Site visit inspection report on compliance with HTA minimum standards

Fisher BioServices

HTA licensing number 11074

Licensed for the

- **storage, distribution and export 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**

16 and 17 May 2018

Summary of inspection findings

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

Although the HTA found that Fisher BioServices (the establishment) had met the majority of the HTA's standards, six minor shortfalls were found in relation to: (i) an absence of a documented plan for the contingency storage of tissues and cells; (ii) an incomplete independent audit; (iii) an absence of a documented plan for the contingency storage of records; (iv) incomplete donor selection and testing criteria; (v) an incomplete set of risk assessments; and (vi) inappropriate review periods for risk assessments.

Advice has been given relating to the Governance and Quality standards.

Particular examples of strength 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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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 licenses 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.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue Category; Tissue Type	Storage	Distribution	Export
Mature Cell, T Cell (DLI); DLI	**E**	**TPA**	**E***
Other; Cord Tissue	**E***	**TPA**	**E***
Other; Retinal Cells (ATMP)	**E**	**TPA**	**E***
Progenitor Cell, Hematopoietic,	**E**	**TPA**	**E***

Bone Marrow; Bone Marrow			
Progenitor Cell, Hematopoietic, Cord Blood; Cord Blood	**E***	**TPA**	**E***
Progenitor Cell, Hematopoietic, PBSC; PBSC	**E**	**TPA**	**E***
Progenitor Cell, Hematopoietic, Unspecified; Whole Blood	**E***	**TPA**	**E***

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Fisher BioServices (the establishment), which was issued an HTA licence in October 2006. This was the sixth HTA site visit inspection of the establishment (the last inspection was in February 2016). The current inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards.

Fisher BioServices is part of the Thermo Fisher Scientific group. Fisher BioServices has more than 20 biorepositories worldwide; it is the UK biorepository which is covered by this HTA licence.

The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended; Q&S Regulations) for the storage, distribution and export of tissues and cells for human application.

The establishment is also licensed under the Human Tissue Act 2004 (HT Act) for the storage of relevant material for use for a scheduled purpose. Relevant material from living and deceased donors is currently being stored for the scheduled purposes of: obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); research in connection with disorders, or the functioning, of the human body ('research'); and quality assurance.

Relevant material stored under the HT Act includes tissue samples: formalin-fixed, paraffin wax-embedded (FFPE) material (blocks and sections on glass slides); isolated cellular preparations (e.g. buffy coat layer); fresh frozen tissue and frozen tissue sections on glass slides; and body fluids (whole blood, cerebrospinal fluid, saliva and urine), swabs (cervical and urethral) and bodily waste products (meconium and faeces). Non-relevant material (e.g. plasma and serum) is also stored.

The establishment is also licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) for the storage, release and distribution of Investigational Medicinal Products and by the Human Fertilisation and Embryology Authority (HFEA) for the contingency storage of human gametes. The establishment has a quality management system that is compliant with International Organization for Standardization (ISO) standard 9001 (2015).

The DI is the Interim Quality Manager, the Corporate Licence Holder (CLH) is Thermo Fisher Scientific and the CLH Contact (CLHC) is the Senior Operations Manager and Site Lead.

There is one Person Designated (PD) working under the licence, the Quality Assurance Team Manager.

Sample management

The establishment stores tissues and cells and relevant material under contract (termed 'quality technical agreements', QTAs) with each of its clients. Client QTAs under the Q&S Regulations include a declaration ('Declaration of Material', DOM) that appropriate and valid consent is in place and that tissues and cells have been tested for mandatory infectious disease markers [see shortfall against standard GQ5(a)]. Client QTAs under the HT Act include a DOM that states that appropriate and valid consent is in place. The establishment then creates 'client specific project plans' (CSPPs) which give detailed work instructions for each client. These are used alongside generic standard operating procedures (SOPs).

Tissue and cellular samples and samples for research are received into the establishment in validated temperature-monitored dry shippers or dry ice containers and are labelled and logged into the tissue register and onto the establishment's electronic database with unique identifiers. There are integrity checks of the sample and the temperature of the shipment packaging as well as checks of the paperwork. Non-conformances are managed by a specific SOP. Transport is under the terms of a Third Party Agreement (TPA) with each of three separate couriers.

The establishment also receives full storage containers from some clients, accompanied by sample manifests. Samples within such containers are not checked individually but the manifests are logged into the establishment's database.

Samples are returned to clients in temperature-monitored containers and there is a procedure for client confirmation of receipt.

The tissue register and database contain information on the location of each sample within the storage facility. The system is updated as samples are returned to the client or used in the establishment's laboratory (or occasionally disposed). The database is backed-up regularly on the main servers.

Storage:

The site is a secure, light industrial unit that houses the plant, offices, laboratory and sample storage areas. Entry and exit points are monitored by closed-circuit television (CCTV) and there is electronic access control. There are out-of-hours intruder and proximity-sensing alarms, which are monitored by the security company. Lone working and out-of-hours unaccompanied access occur occasionally and there are SOPs to cover these activities.

The facility contains 80 lockable liquid nitrogen storage vessels (cryovessels) for vapour phase storage, 170 lockable -80°C freezers, three 'walk-in' -30°C units, one walk-in -20°C unit and a dedicated area for controlled ambient temperature storage. There is also one fully automated -80°C robotic storage archive module. Tissue and cellular samples which are positive for mandatory infectious disease markers are stored separately in 'quarantine' storage containers. All storage containers are linked to a continuous temperature-monitoring unit that feeds into a wireless callout system. Temperature excursions outside the set ranges trigger both audible alarms and the callout system and the system is tested regularly. Power failure also triggers the alarms and the callout system.

