Site visit inspection report on compliance with HTA minimum standards

Royal Orthopaedic Hospital

HTA licensing number 12379

Licensed for the

- **procurement, storage 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**

22-23 October 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 The Royal Orthopaedic Hospital (the establishment) had met the majority of the HTA standards, three major (one cumulative) and eleven minor shortfalls were found in relation to Consent, and Governance and Quality Systems. The major shortfalls relate to the agreement with end users to report Serious Adverse Events and Reactions (SAEARs) within the required timeframe, the absence of an independent audit and the management of records / maintenance of traceability. The minor shortfalls relate to the absence of patient consent to HTLV1 testing, a limited internal audit system, the absence of documented validation of procedures to assure the quality and safety of tissues and / or cells, a lack of documented training / competence programme, the documented procedures for retention of raw data and recall, the absence of information required to maintain traceability (e.g. Single European Code, SEC), the lack of risk assessments for all licensable activities, insufficient monitoring of critical equipment / storage areas and no evidence of ongoing servicing or maintenance for critical equipment.

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone				**E**	**E**		
Musculoskeletal, Bone; Bone Strut				**E**	**E**		
Musculoskeletal, Tendon & Ligament; Menisci				**E**			
Musculoskeletal, Tendon & Ligament; Tendons				**E**			
Other, Cartilage (ATMP)	**E**		**SLA**				

Background to the establishment and description of inspection activities undertaken

The Royal Orthopaedic Hospital, based in Birmingham, is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) for the storage and distribution of femoral heads and bone struts; the storage of tendons and menisci and the procurement of cartilage as a starting material for an Advanced Therapy Medicinal Product (ATMP). The establishment has a satellite site, the Robert Aitken Institute of Clinical Research, located at the University of Birmingham, which is licensed under the Human Tissue Act 2004 (HT Act) for storage of relevant material which has come from a human body for use for a scheduled purpose. The satellite site and therefore the activities licensed under the HT Act were not inspected during this visit.

The establishment purchases femoral heads and bone struts from one HTA-licensed establishment and other allografts (menisci, tendons) from three different HTA-licensed establishments. Upon receipt, the integrity of the outer and inner packaging is checked to ensure there is no damage and that the product is received in a frozen state. For each product, the date of receipt, product type, unique International Standard for Blood and Transplant (ISBT) 128 G number, expiry date, weight / dimensions (as applicable) and the signatures of the theatre personnel (first and second checker) undertaking the task is recorded in the bone register. A unique in-house number is assigned to the products and written on the outer packaging before placing into the -80°C freezer for storage. The different categories of allografts are colour coded within the register for ease of identification when selecting a product for a patient. When a patient requires an allograft, the appropriate product is removed from the -80°C freezer. The date and time of removal, patient identification sticker, theatre number, surgeon name and the name of the theatre personnel removing the allograft is recorded in the bone register against the corresponding allograft entry.

The establishment has an agreement in place to distribute femoral heads / bone struts to a private hospital. The patient's name, date of birth, hospital number and the name of the surgeon is recorded in the bone register against the corresponding allograft entry. The allograft is placed into a validated transport container with freezer packs and transported by courier on the day of surgery.

The establishment also procures cartilage as a starting material for an ATMP. Patients are referred from their GP and cases are reviewed at a multi-disciplinary team (MDT) meeting for eligibility and suitability. Patient consent is recorded by Clinicians on two separate consent forms (Trust and ATMP manufacturer). A maximum of five autologous chondrocyte implantation (ACI) kits are stored on-site within the consumables store room; the unique kit number, expiry date, date / time of receipt and the name of the theatre personnel receiving the kits is recorded in a traceability register. On the day of procurement, the next appropriate ACI kit is selected, the theatre number, surgeon name, patient identification sticker and donation identification sequence (SEC-DI) of the patient is recorded in the traceability register. The cartilage biopsy is placed into the biopsy buffer tube and packaged with the blood sample ready for collection by courier for transfer to the ATMP manufacturer. All tests for the mandatory serology markers except HTLV-1 are undertaken by the ATMP manufacturer. A separate blood sample is collected and sent to another HTA-licensed establishment for HTLV-1 testing.

This was the sixth routine inspection of the site. The visual inspection was undertaken in the theatres department and covered areas where the licensable activities of storage and distribution take place, this included the consumables store room used for the storage of ACI kits.

As part of the inspection process, a traceability audit was carried out. The details of three allografts (two femoral heads and a tendon) entered into the bone register were verified against the tissue stored in the freezer. Two allografts (femoral head and tendon) were located in the freezer but one femoral head was not; following an extensive review of surgeon's registers the establishment was able to reconcile the allograft to a patient.

In addition, details of patients were selected from the bone register (three patients) and operations record (one patient). Firstly, information from the bone register (e.g. date of operation, allograft identification number) was verified against patient notes. In three cases traceability of the allograft used was maintained. Secondly, information from the operations record (e.g. date of operation, patient identification) was verified against patient notes. In this case, traceability of the allograft used was not maintained to end use (see shortfall under GQ6b).

