

Licence application assessment visit report on compliance with HTA licensing standards

Cryo Storage Solutions Ltd

Proposed HTA licensing number 22675

Application to be 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**

25 June 2019

Summary of inspection findings

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

Although the HTA found that Cryo Storage Solutions Ltd (the establishment) had met some of the HTA standards, seven major shortfalls were found in relation to governance and quality systems (GQS) and premises, facilities and equipment (PFE) standards. The shortfalls were related to the absence of documented procedures for licensable activities, agreements, training, systems for tracking of tissues and cells, security measures, systems to deal with emergencies, and temperature monitoring of storage equipment.

11 minor shortfalls were found in relation to GQS, PFE and disposal standards. The shortfalls were related to the back-up of computerised records, retention of data, contingency plans for records in the event of termination of activities, the Single European Code (SEC), procedures for reporting serious adverse events, risk assessment of the premises, systems to maintain the safety of staff and visitors, procedures to control access to the site, systems to ensure critical equipment is identified, validated and regularly inspected, contingency plans for equipment failure and agreements for disposal of tissues and cells.

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.

Proposed licensable activities carried out by the establishment

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell; Hematopoietic; Cord Blood; Cord Blood				E	E		
Other; Cord tissue				E	E		

Background to the establishment and description of inspection activities undertaken

This report describes the licence application assessment visit (LAAV) of Cryo Storage Solutions Ltd (the establishment). The establishment has applied for a licence for the storage and distribution of cord blood and cord tissue under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). The establishment has also applied for

a licence under the Human Tissue Act 2004 to store relevant material which has come from a human body for use for a scheduled purpose.

As part of the licence application process, the establishment submitted documentation relating to document control, record management, traceability of samples, incident reporting, risk assessments, job descriptions and disposal prior to the site visit. A list of standard operating procedures (SOPs) and agreements with proposed suppliers was provided. The documentation was reviewed and it was deemed necessary to undertake a site visit to better understand the establishment's practices to support the activities that will take place under the licence in the future.

The establishment is in the initial stages of setting up a cryo storage facility, and has plans to commission liquid nitrogen storage vessels with vapour phase storage of samples.

A visual inspection was carried out of the facility, which comprises a newly built modular building that is located on an industrial estate. Two new cryo vessels have been installed and these are individually locked; the keys will be kept in a secure electronic key safe once installed. The facility is surrounded by a wire fence on one side of the perimeter and palisade fences on the remaining three sides. The gates are padlocked and authorised personnel must sign out the keys in order to gain access to the facility. There is a fire-proof cabinet for storage of documentation located in the office. Security staff patrol the premises twice a day, and would alert the establishment's staff if needed.

The establishment has one member of staff overseeing the day-to-day activities at the cryo storage facility with remote assistance from the DI. There are plans to train further members of staff working in the local vicinity as a contingency in case the lone member of staff is not available.

Discussions were held with the DI and the Corporate Licence Holder contact (CLHc) in relation to the systems and practices being developed to support the proposed activities under an HTA human application licence. The LAAV did not cover the storage of relevant material which has come from a human body for use for a scheduled purpose under the Human Tissue Act 2004.

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.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	<p>The establishment does not have procedures in place for the following:</p> <ul style="list-style-type: none"> • the receipt of samples from clients, including documented acceptance criteria; • the transfer of stored tissues and/or cells to another licensed establishment in the event of termination of activities; • release of samples to clients; and • the re-provision of services in an emergency. 	Major (cumulative)
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.		
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.		
t) There are procedures for the re-provision of service in an emergency.		
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.	Signed agreements are not in place with the courier that will provide transport services or individuals that will provide out-of-hours security services.	Major
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.	<p>The establishment is in the process of developing a training programme. Procedures are not currently in place to provide training in relation to:</p> <ul style="list-style-type: none"> • all tasks relevant to the work that will be carried out under the licence; • the scientific and ethical principles relevant to the proposed work and 	Major (cumulative)
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.	<p>its regulatory context;</p> <ul style="list-style-type: none"> the quality systems used within the establishment; and the use of equipment and its maintenance where appropriate. 	
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.		
GQ4 There is a systematic and planned approach to the management of records.		
d) There is a system for back-up / recovery in the event of loss of computerised records.	The establishment does not currently have a system in place for the back-up or recovery of computerised records.	Minor
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.	<p>The establishment has stated that it intends to use an electronic tracking system for tissues and cells. This was not in place at the time of inspection.</p> <p>The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.</p>	Major
<p>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.</p> <p>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.</p>	The establishment does not have procedures in place to retain raw data and traceability records as required by Directions 002/2018.	Minor
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.	The establishment does not have written procedures in place to meet this standard.	Minor