The establishment maps the temperature of cryovessels and freezers on a regular basis.

There are fixed oxygen-depletion monitors in the liquid nitrogen storage area linked to an alarm system.

Most, but not all, of the cryovessels are linked to an automated filling system. Failure of the cryofilling system triggers the audible alarms and the wireless callout system.

There are back-up cryovessels and freezers for contingency storage and all storage containers are subject to an annual service under contract.

There is a separate storage area for client containers. These are also linked to the wireless callout system. This area currently houses 70 -80°C freezers.

Sample handling and transfer is by means of proprietary temperature-controlled ‘cryocarts’.

Disposal

Although most samples are returned to clients for disposal, the establishment occasionally disposes of non-conforming consignments. A record of disposed samples is kept in the tissue register and on the database.

The timetable for the site visit inspection was developed after consideration of the establishment’s previous inspection report, communications with the HTA since the last inspection and annual activity data. The inspection included a visual inspection of the sample storage areas and area for sample receipt and distribution. Discussions and interviews were held with key staff and documentation was reviewed. Interviews were held with the current DI, previous (and returning) DI, CLHC, PD, an Operations Team Leader and a project manager.

Audits of traceability were carried out:

- Seven samples from three separate research studies (three frozen tumour samples from one study; two whole blood samples from a second; two FFPE sections on glass slides from the third) were selected from the -80°C freezers or from the ambient temperature storage area. Labelling details and storage location were compared to the paper records (delivery notes, tissue register) and the database. There were no discrepancies noted.
- The electronic and paper records for 10 PBSC donations (for human application) were reviewed. The following information was cross-referenced: presence of signed and up-to-date client QTA, DOM and CSPP; confirmation of consent and serological screening; product labels; and cryovessel storage location. There were no discrepancies noted.

Inspection findings

The HTA found the DI and the CLH 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.		
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.	There is no documented plan for the contingency storage of tissues and cells in the event of termination of activities.	**Minor**
GQ2 There is a documented system of quality management and audit.		
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	The establishment has had one independent audit. This was conducted by an auditor from the sister UK Organisation (Fisher Clinical Services). However, this was only against the shortfalls identified from the last HTA inspection and was not against the full set of applicable standards under the Q&S Regulations.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.	There is no documented plan for the contingency storage of records of traceability and raw data in the event of termination of activities.	**Minor**

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.	Client QTAs and DOMs under the Q&S Regulations do not currently include donor selection criteria for HTLV-1 infection and testing for HTLV-1 when required. HTLV-1 testing at the time of donation is mandatory for donors living in, or originating from, high prevalence areas, or with sexual partners originating from those areas, or where the donor's parents originate from those areas. A repeat antibody test after 180 days would also be necessary for those at risk of recent HTLV-1 transmission.	**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.	There are risk assesments for the premises and storage facilities but there are no risk assessments covering the full traceability requirements for tissues and cells (e.g. receipt, release and disposal).	**Minor**
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.	Risk assessments are currently reviewed every two years.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ3(f)	There is a detailed documented training programme that ensures that staff have adequate knowledge of the regulatory context to their work. This currently covers all regulators and accreditors in one session (HTA, HFEA, MHRA, ISO). The DI is advised to consider dividing the training into separate sessions for each of these regulators and accreditors.
2.	GQ6(d)	The Single European Code (SEC) requirements vary depending upon the time when tissues and cells have been procured and stored. The establishment has been storing collections received from clients since 2010. The DI is advised to refer to the 'HTA guidance on coding and import regulations for tissues and cells in the human application sector' (page 9) for the different SEC requirements for each time period (before 29 October 2016, 29 October 2016-1 April 2018, after 1 April 2018).

Concluding comments

During the inspection, areas of strength and good practice were noted:

- There is evidence of good teamwork and good lines of communication.
- 'Technical agreements' (TPAs) clearly delineate the responsibilities of each party in tabular form.
- There is a comprehensive Quality Manual highlighting a well-controlled Quality Management System.
- The establishment has good follow-up procedures for internal audits, with actions assigned to appropriate staff and findings distributed throughout the team.
- There is a detailed competency assessment training programme for all staff, with trained 'experts' in each area of competency. Staff are observed four times before being signed off and there are annual refresher competency assessments.
- Prior to product release, all temperature storage data is checked for the duration of the storage, allowing for a seamless and timely process on the day of release.
- The establishment has introduced a new system of daily '3 tier' reporting to management, to ensure that all incidents, root causes and corrective and preventative actions are captured and acted upon.
- The establishment has good follow-up procedures for all incidents with regular discussion at monthly Leadership Meetings and quarterly Quality Review Meetings.
- The establishment has introduced a new 'SOP improvement scheme', allowing any member of staff to feed back continual improvement ideas on SOPs.

There are a number of areas of practice that require improvement, including six minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality standards.

The HTA requires that the DI 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: 29 June 2018

Report returned from DI: 4 July 2018

Final report issued: 18 July 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: 29 October 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.
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
C2 Information about the consent process is provided and in a variety of formats.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions Directions 002/2018 is included.

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.
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.
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.
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.
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.
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.

GQ6 A coding and records system facilitates traceability of tissues and / or 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.
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.
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.
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.
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
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.

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.
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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions.

1. **Critical shortfall:**

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

   or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represents a systemic failure and therefore is 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 straight away.

2. **Major shortfall:**

   A non-critical shortfall.

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

   or

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

or

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

or

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

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

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

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major and which can be addressed by further development by the establishment.

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

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

Follow up actions

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

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

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

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