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**

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

16 May 2017

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, two major and seven minor shortfalls were found with regard to the Governance and Quality Systems (GQS) standards. The major shortfalls relate to the development of procedures and to the recording, investigation and reporting of incidents. The seven minor shortfalls were in relation to the documented procedures, governance meetings, agreements, overarching quality management system, system of audits, staff training, contingency agreements and risk assessments.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Licensable activities carried out by the establishment

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

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
BM	**-**	**-**	**-**	**E**	**E/ TPA**	**-**	**-**
DLI	**-**	**-**	**-**	**E**	**E/ TPA**	**-**	**-**
PBSC	**-**	**-**	**-**	**E**	**E/ TPA**	**-**	**-**
UCB	**-**	**-**	**-**	**E**	**E/ TPA**	**-**	**-**

BM = cells derived from bone marrow; DLI = cells for Donor Lymphocyte Infusion; PBSC = peripheral blood stem cells; UCB = umbilical cord blood.

Background to the establishment and description of inspection activities undertaken

This reports refers to the activities undertaken by MTS Cryo Stores UK Ltd. 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) and for the storage of relevant material under the Human Tissue Act 2004 (HT Act 2004). 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 disaster recovery 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 clients 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 and whether they will come under the Q&S Regulations 2007 or the HT Act 2004.

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 in quarantine. In addition to the database, the receipt and distribution of samples is also logged on the shipping log form, which is filed with the customer's personal file. The -80°C freezers have a freezer layout map attached to the door, but this is not always up to date (see *advice and guidance, item 3*).

Sample movement is tracked in electronic and paper format. Electronic tracking is done against the database, and the MTS Cryo Stores UK Ltd Chain of Custody form is filled in and filed with the customer's personal file. 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.

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. Several -80°C freezers are available on the premises to be used for disaster recovery or as contingency storage. The establishment employs a number of engineers who are available to deal with emergencies 24/7. It also runs an ultra low temperature refrigeration repair business offering ongoing freezer maintenance to their customers.

A set of checklists and worksheets are used to record movement of samples in and out of the establishment. The temperature charts for each freezer are printed off daily. For those freezers without a chart recorder, there is a temperature checklist filled in every day, but not at weekends. All storage vessels are temperature-monitored and this feeds into a wireless callout system. Temperature excursions outside the set ranges trigger both audible alarms and the callout system. Power failure also triggers the alarms and the callout system. The system is tested regularly and tests also include the back-up generator system.

The liquid nitrogen storage area has an oxygen depletion monitor also linked to the wireless callout system. Most of the liquid nitrogen vessels are linked to the automated cryofilling system, but some are filled manually. Failure of the cryofilling system or low liquid nitrogen levels, trigger the audible alarms and the wireless callout system. Staff entering the liquid nitrogen storage area are not fitted with personal monitors.

This was the fifth routine inspection of the establishment which has been licensed since January 2008. The inspection comprised of a visual inspection of the premises, several

roundtable discussions with those working under the licence and a review of the documentation of the establishment relevant to the licensable activities.

The traceability audit of four samples was undertaken during the visual inspection, which included:

- The storage and labeling of one sample stored under the HT Act. It was not possible to cross-check the storage location against the electronic records because the customer had not provided an inventory of the storage vessel and the samples contained within.
- The storage and labelling of two samples stored under the Q&S Regulations 2007. It was not possible to cross-check the storage location against the electronic records because the customer had not provided an inventory of the storage vessel and the samples contained within.
- The storage and labelling of one sample stored under the Q&S Regulations was cross-checked against the electronic records. No discrepancies were noted.

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

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.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Although the establishment has a number of standard operating procedures (SOPs), some procedures still need to be put in place. SOPs including, but not limited to the following, must be developed: • training procedure. • serious adverse event and reactions (SAEARs) reporting procedure with a description of SAEs and SARs, relevant links to the HTA website and the procedures to follow in the event of an incident. • retention of critical traceability records (30 years) and raw data (for 10 years). • internal and independent audits; what to include and how often to be performed. • the acceptance and rejection criteria of tissues and cells	**Major**
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	There are currently no regular governance meetings for staff working under the licence covering HTA issues.	**Minor**

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
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 003/2010. s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	Although the establishment has a number of agreements with other HTA licensed establishments and was able to produce them during the inspection, there is no record or register of all the agreements established. The agreements do not specify the reporting arrangements in the event of a SAEAR and do not clearly set out the responsibilities of each of the party. For example, some of the agreements do not include: • the responsibility of the client to provide the establishment with an up to date inventory of the samples provided, where possible, to minimise the risk of loss of traceability; and/or • the responsibility of the client to inform the establishment of samples which are positive for mandatory infectious markers.	**Minor**
GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	Although the establishment has put in place elements of a quality management system, these do not form part of an effective overarching quality system to ensure continuous and systematic improvement. *See advice item below*	**Minor**

