Site visit inspection report on compliance with HTA minimum standards

Princess Grace Hospital

HTA licensing number 11069

Licensed for the

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

21 - 23 January 2014

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder and the premises to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Princess Grace Hospital (the establishment) had met the majority of the HTA standards, three minor shortfalls were found with regard to the Governance and Quality Systems (GQS) standards. The shortfalls were in relation to independent audit, contingency planning for records and raw data, and risk assessments. Advice has also been given relating to the Consent (C), GQS and Premises, Facilities and Equipment (PFE) standards.

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 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.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone	-	-	-	**E**	-	-	-
PBSC	**E**	-	**E**	-	-	-	-
Tendons / ligaments	-	-	-	**E**	-	-	-
Whole skin	-	-	-	**E**	-	-	-

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Princess Grace Hospital (the establishment). The establishment's licensing arrangements cover the Princess Grace Hospital itself (the hub site), and the Wellington Hospital, the London Bridge Hospital and the Harley Street Clinic (the three satellite sites). A further satellite, the Wimpole Street Laboratory, has recently applied to carry out testing for the establishment; this satellite was not inspected on this

occasion.

This was the fourth site visit inspection of the hub since it was issued an HTA licence in December 2006 (the last site visit inspection was in January 2012). Two of the other satellites (the Wellington Hospital and the London Bridge Hospital) had their own HTA licences before becoming part of the hub and satellite system; they were last inspected in January 2012. The third satellite (the Harley Street Clinic) was licensed by the HTA in October 2013. This was the first site visit inspection of this satellite. The current site visit inspection was a routine one to assess whether all sites of the establishment are meeting and continue to meet the HTA's standards.

The establishment as a whole is licensed for the procurement, testing and storage of tissues and cells for human application. In 2013, the establishment received and stored 25 units of bone, 205 units of tendons/ligaments and two units of whole skin for allogeneic end use. The London Bridge Hospital satellite stored the highest number of these products. The establishment also procured four units of peripheral blood stem cells (PBSC) for autologous end use.

The current DI has been in post since July 2013. Since then, a programme of unifying the processes and procedures relating to the licence across all four sites has been initiated. During the current site visit inspection it was noticed that each site had its own particular strengths and weaknesses and, where applicable, these have been highlighted in this report.

<u>The hub site (Princess Grace Hospital) and satellite sites (the Wellington and London Bridge Hospitals)</u>

These sites store packaged, fresh-frozen femoral heads, femoral strut grafts, tendons/ligaments and skin graft jackets for use in elective hip and knee revision and reconstruction surgery. The products are purchased from NHS Blood and Transplant (NHSBT) and from another HTA-licensed establishment.

The hub and satellites also store acellular bone chips and demineralised bone matrix for end use; this activity is not covered by the licence.

Donor selection, consent to donation, procurement and serological testing of donors is undertaken by the two tissue suppliers. The suppliers also arrange for the transportation of products to the establishment in validated, temperature-controlled containers. There are service level agreements (SLAs) in place with both establishments (*see Advice item 1*).

The products, in their transport packaging, are received directly by an authorised person in the respective orthopaedic department and are placed in the freezer after the staff member has followed a procedure to check the quality of the packaging, the donor identity number (the G number for NHSBT, serial number for the other HTA-licensed establishment) and the individual pack or lot number. Some, but not all, of the sites were performing a check to ensure that the time from release by the supplier to depositing in the freezer does not exceed the maximum time indicated by the tissue suppliers (*see Advice item 16*).

The G number/serial number, date (and time) of receipt, expiry date and freezer temperature are entered into the respective tissue register and the date (and time) of receipt and freezer temperature are noted on the dispatch sheet which has accompanied the package, this being stored separately. The details from the tissue register are transferred onto an electronic database, which is backed up as part of the Hospital's IT system (*see Advice item 15*).

At each site the tissue is stored in a secure freezer. There was some variation between freezer running temperatures between sites. At the time of the inspection, the freezers were running at -40°C (Princess Grace), -35°C (Wellington) and -40°C (London Bridge; *see Advice items 20 and 21*). Princess Grace Hospital (but not the other sites) has a freezer running at -30°C which is used as quarantine storage for products which don't pass the acceptance

criteria (e.g. broken packaging, etc.) while the establishment seeks clarification from the supplier as to the fate of the tissue. This freezer also acts as contingency storage for all sites. The temperature of the freezers is monitored and recorded continuously by an outside contractor. There is also a weekly visual check and manual recording of the freezer temperatures.

The freezers are subject to an annual service and calibration plan.

The freezers have an alarm system which links to the outside contractor. If the temperature deviates outside the set range, the freezer alarms locally and a work instruction, laminated to the front of each freezer, details the procedures staff must follow to call the on call engineer (*see Advice item 9*). There is also an electronic list of phone numbers of relevant staff who are contacted each time this deviation occurs. Each orthopaedic department is only staffed during normal working hours but the callout procedure ensures 24 hour coverage.

When needed for surgery, the details of date of removal from the freezer are entered into the tissue register as a separate entry, with the original corresponding entry of receipt scored out. The patient number of the recipient is also added to the register.

Any disposal of tissue, including tissue not used during the operation, is recorded in the tissue register. Tissue is disposed of by incineration and is bagged separately from other clinical waste.

When a patient attends for an operation which may involve allograft bone, that fact is noted as part of the clinical consent (*see Advice item 3*). Detailed consent for this operation is given by the clinician but Patient Information Sheets are not routinely used. The G number/serial number is entered onto the care plan within the patient notes along with details of any prostheses used. A patient file sticker warning of the need to retain the traceability records for 30 years from the date of the operation is attached to the cover of the patient notes.

The present site visit inspection of the hub and these two satellites included a visual inspection of the freezers at each site and the areas where records were kept.

Meetings were held with the following personnel:

Princess Grace Hospital: the Persons Designated (PDs: Theatre Coordinator and Theatre Lead Practitioner);

Wellington Hospital: the PD (General Manager – Theatres);

The London Bridge Hospital: the DI (Chief Nursing Officer), the CLH contact (Director of Nursing and Risk), the PDs (Perfusion Manager and Theatre Coordinator) and a Consultant Orthopaedic Surgeon.

A document review and vertical and horizontal audits were carried out at each site. Details of the audits are provided below.

At each site three packages were located within the freezer and the records were compared with the tissue register and database. No discrepancies were noted.

At each site four sets of patient notes were examined for presence of the G number/serial number within the record of the operation and the presence of the stamp warning of the need for record retention. These records were also traced forward and back through the paper and electronic records and back to the stored dispatch notes. There were no discrepancies.

<u>The Harley Street Clinic satellite site</u>

The Harley Street Clinic undertakes donor selection, consent, procurement and end use of paediatric and adolescent haematopoietic stem cells (HPCs) for human application. The HPCs are peripheral blood stem cells (PBSC). The satellite consists of the clinical areas

where consent is sought and the paediatric/adolescent apheresis unit. Consent is sought by trained consultants (*see Advice items 2, 4, 5*).

The apheresis unit contains one apheresis machine. Procured cells are transported (by courier), processed and stored under an SLA with NHSBT (*see Advice item 1*).

An agreement is in place between the establishment and an organisation for the regular maintenance of the apheresis machine and the competency training of staff on this piece of equipment.

The present site visit inspection of this satellite included a visual inspection of the apheresis unit and the consumables storage cupboard. Meetings were held with the PDs (Oncology Manager and Clinical Nurse Specialist and an Associate Clinical Specialist. A documentation review and audit trail were carried out. Details of the audit are provided below; some anomalies were found and these are discussed in the Advice below.

The records held in the patient notes were reviewed for donations from two patients. The results of this audit from donation to transplantation are discussed in the Advice section below.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
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.	The establishment does not yet have a regular independent audit to verify compliance with protocols and HTA standards.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
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.	There is no plan, procedure or written agreement with another HTA-licensed establishment to transfer traceability records and raw data in the event of termination of licensable activities.	**Minor**
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.	Risk assessments are currently associated with storage of tissue, such as freezer failure or use of expired tissue. There are no risk assessments for activities such as consent and procurement (currently undertaken at the Harley Street Clinic).	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI should ensure that all SLAs are up to date and have been signed.
2.	C1(e)	There is inconsistency in the way consent forms for PBSC procurement are being completed, with fields such as 'date', 'print name' and 'job title' being occasionally left blank. The DI is advised to ensure consistency in consent from completion.
3.	C2(a)	The DI is advised to clarify and improve on the way patient consent to receive an allograft is documented. At the present time, company policy encourages consultants to document this but, at all sites apart from London Bridge Hospital, internal audits are showing that this is seldom done.
4.	C2(c)	Interpreters are sometimes brought in on an ad hoc basis for family members who do not understand English, whereas they are not used for other family members. The DI is advised to examine the inconsistent use of interpreters for different members of the family and find a way of identifying the need for interpreters early in the patient's care pathway, and then recording this so that interpreters are used consistently when needed.
5.	C3(a)	The DI is advised to consider making additional consent training available for clinical staff other than the consultants who currently take consent for PBSC procurement so that there are contingencies if a consultant is not available.
6.	GQ1(b)	The DI and their team have introduced a range of Standard Operating Procedures (SOPs) covering licensable activities which ensures a consistent approach at all sites. The following modifications are suggested, however: - The DI needs to consider the wording of the SOP on handling freezer alarms as at present it states that every time an alarm goes off the establishment should record it on the Hospital incident reporting system and carry out a risk assessment. This is not being carried out in practice and the alarm system is being triggered on a regular basis (*see Advice item 20*). - There is duplication of some documents. For instance, there were three separate documents relating to freezer defrosting/cleaning at London Bridge Hospital.

7.	GQ1(c)	The DI is advised that minutes of governance meetings should include timelines for identified actions and that there is a standing agenda item for discussing progress against actions identified at previous meetings.
8.	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.
9.	GQ1(d)	The DI is advised to include all Work Instructions under the document control system.
10.	GQ2(b)	The scope of audits varies across all sites. London Bridge Hospital has the greatest range. 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 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.
11.	GQ3(f)	There is inconsistency in HTA training across the sites. There is good HTA training at London Bridge and Princess Grace Hospitals. The DI is advised to adopt this training and use it for all staff.
12.	GQ4(a)	The DI is advised to improve the practice of record amendment. Staff are often overwriting records or using correction fluid, rather than crossing through, signing, dating and adding the new record.
13.	GQ4(e)	Dates in the tissue register were seen to be a mix of UK and US formats. This DI is advised to standardise this.
14.	GQ4(e)	The DI is advised to implement a step whereby staff at all sites perform a check to ensure that the time from release by the supplier to depositing in the freezer does not exceed the maximum time indicated by the tissue suppliers, and that this is recorded in the tissue register.
15.	GQ4(e)	Not all sites (for example, London Bridge Hospital) are backing up paper records with electronic spreadsheets or electronic scans of documents. The DI is advised to implement a consistent procedure for this across all sites.
16.	GQ4(e)	The DI is advised to implement a step whereby staff record expiry dates when selecting material for use and to incorporate this in a document-controlled Work Instruction to ensure that stock is rotated and that material is used before the date of expiry.
17.	GQ7(a)	The inspection team identified an incident concerning the storage conditions of Acid-Citrate-Dextrose Solution A (ACDA) at the Harley Street Clinic. For two days the thermometer recorded a temperature range for the

		room outside the specified range. Although there is a system for identifying, recording and acting upon adverse incidents, the establishment had not provided any evidence that the matter was treated as an incident and that any action had been taken against this non-conformance. The DI is advised to ensure that all staff are aware of the need for reporting of adverse incidents and the steps to be taken if they occur.
18.	GQ7(b), (c)	The DI is advised to modify the SOP on Serious Adverse Events and Adverse Reactions (SAEARs) to include: • the dissemination of HTA regulatory alerts. • the identity of personnel who should report SAEARs in the DI's absence. • the submission of a SAEAR follow-up report to the HTA within 90 days. The DI is referred to the HTA's website page for further information: http://www.hta.gov.uk/licensingandinspections/reportingtothehta/adverseeventandreactionreporting.cfm
19.	GQ8(a)	The DI is advised to standardise the template for risk assessments across the organisation so that there is a consistency of practice. This will help ensure that the need for further corrective measures are consistently captured and documented.
20.	PFE3(c)	It was noted that the freezer temperatures at many of the sites rise very rapidly when the doors are opened even for very short periods. This causes the temperature monitoring system to trip at regular intervals. The DI is advised to explore ways of trying to alleviate this problem, such as packing the freezer to avoid rushes of air into the freezer which may contribute to such frequent temperature fluctuations.
21.	PFE3(d)	The DI is advised to obtain written clarification from the tissue suppliers about the exact storage temperature requirements for their products as correspondence received has been conflicting. The DI should also consider how expiry dates are recorded in patient records in the light of this clarification. The DI is advised to amend the appendix to SOP: CCP.HTA.SOP.009, which includes recommended storage conditions/expiry dates for each product, in the light of this written clarification.
22.	PFE5(b), (e)	The DI is advised to ensure that copies of service visits and maintenance agreements are held centrally to ensure that all documents are up to date.

Concluding comments

Following the site visit inspection of the establishment in 2012, three minor shortfalls were found in relation to: document control [GQ1(d)]; the recording of expiry dates [(PFE3(d)]; and, the updating of the disposal policy and procedure [(D1(a)]. All of these were closed following assessment of submitted evidence in 2012. Closure of these shortfalls was confirmed at this current site visit inspection. At the last site visit inspection, nine items of advice were given.

The DI had proactively implemented eight of these items before this current site visit inspection. The ninth piece of advice has been included as an Advice item in this report.

During the site visit inspection of Princess Grace Hospital and its satellites areas of good practice were noted:

The DI has begun the standardisation of governance and quality across all the sites. Specifically:

- SOPs are standardised, with local site variations in practice being incorporated as flow diagrams in an Appendix.
- Governance meetings are held, attended by the DI, PDs from all sites and the CLH contact. These cover reportable incidents, changes to SOPs, audits, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items).
- A standard competency training checklist for all staff working under the licence has been introduced.

There are some areas of practice that require improvement and three minor shortfalls have been identified. The HTA has also given advice to the DI with respect to consent, governance and quality systems and premises facilities and equipment standards.

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: 20 February 2014

Report returned from DI: 5 March 2014

Final report issued: 27 March 2014

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: 21 November 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are highlighted in black. Individual standards which are not applicable to this establishment are highlighted as 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.

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.