ensure consistent governance across the organisation.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	During the site visit inspection the current DI made it clear that they would be leaving the establishment. The CLH and CLH contact should ensure that the process of introducing a new DI is managed appropriately. Information on making a Change of DI can be found on the HTA website.
2.	N/A	The DI should ensure that the SLA with NHSBT is up to date and has been signed.
3.	GQ1(a), 1(d), 2(a)	The DI is advised to update and clarify the organisational chart, which does not show any lines of responsibility between the DI, CLHC and PDs working under the licence. The organisational chart should become a controlled document as part of the Quality Manual.
4.	GQ1(c)	In other establishments, regular governance meetings have covered items such as: reportable incidents, changes to Standard Operating Procedures (SOPs), audits, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). It is advised that these meetings should be governed by an agenda, and minutes circulated. The minutes should include timelines for identified actions and that there is a standing agenda item for discussing progress against actions identified at previous meetings.
5.	GQ1(c)	The DI may wish to consider setting up meetings with other DIs working in this sector, to share information and experience with them and their PDs. This may help facilitate learning and understanding of staff at the establishment as well as being a forum for the discussion of good practices.
6.	GQ1(g), (h)	The DI is advised to ensure that, for tissue received into the establishment, a check is made that the time from release by the supplier to depositing in the freezer does not exceed the maximum validated transport time issued by the suppliers and that this is recorded.
7.	GQ2(b), GQ4(b)	The DI has performed some audits since the last inspection. The DI is now advised to increase the frequency of audits and to divide the audit schedule into small increments, carried out by different team members. This should include horizontal audits to ensure that SOPs accurately reflect current practices and vertical tissue traceability audits, from records of receipt to storage and use. The results of all audit findings, and actions taken against non-conformances, should be formally recorded to ensure continuing improvement of processes and practices.
8.	Principally GQ3(e) but also relevant	As well as competency training, the DI is also advised to consider implementing a training programme that: (i) ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context; and, (ii) ensures that staff understand the

	to standards GQ3(f), (g)	organisational structure and the quality systems used within the establishment.
9.	GQ4(e)	The DI is advised to consider transferring all details held within the paper records relating to tissue/cells into an electronic database or spreadsheet, which could be a backup register. Alternatively, the paper records could be scanned into an electronic folder, which could be backed up by the Trust Information Technology system.
10.	GQ6(c)	The DI may wish to consider the following risk to tissue traceability and to modify the record and audit system accordingly: - Tissue which is requested by the surgeons but which is not used and is disposed of directly from theatre.
11.	GQ8(b)	Having now created risk assessments of licensable activities, the DI is advised to review them on a regular basis.
12.	PFE3(a)	The DI is advised to ensure that refrigerators and freezers and which contain human tissue are appropriately labelled to indicate this, so that staff are aware of the necessity to maintain the quality, safety and security of such material.
13.	PFE3(c)	Although the establishment's storage areas and refrigerator and freezer system are alarmed and temperature monitored, the establishment does not review the recorded temperature plots. The DI is advised to initiate a program by which, at suitable timeframes, the temperature plots from the monitoring system are reviewed. This may help to identify a potential failure of the system before it occurs. The DI is also advised to carry out regular testing of the tissue storage alarm system to ensure that the callout procedure is functioning correctly.
14.	PFE5(b), (e)	The DI may wish to consider keeping copies of records of refrigerator and freezer service visits and agreements with maintenance companies within the unit to ensure that all documents are up to date.
15.	D2(a)	The DI should ensure that the method and reason for disposal of each tissue sample is recorded.

Assessment of existing shortfalls against standards

Following the site visit inspection of the establishment in 2012, two minor shortfalls were found in relation to an absence of: (i) independent audit [GQ1(c)]; and, (ii) risk assessments of licensable activities [GQ8(a)]. One of the actions [against GQ8(a)] was closed following assessment of submitted evidence in 2012. During the current site visit inspection, the DI provided evidence of independent audit and the second shortfall [GQ1(c)] was considered to be addressed.

At the last site visit inspection, four items of advice were given. The DI had proactively implemented three of these items before this current site visit inspection.

Concluding comments

During the site visit inspection of Chelsea and Westminster Burns Unit, areas of good practice were noted:

- There is a small, cohesive body of staff working under the licence. This has provided for continuity and the establishment has derived benefits from this stability and commitment.
- There is a mature and embedded governance system for the burns unit, created by the current DI over several years.
- The DI has set up a contingency agreement with another Burns Unit for the storage of tissues and cells in the event of termination of licensable activities.

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

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

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

Report sent to DI for factual accuracy:	**8 December 2014**
Report returned from DI:	**No factual accuracy or request for redaction comments were made by the DI**
Final report issued:	**19 January 2015**

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: 27 November 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are highlighted with an asterisk (*). Individual standards which are not applicable to this establishment are shown in grey text.

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*.

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 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 failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several ‘minor’ shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

4. 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.