

Site visit inspection report on compliance with HTA minimum standards

Russells Hall Hospital

HTA licensing number 12129

Licensed for the

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

2 November 2018

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 Russells Hall Hospital (the establishment) had met the majority of the HTA standards, four minor shortfalls were found in relation to governance and quality system standards and premises, facilities and equipment standards. The HTA has also given advice to the Designated Individual with respect to refresher training for consent seekers, procedural documentation, document control, governance meetings, agreements with other licensed establishments, audits, risk assessments and transportation.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Licensable activities carried out by the establishment

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, PBSC; PBSC	E				E		

Background to the establishment and description of inspection activities undertaken

The establishment is licensed for the procurement and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Regulations).

The establishment has been licensed by the HTA since October 2008 and this is the fifth routine site visit inspection to assess whether or not the establishment continues to meet the HTA's standards. Annual activity data, pre-inspection discussions with the DI and the

previous inspection report were used to inform the timetable that was developed for this inspection.

The establishment procures peripheral blood stem cells (PBSCs) from adult donors for autologous and allogeneic use. Donors of PBSCs for allogeneic use are referred from another licensed establishment. Allogeneic donor selection and donor testing is undertaken by the referring establishment. However, a donor blood sample for mandatory serological testing is also taken on the day of PBSC procurement. In relation to allogeneic donors, the establishment (Russells Hall) is acting only as a procurement service which is covered by an SLA between the two licensed establishments (see advice item 5). Russells Hall patients, who have been identified as requiring an autologous stem cell transplant as part of their treatment, have PBSCs procured at the establishment.

Consent for serological testing and the collection, storage and discard of the PBSCs is sought by one of three consultant clinicians who have received training in the seeking of consent (see advice item 1). Serological testing of donors for the mandatory infectious disease markers is undertaken by another licensed establishment which is also where the collected cells are sent for processing and storage. Blood is taken for serological testing up to 30 days prior to the planned PBSC collection date with a second blood being taken for testing on the actual day of procurement.

The apheresis machine used for collection of the PBSCs is stored in the theatre room, part of the establishment's unit where various non-licence related procedures are undertaken such as bone marrow sampling for diagnostic purposes. The theatre room is located away from the general patient area and the apheresis machine is moved, when needed, to a dedicated area of the clinic where PBSC collections are undertaken. Collection kits for the apheresis machine and anticoagulant are stored within the theatre room also, with saline being stored in the establishment's clinic itself in a fluid cupboard. Labels, which are supplied by the establishment which processes and stores the cells, are attached to the cell collection bags at the end of the apheresis procedure while the donor is still on the machine. The procured cells are taken directly to the Trust's blood bank by the apheresis nurse. The blood bank staff re-pack the cells, a donor blood sample for serological testing and cool packs into a validated shipping box supplied by the other licensed establishment undertaking processing and storage. PBSCs are transported to the other licensed establishment undertaking processing and storage by the Trust's transport provider. The blood bank records, on behalf of the establishment, the time that the cells were received at the blood bank, the time the cells left blood bank via the Trust's transport courier, and the time of receipt at the processing and storage establishment. The blood bank monitors the transport of cells and if no confirmation of receipt has been received from the processing and storage establishment, blood bank staff contact the delivery driver and the other establishment to follow up. Following processing of the cells, the establishment receives both interim and final quality reports from the licensed establishment which undertakes processing. When required, the establishment requests the return of cells for transfusion. The establishment that processed and stored the cells is responsible for transporting the cells back directly to the ward where they will be infused.

Audit exercise

During the inspection audits were carried out for two sets of records for donors who had autologous PBSCs procured and reinfused. The records reviewed for each donor included a process checklist, a pathway document for harvest patient, consent forms, donor serological testing results, final cell quality report, a collection pathway document, traceability records relating to transport of cells to the processing establishment, records of collection kits and reagents used, and records of infusion. One minor anomaly was identified during the audit in that one set of donor records did not include a copy of the processing establishment's consent for testing, storage and discard of cells. This was due to the form being sent with the cells to the processing establishment. The establishment has followed up with the processing

establishment who have confirmed that copies of the forms are in their records. The establishment has now amended its procedures to assure the DI that copies of this consent form will always be included in the donor records. No other anomalies were identified.