Records for four patients that had undergone cartilage procurement were also reviewed and no discrepancies 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

Consent

Standards	Inspection findings	Level of shortfall
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) 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, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice.	The establishment has taken the decision to test all donors undergoing the ACI procedure for HTLV-1; however, in the four patient records reviewed, there was no documented evidence of patient consent to undergo the test. The test results are available electronically but there is no audit trail to demonstrate the result is reviewed prior to procurement of the cartilage biopsy.	**Minor**

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.		
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	At the previous inspection a shortfall was identified because the third party agreement with the private hospital did not specify that SAEARs should be reported to the establishment within 24 hours of discovery. Following the inspection, the establishment implemented a contract variation in January 2017 to include the requirement for SAEARs reporting. However, the current agreement has not retained the contract variation. The reoccurring nature of the omission means the level of the shortfall is classified as major.	**Major**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Although three audits have been completed for Bone Bank activities (traceability for transplanted tissue; ACI procedure and supplied tissue) in October 2018, the scope of the internal audits is limited and no other audits have been undertaken since the previous inspection.	**Minor**
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.	There has been no independent audit undertaken since the last inspection, and there is no arrangement in place currently for this audit to be completed. A similar shortfall was identified during the previous inspection in 2016; the reoccurrence therefore means the level of the shortfall is classified as major.	**Major**
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.	The establishment's procedures make reference to returning bone tissue to the freezer within 30 minutes if it is decided it is not required for surgery (HTA7 Receiving Unused Bone Tissue Back into Freezer). The basis for this timeframe was not documented and the establishment was not able to provide validation data to support this approach.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Although staff are trained in the procedures undertaken in theatres in relation to allograft products (e.g. receiving and recording the use of bone), there is no documented training programme and staff competence is not recorded. The establishment's training programme for the ACI activities is well established.	**Minor**
GQ4 There is a systematic and planned approach to the management 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. 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.	Although three audits were completed in October 2018, the establishment has no system for the regular audit of records (e.g. the bone register) and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found. During the traceability audit, a range of issues were identified in relation to the establishment's records and holdings. For example: • no date of allograft use or disposal • no details of the patient receiving the allograft • allograft use recorded in the incorrect place • the indication that an allograft should be in the freezer but it was not • details of the femoral head used in a patient were not recorded in the patient record.	**Major (cumulative)**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
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.		

GQ4 There is a systematic and planned approach to the management of records.		
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.	Raw data, such as temperature records are retained by the establishment; however, it has not been documented that they must be kept for 10 years after the use, expiry date or disposal of tissues and / or cells.	**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 SEC was not recorded in the patient notes for the allograft products.	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
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.	There is no documented procedure for the recall of products (e.g. allografts) distributed to the establishment or end users in the event of an adverse incident. Although there is a Trust policy entitled 'Policy for Patient or Staff recall for a potential adverse event', there is no reference to allograft products within this policy.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes.	Although the establishment had documented risk assessments for the activities associated with the ACI processes, there were no comparable risk assessments associated with processes relating to allograft products (e.g. receiving and recording the use of bone; transporting bone to other hospitals).	**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.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	Establishment staff manually record the temperature of the -80°C freezer once a day (Monday – Friday). The -80°C freezer was connected to a continuous temperature monitoring system in February 2018, but this has not been fully implemented within the theatres department and staff do not currently have access to the system. As a result, they are currently unable to assure themselves that products stored within the -80°C freezer are maintained within the expected temperature range out of hours and at weekends. ACI kits are stored within the consumable store room and establishment staff manually record the temperature of the room once a day (Monday – Friday). They are unable to assure themselves that the kits stored here are maintained within the expected temperature range (5 – 25°C).	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
e) There are documented agreements with maintenance companies.	During discussions with staff, the inspection team were advised that it was the policy of the department to have service / maintenance contracts in place for freezers. However, the establishment was not able to produce documented agreements with maintenance companies for such work, and the freezers (the main -80°C storage and -40°C contingency freezers) had not been serviced since prior to the previous inspection in 2016.	**Minor**
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	The establishment's procedure for decontamination of the freezer (HTA4 Decontamination of Bone Freezer) states that the bone freezer must be decontaminated every six months. There is no documented evidence to demonstrate that this has been undertaken.	**Minor**

Human Tissue Act 2004 Standards

The activities under the HT Act 2004 licence were not inspected during this visit.

Advice

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

No.	Standard	Advice
1.	GQ1b	The DI is advised to ensure that standard operating procedures (SOPs) accurately reflect current practices. For example, the fax back form in procedure HTA11 is no longer in use; HTA3 refers to purchasing from NHSBT but other suppliers are also used; HTA12 refers to storing bone from NHSBT only.
2.	GQ1r	The DI is advised to review section six of the agreement with the private hospital to ensure the roles and responsibilities are clearly described.
3.	GQ2a GQ3k	During the course of this inspection, a number of shortfalls were identified in relation to aspects of the QMS (see shortfalls table). There is one member of staff (Technical Standards Lead) with responsibility for maintaining the QMS associated with activities within the theatre department, with no contingency for sickness or absence. The DI is advised to ensure sufficient resource is available to effectively maintain the QMS in order that there is continual quality improvement.
4.	GQ3g	The DI is advised to ensure that staff induction includes a description of the quality systems in place within the theatres department.
5.	GQ4c	The DI is advised to ensure when staff amend a record, the person records their initials and the date of the amendment.
6.	GQ7b	The DI distributes HTA updates to the whole trust via the Communications department; the DI is advised to distribute updates specifically to staff involved with licensable activities.

Concluding comments

There are a number of areas of practice that require improvement, including three major shortfalls and eleven minor shortfalls. In addition, there are some areas of practice that may benefit from further improvement and HTA has given advice to the Designated Individual with respect to these.

Two shortfalls, relating to third party agreements and audit, identified during this inspection were identified previously in 2016 and this is reflected in the level of shortfall for these standards in this report.

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: 19 November 2018

Report returned from DI: 3 December 2018

Final report issued: 14 December 2018

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: 24 May 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
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.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
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.
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.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
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
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.