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment does not have procedures in place to capture the Single European Code (SEC) to ensure the traceability of tissues and cells. The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.	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.	SOP 'CSS SOP 007' states that "Initial reporting of an adverse event/incident under the HTA licence must be made to the DI within 24 hours of the adverse event/incident occurring or being known". The SOP does not specify the requirement for the DI to report the event to the HTA within 24 hours of discovery or determination. The establishment's documentation does not set out the threshold for events which would be reportable as a serious adverse event to the HTA.	Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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.	The current premises risk assessment only covers the health and safety aspects of working practices and does not consider risks to the quality and safety of tissues and cells stored under the licence or the security of the premises.	Minor
b) There are procedures to review and maintain the safety of staff, visitors and patients.	The establishment has identified that an oxygen deficiency monitoring system is essential for the safety of the individuals entering the facility. This was not in place at the time of inspection. The establishment took action to address this shortfall before the issue of the final	Minor

	report. The HTA now assess this standard as fully met.	
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.	There are no formal procedures in place to control access to the site; currently staff from the neighbouring company are able to gain access to the site. The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.	Minor
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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.	The establishment has plans to install a security alarm system, closed circuit television (CCTV) and security lighting for the cryo storage facility. However, these security measures were not in place at the time of inspection. The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.	Major
b) There are systems to deal with emergencies on a 24 hour basis.	Currently there are no systems in place to deal with emergencies on a 24-hour basis. The establishment plans to achieve this by putting an agreement in place with a neighbouring company, which would provide out-of-hours security services. The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.	Major
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	The establishment has plans to install a temperature monitoring system for the cryo vessels, as well as an auto-dialler alert system. These systems were not in place and operational at the time of the inspection. The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.	Major
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
a) Critical equipment and technical devices are identified, validated,	The establishment has created an asset table for critical equipment. However, this	Minor

regularly inspected and records are maintained.	table has not yet been populated. The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.	
k) There are contingency plans for equipment failure.	Although the establishment has provisional plans to respond to a failure in the storage systems, these have not been formalised through appropriate agreements and procedures.	Minor

Disposal

Standard	Inspection findings	Level of shortfall
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.	Although the establishment has documents in place relating to the disposal of tissues and cells, the agreements relating to this activity have not been signed.	Minor

Advice

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

No.	Standard	Advice
1.	GQ2b	The establishment has created a monitoring and internal audit section for every SOP. The DI is advised to check that the frequency of the audits are achievable to ensure compliance.
2.	GQ8a	The DI is advised to review the format of the establishment's risk assessments to ensure that the control measures are clearly linked to specific risks. The DI is a
3.	PFE1a	The DI is advised to consider risk assessing whether pest control is required for the cryo storage facility.

Concluding comments

The establishment has made progress since the initial licence application and has shown commitment to putting systems in place to comply with the applicable HTA standards. The HTA has visited the site in the early stages of setting up the cryo storage facility, which is reflected in this report.

There are a number of areas of practice that require improvement, including seven major shortfalls relating to the absence of documented procedures for licensable activities, agreements, training, systems for tracking of tissues and cells, security measures, systems to deal with emergencies, and temperature monitoring of storage equipment.

11 minor shortfalls were found in relation to the back-up of computerised records, retention of data, contingency plans for records in the event of termination of activities, the Single European Code (SEC), procedures for reporting serious adverse events, risk assessment of the premises, systems to maintain the safety of staff and visitors, procedures to control access to the site, systems to ensure critical equipment is identified, validated and regularly inspected, contingency plans for equipment failure and agreements for disposal of tissues and cells. The HTA has given advice to the Designated Individual with respect to the frequency of internal audits and risk assessments.

The HTA requires the proposed Designated Individual to address 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 will assess the establishment for the suitability of the licensable activities specified; subject to corrective and preventative actions being implemented to meet the shortfalls identified during the LAAV. The establishment will then be notified of the follow-up actions the HTA will take (as detailed in Appendix 2) in order to offer the establishment a HTA licence.

Report sent to DI for factual accuracy: 23 July 2019

Report returned from DI: 31 July 2019

Final report issued: 27 August 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.
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.
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.
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.
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.
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

Governance and quality system standards

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process

a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.

b) There is a document control system.

c) There are change control mechanisms for the implementation of new operational procedures.

d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.

e) There is a system for managing complaints.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits covering licensable activities.

b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- a) Qualifications of staff and all training are recorded, records showing attendance at training.
- b) There are documented induction training programmes for new staff.
- c) Training provisions include those for visiting staff.
- d) Staff have appraisals and personal development plans.

GQ4 There is a systematic and planned approach to the management of records

- a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
- b) There are provisions for back-up / recovery in the event of loss of records.
- c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).

GQ5 There are systems to ensure that all adverse events are investigated promptly

- a) Staff are instructed in how to use incident reporting systems.
- b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

- a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
- b) Risk assessments are reviewed regularly.
- c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail

- a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
- b) A register of donated material, and the associated products where relevant, is maintained.
- c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
- d) A system is in place to ensure that traceability of relevant material is maintained during transport.
- e) Records of transportation and delivery are kept.
- f) Records of any agreements with courier or transport companies are kept.
- g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner

- a) Disposal is carried out in accordance with the HTA's Codes of Practice.
- b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards

PFE1 The premises are secure and fit for purpose

- a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
- b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
- c) There are documented cleaning and decontamination procedures.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

- a) There is sufficient storage capacity.
- b) Where relevant, storage arrangements ensure the dignity of the deceased.
- c) Storage conditions are monitored, recorded and acted on when required.
- d) There are documented contingency plans in place in case of failure in storage area.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

- a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
- b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
- c) Staff are provided with suitable personal protective equipment.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

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

Or

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

Or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

- (1) A notice of proposal being issued to revoke the licence
- (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

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

or

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

or

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

or

A shortfall which indicates a breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

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

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

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

3. Minor shortfall:

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

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

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

Follow up actions

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

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

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

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