Site visit inspection report on compliance with HTA minimum standards

MTS Cryo Stores UK Ltd

HTA licensing number 22499

Licensed for the

- **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**

16 May 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 MTS Cryo Stores UK Ltd (the establishment) had met the majority of the HTA standards, eight minor shortfalls were found in relation to governance and quality systems (GQS) and premises, facilities and equipment (PFE) standards under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations 2007) (as amended). The shortfalls were related to the lack of procedures in place for the tissues and/or cells to be transferred to another licensed establishment in the event of termination of activities, agreements, internal audits, training, incident reporting procedures, risk assessments and the absence of equipment maintenance records. One minor shortfall was found in relation to the traceability standards under the Human Tissue Act 2004.

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.

'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	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell; Hematopoietic; Bone Marrow; Bone Marrow				**E**	**E/ TPA**		
Mature Cell, T Cell (DLI); DLI				**E**	**E/ TPA**		
Progenitor Cell, Haematopoietic, PBSC; PBSC				**E**	**E/ TPA**		
Progenitor Cell; Hematopoietic; Cord Blood; Cord Blood				**E**	**E/ TPA**		

Background to the establishment and description of inspection activities undertaken

This reports refers to the activities carried out by MTS Cryo Stores UK Ltd (the establishment). The establishment is licensed for the storage and distribution of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations 2007) (as amended). It is also licensed for the storage of relevant material under the Human Tissue Act 2004 (HT Act 2004). The establishment was first issued a HTA licence in 2008 and this was the sixth routine site visit inspection to assess whether the establishment is continuing to meet the required HTA standards. The establishment also has International Organisation for Standardisation (ISO) 9001 certification.

The establishment stores tissues and cells, under contract, on behalf of their clients within a secure warehouse. MTS Cryo Stores UK Ltd also offer a contingency storage service to other human application and/or research HTA-licensed establishments. Before any samples are accepted the establishment performs a gap analysis to determine the feasibility of removing the freezers/liquid nitrogen storage vessels from the client's premises. Once this is confirmed, the establishment signs an agreement with the client. The agreement requires for an inventory of the samples to be stored, to be generated, and information to be provided regarding whether the samples will be stored under the Q&S Regulations 2007 or the HT Act 2004. The establishment receives full storage tanks or freezers from some clients to store in their facilities, which are not always accompanied by an inventory. Samples within these vessels are not checked individually or logged into the establishment's database.

Individual samples are received into the establishment and staff at MTS Cryo Stores UK Ltd undertake visual checks of packaging before the samples are checked against the inventory provided by the customer. The individual samples are scanned and logged into the establishment's proprietary database. Any non-conforming samples are placed into quarantine. In addition to the database, the receipt and distribution of samples is also logged on a shipping log form, which is filed with the customer's personal file. Sample movement is tracked in electronic and paper format. Electronic tracking is carried out against the database, and the chain of custody form is filled in and filed with the customer's personal file.

The establishment has a range of -20°C, -40°C, -80°C freezers, vapour phase liquid nitrogen vessels and a dedicated area for controlled ambient temperature storage. The freezers with human samples are labelled accordingly and are locked using individual keys which are kept in a secure key box. Several -80°C freezers are available on the premises to be used for contingency storage. The establishment employs a number of engineers who are available to deal with emergencies 24 hours a day.

A set of checklists and worksheets are used to record movement of samples in and out of the establishment and a freezer entry log is affixed to the door of each freezer. All freezers are continuously temperature-monitored and the data is backed-up weekly. In addition to this, some of the freezers are temperature monitored using chart recorders; these record one week of data at a time. The charts are replaced weekly and these are scanned and saved onto a server every three months. There is a daily temperature monitoring form which is filled in every day, but not at weekends for those freezers owned by clients who have opted not to have a temperature chart recorder.

All freezers and storage vessels are temperature-monitored using equipment which feeds into an automatic call-out system. Temperature and liquid nitrogen level excursions outside the set ranges trigger both audible alarms and the call-out system. Power failure or failure of the cryo-filling system also triggers the alarms and the call-out system. The system is tested regularly, as is the back-up generator system. There are a series of checklists for recording routine operational checks, maintenance and testing of the alarms of the equipment in the storage areas.

The liquid nitrogen storage area has an oxygen depletion monitor also linked to the wireless call-out system and the staff entering the liquid nitrogen area use an additional personal oxygen monitor. Most of the liquid nitrogen vessels are linked to the automated cryo-filling system, but some are filled manually.

The inspection consisted of a visual inspection of the storage facilities, several discussions with those working under the licence and a review of the establishment's documentation relevant to the licensable activities.

A traceability audit of three sets of samples was performed during the visual inspection, which included the storage and labelling of the samples stored under the HT Act 2004. Two sets of samples were found in the correct location in the -80ºC freezer. However, there was a discrepancy with the third set of samples which could not be traced to paper or electronic records.

Inspection findings

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

Compliance with HTA standards

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
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 procedure to ensure that in the event of termination of activities, stored tissues and/or cells are transferred to another licensed establishment.	**Minor**
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.	The agreement with the courier does not clearly specify the responsibilities of the third party as set out in the Directions 002/2018. The third party agreement (TPA) with courier does not specify: • that the third party will inform the establishment in the event of a serious adverse event; • that, in the event of a dry shipper belonging to the third party being used to transport samples, a copy	**Minor**

	of the temperature data will be provided to the establishment for the shipment; • that the third party dry shippers are serviced, maintained and decontaminated between use and a copies of associated records will be provided to the establishment as required; and • that, in the event that the courier company uses subcontractors for shipments, the subcontractors are trained in handling shipments, documentation completion and the incident reporting requirements.	
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Although an internal audit has been conducted since the last inspection, the scope of the audit was limited and there was no evidence that follow up actions had been taken to address the findings. In addition to this, the documentation for the stock audit could not be produced during the inspection.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
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.	There is no documented training programme encompassing the regulatory context or scientific and ethical principles relevant to the establishment's work.	**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.	The establishment currently has three different standard operating procedures (SOPs) for reporting incidents: serious adverse event reporting, emergency events, and deviation reporting. However, the records of the reported incident/events seen at the time of inspection lacked sufficient information to fully understand what had happened for the investigation to be effective. See *Advice,* item 3, below.	**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.	The establishment's risk assessments were updated in 2018 and have superseded the previous versions. However, the latest versions of the risk assessments only cover the health and safety aspects of working practices and do not consider risks to the quality and safety of tissues and cells stored under the licence. See *Advice,* item 7, below.	**Minor**
c) Staff can access risk assessments and are made aware of local hazards at training.	Risk assessments are not made accessible to the staff carrying out licensable activities.	**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.	During the documentation review, it was identified that there were a number of servicing records missing for the six cryo-tanks in use for the past two years; the establishment could not locate the missing records.	**Minor**

Human Tissue Act 2004 Standards

Traceability standards		
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail	**Inspection findings**	**Level of shortfall**
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	A review of the establishment's internal reporting system identified an incident in which the wrong samples were shipped to a client. The establishment did not have	**Minor**

sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	any records detailing what had happened to the samples that were sent, resulting in a loss of traceability. In addition to this, during the traceability audit, there was a discrepancy with the third set of samples, which could not be traced to paper or electronic records.	

Advice

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

No.	Standard	Advice
1.	GQ1c	Since the last inspection, two governance meetings have been carried out in December 2018 and May 2019. The DI is advised to consider carrying out these meetings on a more regular basis, and to expand on the items discussed to include incidents, risk assessments, findings from audits and the actions taken. This approach may help raise awareness amongst the staff involved in this work of the associated regulatory requirements, and facilitate the integration of the licensable activities into the governance and quality management system used by the establishment.
2.	GQ2c	The DI is advised to expand the scope of the next independent audit to include a traceability audit of samples (GQ6c) and the Single European Code (SEC) (GQ6d) standards. The DI is also advised to clearly document any findings and evidence of corrective actions taken following audits.
3.	GQ3e, GQ7a	The DI is advised to consider updating the event/incident reporting form to include near misses and allow the capture of any corrective actions taken, what happened to the tissues and cells and the lessons learned to provide continuous improvement to the quality management systems. The DI is also advised to arrange training for staff who are responsible for reporting incidents and to document their competency.
4.	GQ3e	The DI is advised to update the competency documents and training records for the staff to ensure the right levels of training have been documented for each individual. This should include a sign-off section to record that the individual has been trained and is fully competent to work independently.
5.	GQ3e, GQ4b	Several forms filled in by engineering staff for the freezer servicing were not fully completed with fields consistently left empty. In addition to this, the 'Induction policy and procedure' was not document-controlled. The DI is advised to consider extending the scope of document audits to include a check for completeness, legibility and accuracy and to resolve any discrepancies found and implement good documentation practice training for the staff completing records.
6.	GQ5d	The DI is also advised to include a reference to the HTA's "Guide to Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment" in section 1-8 of the technical agreement relating to donor testing instead of referencing www.hta.gov.uk.

7.	GQ8a	The DI is advised to carry out risk assessments for staff lone working and taking the back-up hard drive, which holds the electronic data and records relating to the licensable activities, home on a regular basis.
8.	PFE5a	The establishment purchases pre-calibrated personal oxygen monitors for staff entering the liquid nitrogen cryo-storage room. At the time of inspection the calibration certificate for the logger in use could not be found, although the establishment was able to contact the supplier to obtain a copy of the certificate. The DI is advised to retain copies of the calibration certificates for the personal oxygen monitors.

Concluding comments

There are a number of areas of practice that require improvement, including nine minor shortfalls. The shortfalls were related to the lack of procedures in place for the tissues and/or cells to be transferred to another licensed establishment in the event of termination of activities, agreements, internal audits, training, incident reporting procedures, risk assessments, the absence of equipment maintenance records and traceability of samples.

The HTA has given advice to the Designated Individual with respect to a number of the establishment's procedures related to the governance and quality management systems, audits, training, document completion, agreements and risk assessments with a view to helping the establishment further develop its working practices.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 14 June 2019

Report returned from DI: 04 July 1019

Final report issued: 19 July 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

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.
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.
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.
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.
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.
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.
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. 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.

- **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

- **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.

- **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.