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

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	Labels for cell collections are provided by the HTA-licensed establishment that processes and stores the tissue and cells on behalf of Russells Hall Hospital. Neither the label or information accompanying the cells to the processing and storage centre have the Single European Code-Donation Identification Sequence (SEC-DI) applied. The SEC is applied using a new label during processing at the other establishment.	Minor
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
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.	The establishment's risk assessments are currently reviewed on a two-yearly cycle and not annually as required.	Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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.	<p>Saline used during the apheresis procedure is stored separately in a fluid cupboard in the establishment's clinic. Although the establishment's Trust has recently distributed temperature monitors around the hospital to areas where fluids are stored, these are not controlled or reviewed by the establishment's staff.</p> <p>A review of the temperature data from the saline temperature monitoring probe showed that there had been multiple temperature excursions above the manufacturer's stated upper temperature limit.</p> <p>In addition, a review of the temperature monitoring data for the anticoagulant stored in the theatre room also showed that there had been excursions from the manufacturer's defined storage temperature range. The establishment reported that in the past, the manufacturer has given assurance that excursions up to 30°C were permissible. However, this was not documented or defined within the establishment's governance and quality systems.</p>	Minor
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.	<p>The establishment has been sending the temperature monitors used to monitor the temperature in the collection room and anticoagulant/collection kit storage areas for re-calibration on a two yearly cycle. However, the manufacturer of the temperature monitoring devices states that the calibration should be carried out annually.</p>	Minor

Advice

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

No.	Standard	Advice
1.	C3(a)	<p>A recent internal audit identified that consent forms were not always completed in the same way by the three clinicians who seek consent. In addition, the establishment is introducing a procedure through which some information can be attached to the consent form using a sticker to standardise information regarding the risks of the cell procurement procedure.</p> <p>The DI is advised to run refresher training to all staff responsible for seeking consent, to both help to assure the DI regarding a consistent approach to the form's completion and to decide on how best to use the information that can be added by attaching a sticker to the consent form.</p>
2.	GQ1(b)	<p>The establishment's standard operating procedure (SOP) covering maintenance of the apheresis machine (SOP/HPCT/APH/117) has not been updated following a change in practice from apheresis equipment being cleaned with water and detergent to being cleaned with antimicrobial wipes. The DI is advised to update this SOP so that the establishment's current practice is reflected.</p>
3.	GQ1(c)	<p>In addition to governance meetings covering the licensable activity such as the Quality and Practice Development Team (QPDT), annual service meetings and user group meetings with the establishment that processes and stores the cells, there are ad-hoc meetings with the immediate cell transplant team including the haematologists and nursing staff. These ad-hoc meetings, however, are not minuted.</p> <p>The DI is advised to discuss any ad-hoc meetings that may have taken place and any significant actions arising from them during the QPDT meetings, which are minuted. This may help to provide a way of capturing the ad-hoc meetings in a more formalised manner.</p>
4.	GQ1(d)	<p>The establishment's current document control SOP (SOP/HPCT/MISC/001) states that documents are reviewed on a "two to three" yearly basis. This wide range of review periods may be confusing to staff. The DI is advised to clarify within the document control SOP that establishment SOPs are reviewed every two years while Trust level policies and procedures are reviewed every three years.</p>
5.	GQ1(r)	<p>The establishment has an SLA with another HTA-licensed establishment through which allogeneic donors selected by the other licensed establishment have their cells procured at Russells Hall Hospital. The DI is advised to review and amend this SLA so that it clearly sets out that donor selection assessments and decisions are being undertaken by the other licensed referring establishment as opposed to this taking place under the DI's licence.</p>
6.	GQ2(b)	<p>The establishment has undertaken a range of internal audits since the last inspection, including audits of the apheresis machine efficiency, donor pathway document completion, cleaning of the apheresis equipment after use and audits of the environment during cell collection to assure the establishment that temperatures were within the apheresis machine manufacturer's recommended range.</p> <p>The DI is advised to continue with the establishment's programme of internal audits and to expand on the current projected audits by including audits of areas</p>

		where reagents and consumables are stored and vertical audits of procured cells from donor consent to re-infusion.
7.	GQ2(c)	<p>The establishment commissioned an independent audit, which was undertaken by staff employed at another HTA-licensed establishment. The other establishment also procures PBSCs and the staff are familiar with the related licensing framework and the HTA's licensing standards. Although findings and outcomes from the independent audit were documented as part of the establishment's governance and quality system, the detail of what was reviewed as part of the audit was not recorded.</p> <p>The DI is advised that when the next independent audit takes place in 2019, in addition to documenting audit findings, all areas that were audited should be documented and a list of applicable HTA standards that have been reviewed included.</p>
8.	PFE1(a)	<p>Anticoagulant and apheresis kits are stored within a cupboard in the theatre room, a part of the establishment's unit where various non-licence related procedures are undertaken such as bone marrow sampling for diagnostic purposes. Although the room is located away from the general patient area, the room and the cupboard where the anticoagulant and consumables are stored are not locked.</p> <p>The DI is advised to risk assess the storage of the reagents and consumables in this area to assure himself that it is appropriate.</p>
9.	PFE4(b)	<p>The establishment uses the Trust's transport service for sending procured cells to the other licensed establishment where they are processed and stored. The establishment developed an instruction sheet for any new drivers to read through and acknowledge by signing. However, the use of this form has stopped.</p> <p>The DI is advised to re-instate the use of the new driver form as it may help to assure him that any new drivers are aware of the correct procedures and location for delivery of cells.</p>

Concluding comments

Areas of good practice were observed during the audit. The tracking of procured cells from receipt at the blood bank to arrival at the processing establishment which is undertaken by the blood bank on behalf of the establishment provided assurance to the DI that expected transport times were being achieved.

There are a number of areas of practice that require improvement, including four minor shortfalls. The HTA has given advice to the Designated Individual with respect to refresher training for consent seekers, procedural documentation, document control, governance meetings, agreements with other licensed establishments, audits, risk assessments and transportation.

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: 30 November 2018

Report returned from DI: No Comments received

Final report issued: 3 January 2019

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: 17 June 2019

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 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 002/2018 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 002/2018.
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 002/2018.

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 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
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 002/2018 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 002/2018.
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 002/2018.
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 002/2018.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
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 002/2018.
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 002/2018.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.

h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Human Tissue Act 2004 Standards

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
<p>a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.</p> <p>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.</p> <p>c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.</p> <p>d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.</p> <p>e) Language translations are available when appropriate.</p> <p>f) Information is available in formats appropriate to the situation.</p>
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
<p>a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.</p> <p>b) Records demonstrate up-to-date staff training.</p> <p>c) Competency is assessed and maintained.</p>
Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
<p>a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.</p> <p>b) There is a document control system.</p> <p>c) There are change control mechanisms for the implementation of new operational procedures.</p> <p>d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.</p> <p>e) There is a system for managing complaints.</p>
GQ2 There is a documented system of audit
<p>a) There is a documented schedule of audits covering licensable activities.</p> <p>b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.</p>

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- a) Qualifications of staff and all training are recorded, records showing attendance at training.
- b) There are documented induction training programmes for new staff.
- c) Training provisions include those for visiting staff.
- d) Staff have appraisals and personal development plans.

GQ4 There is a systematic and planned approach to the management of records

- a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
- b) There are provisions for back-up / recovery in the event of loss of records.
- c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).

GQ5 There are systems to ensure that all adverse events are investigated promptly

- a) Staff are instructed in how to use incident reporting systems.
- b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

- a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
- b) Risk assessments are reviewed regularly.
- c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail

- a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
- b) A register of donated material, and the associated products where relevant, is maintained.
- c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
- d) A system is in place to ensure that traceability of relevant material is maintained during transport.
- e) Records of transportation and delivery are kept.
- f) Records of any agreements with courier or transport companies are kept.
- g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner

- a) Disposal is carried out in accordance with the HTA's Codes of Practice.
- b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards**PFE1 The premises are secure and fit for purpose**

- a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
- b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
- c) There are documented cleaning and decontamination procedures.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

- a) There is sufficient storage capacity.
- b) Where relevant, storage arrangements ensure the dignity of the deceased.
- c) Storage conditions are monitored, recorded and acted on when required.
- d) There are documented contingency plans in place in case of failure in storage area.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

- a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
- b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
- c) Staff are provided with suitable personal protective equipment.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

Or

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

Or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

- (1) A notice of proposal being issued to revoke the licence
- (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

or

A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

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

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed

by further development by the establishment.

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

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

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.