Site visit inspection report on compliance with HTA minimum standards

Joint Operations (UK) LLP

HTA licensing number 22662

Licensed for the

- **import, storage, distribution and export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended); and**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

11-12 June 2018

Summary of inspection findings

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

Although the HTA found that Joint Operations (UK) LLP (the establishment) had met most of the HTA standards, six minor shortfalls were found with regard to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards. The six minor shortfalls were in relation to the requirement for imports from outside the EEA to be compliant with the timing of the donor testing and requisite air particle monitoring requirements, the content of end user agreements (EUAs), the scope of the internal audits and risk assessments, the lack of a nominated, registered medical practitioner and / or a scientific advisor and the lack of calibration of temperature probes used to determine the temperature of cold and frozen products upon receipt at the establishment.

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

Tissue category; Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Membrane, Amniotic; Amniotic Membrane				**E**	**E**	**E**	**E***
Musculoskeletal, Tendon & Ligament; Tendons				**E**	**E**	**E**	**E***
Musculoskeletal, Tendon & Ligament; Menisci				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; Acellular Bone				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; Cancellous Bone Particles				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; Bone				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; DBM				**E**	**E**	**E**	**E***
Musculoskeletal, Bone; Bone Strut				**E**	**E**	**E**	**E***
Musculoskeletal, Tendon & Ligament; Tendon				**E**	**E**	**E**	**E***
Musculoskeletal, Tendon & Ligament; Ligament				**E**	**E**	**E**	**E***
Membrane, Fascia Lata; Fascia Lata				**E**	**E**	**E**	**E***
Skin; Skin				**E**	**E**	**E**	**E***
Musculoskeletal, Cartilage; Cartilage				**E**	**E**	**E**	**E***

‘E’ = Establishment is licensed to carry out this activity.

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

Background to the establishment and description of inspection activities undertaken

Joints Operations (UK) LLP (the establishment) is licensed for the import, storage, distribution and export of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). The establishment imports a range of products including fresh bone, tendons, ligaments, skin, amniotic membrane and acellular tissue and cell (T&C) products. The establishment is located at Swindon.

All the material is procured from deceased donors, with the exception of amniotic tissue which is procured from living donors following childbirth. The T&C products are processed in four tissue banks based in the USA. The four tissue banks are third country suppliers (3CS) of the establishment. The four 3CS undertake the processing of the T&C products. The donation, procurement and the mandatory serology testing for infectious diseases of all the donors of the T&C products is not always carried out by the four 3CS and several subcontractors (SCs) may carry out these activities on their behalf. The establishment imports the T&C products directly from the four 3CS in the USA.

The establishment receives ambient temperature, chilled and frozen products. Upon receipt of the products, staff at the establishment undertake visual checks of the packaging, the labelling and documentation and record the date the tissue was received on the tissue release form. For chilled products, a temperature probe is used to ensure the temperature in transit is between 2-8°C. For frozen products, the establishment uses a digital probe to confirm the temperature of products is below -40°C, in the event they are 80% or less covered by dry ice (*see shortfall against standard PFE5 (b)*). For frozen products deemed to have their temperature raised between -40 to -20°C in transit, the shelf life is reduced to a maximum of six months. All tissue received have a single European Code (SEC) generated and the establishment allocates and applies the SEC on the products upon arrival. In the event where the expiry date is reduced the SEC is updated to reflect the new “use by” date.

The documentation that accompanies products includes details of the donor consent, the mandatory serology test results and traceability information. The Designated Individual (DI) or Person Designate (PD) review all the documentation and mark if the products are acceptable or not on the tissue release form. Until the review takes place the products are placed in the quarantine section of the ambient temperature cabinet, or the refrigerator or the ultra-low temperature smart freezers (ULTSF), depending on the temperature requirements of the products.

Following the checks, the products can be deemed suitable for release, be put under quarantine or be marked for disposal. The customer / technical services team registers on paper and in the electronic-based records the products deemed suitable for release to end users, along with their location and the SEC number. Any products marked for disposal are rejected on the electronic system and the paper-based records and are sent to a company specialising in the disposal of human tissue. Electronic data are backed up daily on two alternating hard drives and also remotely on cloud storage.

The electronic system only allows T&C products deemed suitable for release to be distributed for end use. Products are picked on a first expiry first out basis. The establishment is not currently undertaking any export activity.

The establishment has been licensed by the HTA since April 2016. This inspection was the establishment's first routine inspection since the establishment was licensed. The inspection included interviews with the DI and other key members of staff and a review of documentation including the:

- processing records of eight imported products selected prior to the inspection and already distributed to end users;
- a traceability audit of a tendon, a meniscus and bone product in storage, deemed suitable for release to end users; and
- a traceability audit of a rejected patella marked for disposal.

Representative records associated with each product were reviewed. These included the batch processing records, including mandatory serology and sterility testing, release forms and the results of environmental monitoring or terminal sterilization certificates, where relevant. No discrepancies were noted.

Joint Operations UK (LLP) also stores grafts for educational, training and research purposes only; these sample are stored in a separate drawer of one of the two ULTSF freezers. No research samples were reviewed during the audit of the establishment.

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 (as amended).

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.		
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018.	The documented procedures for donor testing of three of the 3CS do not include the requirement for blood specimens to be collected within seven days before tissue recovery, or if not possible, within 24 hours following tissue recovery. For example, the 3CS set out that 'blood specimens can be collected within 7 days before or after tissue recovery'. In practice, the mandatory serology samples are collected no later than 24 hours following tissue recovery. However, the documented procedure allows for an extended period of collection of the samples intended for serology testing. Also, three of the 3CS's of the establishment that aseptically process T&C products, did not meet the requisite air particle monitoring requirements at rest and in operation as set out in Directions 002/18.	**Minor**
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	The EUAs do not adequately capture the reporting requirement of serious adverse events and reactions (SAEARs) as set out in Directions 002/2018. (see Advice, item 2) *Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the above shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.*	**Minor**
GQ2 There is a documented system of quality management and audit.		

b) There is an internal audit system for all licensable activities.	The internal audits do not cover the full range of activities carried out by the establishment and are not against all applicable HTA standards. (*see Advice, item 3)* *Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the above shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.*	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes.	Although the establishment has carried out a number of risk assessments, these were limited in scope and did not adequately capture all of the risks associated with the activities being carried out under the licence. (*see Advice, item 5)*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.		
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.	The establishment does not have access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and review records, where required. *Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the above shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.*	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The establishment uses temperature probes to check the temperature of frozen and cold-chain T&C products upon receipt. These have not been calibrated in accordance with the manufacturer's instructions. *Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the above shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1 (b)	Although the establishment has an SOP for the application of the SEC to products this does not reflect that the establishment allocates and applies the SEC upon arrival of the T&C products.
2.	GQ1 (r)	The DI is advised to include in the EUAs that end users cannot store non-acellular T&C products for longer than 48 hours without a Human Application HTA licence for storage.

3.	GQ2 (b) (c)	The DI is advised to review the audit template used to carry out the internal and independent audits and include the content of what was audited against each applicable HTA standard. The DI is advised to expand the scope of the audits of the 3CS to also include horizontal audits of batch processing records for each of the tissue types imported by the establishment to ensure that the products supplied by the 3CS meet the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).
4.	GQ3 (f)	The establishment has a documented training programme. The DI is advised to include within the training procedure the content of the material provided to staff as part of the training of staff on HTA matters.
5.	GQ8 (a)	The DI is advised to document in the establishment's risk assessments the full range of control measures in place which help to mitigate identified risks to the quality and safety of the tissues.
6.	D1 (a)	The EUA references the old Code of Practice on disposal, which is now superseded by new HTA Codes of Practice. The DI is advised to review the establishment's documentation to ensure it includes up-to-date references to the new HTA Codes of Practice.
7.	D1 (c)	The DI is advised to update the disposal procedure and document fully the process where staff carry out periodic checks of the T&C products in stock and identify products nearing expiry and those suitable for disposal.
8.	N/A	The DI is advised to review all documents to ensure reference to the correct legislation - the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).

Concluding comments

The HTA saw various examples of good practice during the inspection.

The establishment uses a red / amber / green colour "traffic light" system to record the location of the T&C products and makes use of specific shelves in the ambient temperature cabinet, the fridge and freezers to physically and visually separate the rejected / pending release (quarantine) / ready for release products. This minimises the risk of T&C products being issued incorrectly or being misplaced.

There is a ULTSF Access Record chart at the front of each of the freezers where the time / date and reason for accessing the freezer is noted by all members of staff. This can be mapped against the temperature data and directly account for any temperature deviations i.e. if they are linked to goods coming in or out, stock take or cleaning of the freezers. The establishment makes use of net mesh bags to pack dry ice to prevent dry ice-related injuries by members of staff and end users. The establishment is also looking into preparing educational material with advice on handling and receipt of products and unpacking for their end users.

The establishment makes use of a spreadsheet that prevents SEC labels being printed unless there are the correct number of digits. Duplicate SEC labels (six for each product) are also produced and sealed within ziplock bags attached to the product to reduce the likelihood of transcription errors by the end users.

Six areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. The HTA requires that the Designated Individual addresses the minor 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: 2018/ 08/ 07

Report returned from DI: 2018/ 08/ 20

Final report issue: 2018/ 10/ 02

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: 2019/ 07/ 31

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.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018.
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.
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.

f) There are procedures to ensure that donor documentation, as specified by Directions 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
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.
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.
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.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.

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.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Human Tissue Act 2004 Standards

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records. b) There are provisions for back-up / recovery in the event of loss of records. c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems. b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. b) Risk assessments are reviewed regularly.

c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it. b) A register of donated material, and the associated products where relevant, is maintained. c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom. d) A system is in place to ensure that traceability of relevant material is maintained during transport. e) Records of transportation and delivery are kept. f) Records of any agreements with courier or transport companies are kept. g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice. b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity. b) