Site visit inspection report on compliance with HTA minimum standards

Castle Hill Hospital

HTA licensing number 12174

Licensed for the

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

18-19 October 2016

Summary of inspection findings

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

Although the HTA found that Castle Hill Hospital (the establishment) had met the majority of the HTA standards, six minor shortfalls were found in relation to governance and quality systems and premises and facilities and equipment. The shortfalls relate to the establishment's scope of audits and risks assessments, the validation of processes, documentation of training provided, the donor selection criteria and the content of the standard operating procedures (SOPs) not reflecting current working practices.

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

The HTA's regulatory requirements

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

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

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

- the conditions of the licence are complied with.

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

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

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

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

Licensable activities carried out by the establishment

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone	**E**		**E**	**E**	**E**		
Cranial flaps	**E**		**E**	**E**	**E**		
Tendons				**E**			

Background to the establishment and description of inspection activities undertaken

Castle Hill Hospital (the hub) is one of three hospitals where licensable activities take place. Castle Hill Hospital is licensed for the procurement of femoral heads, donor testing, storage and distribution of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. There are two further hospital sites, which are satellite sites to the hub. The satellites are:

- Spire Hull and East Riding Hospital
- Hull Royal Infirmary (HRI)

Femoral heads are procured from patients undergoing elective hip replacement surgery at both the hub and one of the satellites Spire Hull and East Riding Hospital. At the hub, during their pre-assessment visit, patients are given an information sheet on elective hip surgery. On the day of surgery, the bone bank coordinator will identify and seek consent from potential donors. At the satellite, consent is sought during the pre-assessment visit of the donor at the hospital. The pre-assessment nurse takes past medical history, travel history and assesses overall fitness for the surgery. The theatre list is reviewed the day before and donors who

have given consent are highlighted. The collection pots along with the bone bank number and related labels are provided by the bone bank coordinator at the hub.

Blood samples for the mandatory serological testing are taken from the donor on the day of donation by the anaesthetist. In addition, the scrub nurse will take swabs and bone chips from procured femoral heads. The femoral head is placed in a sterile tamper evident screw capped pot which is, in turn, placed in a second sterile tamper evident screw capped pot. Femoral heads are assigned a unique bone bank number, and a patient ID label and a “Not For Implant” allograft sticker are applied to the pot. The procured femoral head and blood sample are delivered from the satellite to the hub by either hospital porters or a courier. The blood samples are sent to the testing laboratory located at the hub and the swabs and bone chips are sent for microbiological testing at the Hull Royal Infirmary. All femoral heads prior to being placed in the quarantine section of the bone bank -80°C freezer are weighed and details of each procurement are entered into the bone bank register and an electronic spreadsheet.

The bone bank co-ordinator contacts all the donors after 180 days to arrange for the repeat mandatory serological testing and arranges either a home visit or, for donors from the Spire Hull and East Riding Hospital, arranges to collect a blood sample during their six-month post-surgery review. The first and second serology test results, as well as the microbiology test results, are recorded on the bone bank register and electronic spreadsheet. Once the serology and microbiology test results are reviewed, and if all results are negative, the bone bank coordinator transfers the femoral head to the “end use” shelf of the freezer and a “For Implant” sticker is affixed to the pot. Any samples with a positive result are disposed of.

The majority of femoral heads stored at the hub establishment are for allogeneic use. Occasionally, femoral heads are also procured for autologous use and stored in a separate section of the freezer at the hub establishment until they are needed for end use. The hub also stores and distributes tendons and bone struts, which are purchased from another HTA-licensed establishment. These are stored on a separate shelf in the -80°C freezer and records are maintained in a separate section of the bone bank register.

The second satellite, Hull Royal Infirmary, procures cranial flaps during neurosurgery for autologous use at a later date. The surgeon consents the patient when possible, otherwise consent is sought from the next of kin or consent may also be assumed, if the patient is unable to consent. A blood sample, bone chips and a swab of the cranial flap are taken in the operating theatre once the surgeon confirms that the cranial flap can be harvested.

Upon harvest, excess tissue is removed and the cranial flap is placed in the appropriate collection pot, assigned with a hospital number, patient ID sticker, and an ‘autologous use’ sticker. The hub establishment is notified and the Trust’s internal courier service is contacted to arrange transportation of the cranial flap along with the associated paperwork. The samples for serology and microbiology tests are sent to the pathology lab within HRI from where they are distributed accordingly. At the hub the donor paperwork is filed, tissue and donor identifiers are recorded and the cranial flap is stored in a separate section of the -80°C freezer to the femoral heads. If needed at a later point for re-implantation, Castle Hill Hospital is notified and the cranial flap is returned to HRI for immediate end use. Patient records and the bone bank register are updated to ensure traceability.

