Site visit inspection report on compliance with HTA minimum standards

Royal Bournemouth Hospital

HTA licensing number 11129

Licensed for the

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

- **storage of relevant material which has come from a human body for use for a scheduled purpose**

13-14 March 2019

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 Royal Bournemouth Hospital (the establishment) had met the majority of the HTA standards, seven minor shortfalls were identified. Of these, six related to the governance and quality standards, specifically the review and distribution of standard operating procedures (SOPs), the content of agreements, procedures for the documentation of incidents and reporting of serious adverse events and reactions (SAEARs), overdue competency assessments and risk assessment reviews, and a lack of procedures for the allocation of the Single European Code Donor Identification sequence (SEC-DI). A further shortfall under the premises, facilities and equipment standards related to the calibration certificates for recently purchased maximum-minimum thermometers not being retained by the establishment. This shortfall was resolved prior to the issue of the final report.

Particular examples of strengths and 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.

'SLA' = Service level agreement; the establishment is licensed for this activity but another establishment (licensed) carries out the activity on their behalf.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, Peripheral Blood Stem Cells (PBSC); PBSC	**E**		**SLA**		**E**		

Background to the establishment and description of inspection activities undertaken

The Bournemouth Transplant Unit (BTU) at Royal Bournemouth Hospital (the establishment) has been licensed by the HTA since September 2006. The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q&S Regulations) for the procurement, testing and distribution of peripheral blood stem cells (PBSC). The establishment also holds a licence for storage of relevant material for a scheduled purpose under the Human Tissue Act 2004. This inspection focused on activities licensed under the Q&S Regulations.

The establishment procures PSBC from adult autologous donors undergoing treatment for lymphoma and myeloma. Patients are referred within the Royal Bournemouth and Christchurch Hospital Foundation Trust (RBCHFT) and from Dorset County Hospital. Patients are also occasionally referred from Jersey and Guernsey.

Procured PBSC are sent to a nearby HTA-licensed establishment for processing and storage. This establishment has also recently started to perform the mandatory serological testing of patients, which had previously been performed under agreement by another HTA-licensed establishment. The previous agreement has been retained, and used as a contingency when patients could not be sampled within the timeframe required by the processing and storage establishment. Serological samples are taken no more than 30 days prior to procurement.

Patients are provided with information and opportunities to ask questions during dedicated outpatient clinics. Consent is sought by trained staff using two controlled forms. One captures the patient's consent for mobilisation and apheresis. The other form captures consent for processing, storage, disposal and serological testing. On the first day of procurement apheresis nurses verbally reconfirm consent, and this is documented in the apheresis record.

Procured cells are labelled at the bedside, packed into an interim transportation bag and taken to the hospital's transfusion laboratory. The laboratory is responsible for repacking the cells in a validated transport container surrounded by pre-cooled cold packs. The cells and associated paperwork are transported to the processing and storage laboratory by a trained and experienced courier. Records of collection, delivery and receipt are retained.

Following processing, the establishment receives a summary report from the processing and storage establishment. This doubles as an order form, which the establishment uses to request specific bags for reinfusion. Each stored bag is allocated a unique Single European Code (SEC) in accordance with the Directions 002/2018. The report and request information are retained in patient records.

Cells are supplied in a temperature-controlled dry shipper, and transported by the same experienced courier. Upon receipt, establishment staff check the dry shipper seal is intact and the temperature alarm has not been triggered. Prior to reinfusion, the bag labelling and paperwork are checked against the request and patient identifiers.

When requested, the processing and storage establishment carry out disposal of cells. Records are retained of the disposal request, reason for disposal, authorisation, unique identifiers of the bags disposed, and the date the disposal was carried out.

Consumables are stored at room temperature in a secure storage area. The temperature of the storage area and apheresis room are monitored on each working day by establishment staff using maximum-minimum thermometers. These thermometers are purchased with calibration certificates, and replaced when the calibration expires.

ACD-A is stored in a cabinet, whilst saline and apheresis kits are stored on a neighbouring shelf. The thermometer is located in the cabinet with the ACD-A. During the inspection, staff were advised to move the thermometer to the same shelf as the ACDA to ensure readings accurately reflected the ACD-A storage environment.

This was the establishment's sixth routine site inspection. A visual inspection of the premises was conducted, including the apheresis room, consumables storage area and transfusion laboratory. Round-table discussions were held with establishment staff to discuss governance and quality systems. Records of audits, governance meetings, incidents, equipment maintenance, staff training, cell transport and disposal were reviewed. In addition to this, four sets of patient records were reviewed. These included checklists, consent forms, apheresis records, reports from the processing and storage establishment, ordering and receipt records, and reinfusion records. No discrepancies were identified.

Inspection findings

The HTA found the Designated Individual (DI) 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
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
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.	Establishment documents are managed by an electronic document control system. The distribution list for several standard operating procedures (SOPs) did not include all staff carrying out the procedures described. Therefore there is a risk that staff would not be made aware of procedural updates as soon as they are made effective. A number of SOPs had not been reviewed in the minimum 24 month timeframe stipulated in establishment procedures.	**Minor**
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. s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event	During the inspection a number of issues were identified in the agreements the establishment held with other parties: - The agreement with the establishment carrying out processing, storage and serological testing activities had not been signed by Royal Bournemouth Hospital (RBH) representatives. - The amendment to the agreement with the courier company which sets out SAEARs reporting requirements had	**Minor**

	not been signed on behalf of the courier company. - The agreement with another HTA-licensed establishment, who until recently conducted donor serology testing on behalf of RBH and remain a contingency option, did not include SAEARs reporting instructions, as required by the Directions 002/2018 - The contingency agreement for provision of emergency apheresis services did not specify that the DI would be informed of any incidents related to activities performed on their behalf, or that potential SAEARs would be reported as required by the Directions 002/2018.	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Establishment training procedures include annual competency assessments for staff undertaking procurement. Training records for two apheresis nurses indicated that these had not been undertaken since 2016.	**Minor**
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.	The establishment does not currently have procedures in place to ensure that the SEC-DI is applied after procurement as set out in Directions 002/2018.	**Minor**
GQ7 There are systems to ensure that all adverse events 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. c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.	Establishment procedures describing SAEARs reporting (e.g. documents BTU-GEN-SOP-009 and BTU-APH-SOP-108), have not been updated to reflect the identity of the current DI. Procedures require staff to report SAEARs within 24 hours *or as soon as possible*, which is not in keeping with the requirements of the Directions 002/2018. Discussions during the inspection identified delays in the documentation of some variances, such as a report from the processing establishment of a small clot in	**Minor**

	a bag of apheresed cells. Taken together, these findings amount to a risk that SAEARs events may not be promptly categorised or reported to the DI within a timeframe sufficient to enable reporting to the HTA within 24 hours of discovery.	
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.	A review of the electronic document management system determined that some risk assessments had not undergone an annual review in 2018.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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.	The establishment purchases pre-calibrated maximum-minimum thermometers to monitor the apheresis room and the room used to store temperature sensitive reagents. Calibration certificates for the thermometers that were in use at the time of the inspection had not been retained in error.	**Minor** The establishment were able to obtain copies of the certificates from the supplier so this shortfall was closed prior to issue of the final report.

Advice

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

No.	Standard	Advice
1.	GQ1b	Establishment procedures require two-person checks of apheresis material. At present, due to staff availability, the second person check does not always take place. The DI is advised to risk assess this practice and, depending on the

		outcome, either reinstate the two-person checks or update formal procedures to reflect current activities.
2.	GQ2b	Temperature monitoring records for the apheresis and reagent storage areas are reviewed prior to being uploaded to the establishment's electronic management system. This review is not formally documented or included in the establishment's auditing schedule. The DI is advised to update the relevant SOP(s) and temperature monitoring form, to prompt staff to document this review step.
3.	GQ7	In responding to the shortfall against the GQ7 standard above, the DI is advised to update reporting form BTU-GEN-FORM-130, moving the prompt for consideration of whether an event constitutes a SAE or SAR earlier in the process, rather than after sections capturing root cause analysis and investigations. This would help ensure that SAEARs are reported within 24 hours of discovery, as required by the Directions 002/2018. The DI is further advised to expand the form to include guidance on what would constitute a reportable event so that staff have this information immediately to hand when needed. The reporting form has occasionally been used to capture planned deviations from formal procedures, such as the use of the contingency testing establishment. The DI is advised to consider including instructions in the SOP on how to document planned deviations, so that the planning, risk assessment and formal approval of planned deviations can be captured before the deviation takes place.
4.	PFE3a	The DI is advised to risk assess the storage of apheresis collection kits and the positioning of the maximum-minimum thermometer, to assure themselves that any excursions from the required temperature range would be detected.
5.	PFE3d	The establishment have assigned a storage period to their apheresed cell products. This does not match the expiry date that forms part of the SEC code assigned to each bag of stored cells by the processing and storage establishment. The DI is advised to consider reviewing the required storage period with the processing and storage establishment. The assessment of whether there are any risks associated with this difference should be formally documented, and used to identify any further actions required in relation to this difference.
6.	PFE4 General	The establishment contracts a local courier company to transport cell products between Royal Bournemouth Hospital and the establishment that carries out processing, storage and testing. Due to the size of the courier company this results in a reliance upon one trained and experienced courier. This presents a risk to planned activities should the individual be unavailable, for example at short notice. The DI is advised to explore contingency options and document these in establishment procedures.
7.	PFE5b	The DI is advised to review the acceptable temperature range for the apheresis area (SOP BTU-GEN-SOP-11) to ensure it is in line with the manufacturer's recommendations for the operation of the apheresis equipment. Currently the environmental monitoring SOP states that there is "legally no upper maximum temperature limit".

Concluding comments

The HTA saw examples of strengths and good practice during the inspection. Apheresis and Quality Management staff are experienced, knowledgeable and have taken steps to ensure continuity of care during recent staff changes and periods of illness. The DI, although new to the role and the establishment, has worked hard to develop understanding of the licensing requirements and to implement effective lines of communication with all staff involved in the apheresis service.

Although the HTA found that Royal Bournemouth Hospital (the establishment) had met the majority of the HTA standards, there are a number of areas of practice that require improvement, including seven minor shortfalls. Of these, six related to the governance and quality standards, specifically the review and distribution of standard operating procedures (SOPs), the content of agreements, procedures for the documentation of incidents and reporting of serious adverse events and reactions (SAEARs), overdue competency assessments and risk assessment reviews, and a lack of procedures for the allocation of the Single European Code Donor Identification sequence (SEC-DI). A further shortfall under the premises, facilities and equipment standards related to the calibration certificates for recently purchased maximum-minimum thermometers not being retained by the establishment. This shortfall was resolved prior to the issue of the final report.

The HTA has given advice to the Designated Individual with respect to the review of approved procedures, the content of agreements, capturing the audit of temperature monitoring records, updating the design and content of incident reporting forms, documenting a contingency arrangement in case of the regular courier being unavailable, reviewing the temperature limits for the apheresis room and assessing the necessity to monitor the temperature of the apheresis kits during storage.

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: 11 April 2019

Report returned from DI: 25 April 2019

Final report issued: 07 May 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: 30 September 2020

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 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.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
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.
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.
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.
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.
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.
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.
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.
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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.
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.
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.
e) Language translations are available when appropriate.
f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
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.
b) Records demonstrate up-to-date staff training.

c) Competency is assessed and maintained.

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
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
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.