GQ2 There is a documented system of quality management and audit.		
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.	Although internal audits are carried out there were no written procedures detailing how audits will be performed. The scope of the audits was also limited, and did not cover the full range of activities carried out under the licence. In light of the absence of inventory of client storage containers, the DI must fully review the procedures associated with sample transit and receipt to include: • the extent and scope of the establishment's random sample audits to ensure that samples are fully traceable upon arrival. • the regular audit of the records and their content to check for completeness and to resolve any discrepancies found. Although an independent audit had been conducted since the last inspection, it did not verify compliance with protocols and all relevant HTA standards. *See advice item below*	**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. g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.	Although members of staff are trained, the competency of the staff is not recorded and assessed in the existing training records. Furthermore, there is currently no continuous professional development plan for new and existing members of staff. The establishment has a training records SOP that describes what documentation and evidence is to be included in the staff training records. The DI must review this procedure to ensure the staff training records are completed as per the documented procedure.	**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.	Although the establishment has two contingency agreements in the event of a disaster or emergency these do not include provisions for termination of activities and for raw data and records of traceability to be maintained for 10 and 30 years respectively.	**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. 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.	In April 2017, failure of a customer's liquid nitrogen tank resulted in the movement of all the samples to a contingency tank. During this process, staff discovered 25 samples floating in the original liquid nitrogen tank. Although the incident was reported to the client, also HTA- licensed, it was not reported to the HTA as an SAE. The establishment has documents that make reference to adverse event and incident management; however, they do not include the requirement to report SAEARs to the HTA within 24 hours as set out in Directions 003/2010. Furthermore, procedures for the reporting of such incidents and the responsibilities of personnel investigating them, are lacking. The DI must update the event/ incident log to ensure that in the future the following information is included for each event/incident: • the event/ incident, • action taken, • the impact, • the investigation • when the incident was closed • whether or not the incident was reported to the HTA and rationale	**Major (cumulative)**

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 has carried out a number of risk assessments, they were limited in scope and did not adequately capture all of the risks associated with the activities being carried out under the licence or the full range of control measures that are in place.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI is advised to consider appointing Persons Designated (PDs) to assist him in the role.
2.	N/A	The DI is advised to keep the freezer entry log in a position where it will not get wet to minimise the risk of the ink running due to the condensation.
3.	N/A	Individual freezer layout maps are electronically available on the item tracker database. The DI is advised to update where possible the freezer layout map attached to the door of the freezers.
4.	GQ1b, c	In addressing the shortfall above against GQ1b, c the DI is advised to include in the agenda for the governance meetings the work undertaken by the establishment, any updates from the HTA, incidents, and issues that may arise. This will help raise awareness among 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.
5.	GQ2a	In addressing the shortfall above against GQ2a the DI is strongly advised to consider the creation of a high level document that would provide an overview of the establishment's individual processes and controls in place, including but not limited to: • purpose and scope of a quality management system • responsibilities and roles of people working under the licence • procedures • reporting requirements • agreements

		• control of records
6.	GQ2b, c	The DI could consider dividing the internal audits in small, manageable tasks and nominating it to the PDs under the licence. The DI is advised to schedule the independent audit to occur in the intervening year between HTA inspections. The DI is advised to formally record and discuss at governance meetings the results of all audit findings, and actions taken, to ensure continuing improvement of processes and practices.
7.	GQ4b	During the inspection the rack labelling of the freezers was difficult to read. The DI is advised to consider improving the labelling to avoid the possibility of misidentifying the samples.
8.	PFE3b, 5a	The DI is advised to ensure that staff carry portable oxygen depletion monitors during periods of lone working within the storage facility.

Concluding comments

The HTA observed a number of good practices during the course of the inspection.

The establishment offers a disaster recovery service to other HTA-licensed establishments. As part of this, the establishment employs engineers with expertise in the maintenance, repair and calibration of ultra-low temperature storage containers, which are on call at all times to provide technical help. When a new disaster recovery agreement is being set up the establishment performs a gap analysis service to determine feasibility. In cases where emergency cryostorage is required, a number of back up freezers are on site, which can be transported to the customer if required.

The premises are appropriately monitored and maintained. The wireless online system allows for sample movements to be tracked. The temperature of the freezers is monitored daily and linked to a “daisy chain system” so that if one breaks down the alarm will activate and notify, in turn, all the key holders. There is the option of a monthly report of the daily temperature charts for clients that opt to have one. Two different servers are used to back up the electronic data.

There are a number of areas of practice that require improvement, including two major shortfalls and seven minor shortfalls. The HTA has given advice to the Designated Individual with respect to a number of the establishment’s procedures, quality management system, agreements, internal and independent audits 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: 20/06/2017

Report returned from DI: 26/06/2017

Final report issued: 17/07/2017

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: 18 June 2018

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.
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 003/2010.
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 003/2010.
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 003/2010 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 003/2010.
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.
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.
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.
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.

PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
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.

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.

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