The -80°C freezer is plugged into a power socket, which is on an uninterrupted power supply. The temperature is monitored by a wheel chart which is reviewed and replaced weekly. The freezers are alarmed to the switchboard, which will notify the bone bank coordinator or other

nominated staff both in and out of hours in the event of a deviation from the required storage temperature.

The establishment has been licensed since March 2007. This report describes the establishment's fifth routine inspection which took place over two days on the 18-19 October 2016. Interviews were held with the Designated Individual (DI), the Bone Bank Co-ordinator at the hub and the Clinical Governance Manager at the Spire Hull and East Riding Hospital. A review of documentation relevant to the establishment's licensable activities and a visual inspection of the areas of the establishment where tissue storage and serology testing take place were also included as part of the inspection.

Audits of traceability were carried out and included three femoral heads, one strut and one cranial flap cross-checked against the bone bank register and patient notes. For the cranial flap the audit trail was followed to the serology testing lab where date and time of the blood sample being booked in and operators of the sample processing were confirmed. A total of six donor files and two recipient files were reviewed to ensure that they contained all the relevant documentation, including serology and microbiology test results. There were a few inconsistencies in the filling in and completion of the consent forms and the bone bank register (see advice 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
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Although there are a number of SOPs detailing the procedures for all licensable activities these do not always accurately reflect the current working practices. Examples of these include, but are not limited to: • The SOP for Blood Screening for the procurement of femoral heads states consent may be sought from the next of kin if the patient is unconscious. Consent may also be assumed if the patient is unable to consent. Neither of these scenarios apply to the procurement of femoral heads. • The SOP detailing the procedure for femoral head collection makes no reference to, and provides no example of, the femoral head checklist used at Spire Hull and East Riding Hospital. • The SOP detailing the procedure for procuring femoral heads for a patient's own use does not provide sufficient information on the labelling of the pot. For autologous femoral heads, the establishment's practice is to add the folllowing information to the pots: patient sticker, "not for implant" sticker and an "own use" sticker. Once labelled, pots are placed in the not for implant section of the freezer. Once cleared for issue, unlike allogeneic femoral heads, autografts are left on the same shelf. • Although the use of the bone bank register for recording details of each procurement, serology and microbiology test results is captured in SOPs, the use of the electronic spreadsheet is not. The above details are not captured in the establishment's SOPs. (*See Advice below*)	**Minor**

GQ2 There is a documented system of quality management and audit.		
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.	Although internal audits are carried out there were no written procedures detailing how audits will be carried out. The scope of the audits was also limited, and did not cover the full range of activities carried out under the licence. Although an independent audit had been conducted since the last inspection, it did not verify compliance with protocols and all relevant HTA standards. (*See Advice below*)	**Minor**
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.	The establishment's procedures require femoral heads to be placed into storage within four hours of procurement. Furthermore, femoral heads issued for end use may be returned to storage and re-issued at a later date providing that this timeframe is not exceeded. However, the basis for this timeframe was not documented and the establishment was not able to provide validation data to support its use.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded. e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Although training is provided to new and existing members of staff, this is not formalised or captured in training records. For example, during the inspection it was noted that members of staff were accessing and/ or handling tissue without the records evidencing that they had received relevant training. (*See advice below*)	**Minor**
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.	The establishment has documented procedures for donor selection and exclusion. These do not include all of the donor exclusion criteria as set out in Annex A of the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment. For example, medical history / lifestyle questionnaires do not include questions regarding "Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health" or give consideration to the possibility the donor may have undergone "transplantation with xenografts"	**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.	Although the establishment has carried out a number of risk assessments, they were limited in scope and did not adequately capture all of the risks associated with the activities being carried out under the licence or the full range of control measures that are in place.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1 d	Although there is a document control system in place, none of the documents were version controlled. The DI is advised to ensure that all SOPs, risk assessments and forms are updated to include this information. The DI is also advised to ensure that documents include revision histories, pagination and the names of both the author and reviewer as relevant. Reference to guidelines within SOPs should be reviewed and updated on a regular basis to ensure that they remain current. For example, the reference to "Every Thing You Wanted to know about Donating Bone" Hull and East Yorkshire Hospitals NHS Trust Leaflet 2001 has been replaced by the Total Hip Replacement – Benefits, Risks and Outcome information leaflet (Reference Number: HEY-380/2016). The DI should also consider the use of a document management system, such as used elsewhere in the Trust, to enable a more efficient document control.
2.	GQ3 c, e	The Bone Bank Co-ordinator often observes procurement and implantation procedures at Spire Hull and East Riding Hospital, in part as a means of ensuring staff are competent to carry out activities under the licence.This is not recorded on the training records of the members of staff. The DI is advised to formalise and record training processes such as this to ensure that new and existing members of staff are kept current with all working practices and that this is reflected in the establishment's records. The Hull Royal Infirmary has commenced re-validating the training provided, however, the records to date are on loose pages and are not sufficiently detailed to provide a clear record of the training provided. The DI is advised to include in the training records, as a minimum, the date and training provided, together with the names and signatures of the trainer and attendees. As the hub has sufficient numbers of femoral heads in storage, procurement of tissue at the satellite has ceased for the time being. The DI is advised that when procurement re-commences, all processes should be reviewed to take into account any changes that may have occurred in the interim. Depending on the duration of

		the hiatus, the DI should also consider whether refresher training is needed prior to procurement activities recommencing.
3.	GQ2 b, c GQ4 b, c	A number of discrepancies were noted during the audit of the establishment's written records, including, but not limited to: • For some consent forms, the signature of either the donor or the person seeking consent was missing, the form was not dated or the question "are you at risk of HIV exposure" was not always completed. • It was noted that there was overwriting of records in the bone bank register. The DI is advised to review the establishment's approach to the audit of records. Consideration should be given to the extent and scope of the establishment's internal audits to ensure that records are completed accurately. The results of all audit findings, and actions taken, should be formally recorded and discussed at governance meetings, to ensure continuing improvement of processes and practices. The DI is advised to schedule the independent audit to occur in the intervening year between HTA inspections.
4.	GQ6b	For cranial flaps a 180-day serology test is not required. This is recorded as "-" in the register. The DI is advised to record this as not applicable (N/A). For femoral heads, if the 180-day serology test cannot be undertaken the tissue is discarded. Staff at the Spire Hull and East Riding Hospital are not informed of this, if it relates to donors from this site. As a result, disposal of the femoral head is not recorded in the patient's notes. The DI is advised to inform staff at the satellite so that the patient records are updated accordingly. **Prior to the Final report being issued the DI has made arrangements for the bone bank notes of femoral head donors from Spire Hull and East Riding Hospital to include, when relevant, information regarding reasons for disposal. The DI has made arrangements with staff at the Spire Hull and East Riding Hospital to file the bone bank notes when complete with the patient medical records, so staff that need to be aware of this are.**
5.	PFE4 e	Femoral heads may be transported to the hub by hospital porters or a courier. This is not reflected in the Spire Hull and East Riding Hospital's checklist for femoral head harvesting.The DI is advised to update the checklist accordingly.
6.	N/A	Current practice is for the DI to always report serious adverse events and adverse reactions (SAEARs). Currently no other member of staff has been formally nominated to report SAEARs to the HTA in the DI's absence. The DI is advised to identify at least one other member of staff who could report SAEARs in his absence and to ensure that they have access to the HTA's Portal for this purpose. The DI is advised to appoint additional menbers of staff at the satellite establishments as Persons Designate (PD).

7.	N/A	During the inspection, it was noted that the hub no longer retained patient notes for femoral head procurement from the satellite site. Notes are now returned to the satellite to be filed in the patient's notes. Staff at Spire Hull and East Riding Hospital were not aware of this. The DI should formally notify staff at the satellite of any changes to practices. **This has been addressed- refer to advice item 4.**
8.	N/A	The DI is advised to consider introducing racking into the freezer to facilitate the location of specific femoral heads.

Concluding comments

The HTA observed several examples of good practice during the course of the inspection. Overall the hub and satellite sites work well together to provide a well-organised and co-ordinated service for patients. The bone bank staff often carry out home visits to obtain samples for the mandatory repeat testing, which in turn minimises the risk of femoral heads being discarded.

Six areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. The HTA has also given advice to the Designated Individual with respect to a number of the establishment's procedures, documents, internal and independent audits with a view to helping the organisation further develop its working practices.

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: 07 December 2016

Report returned from DI: 15 December 2016

Final report issued: 13 January 2017

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 July 2017

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 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.
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.
o) There is a complaints system in place.
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.

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.
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.

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.
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.
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.
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.
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.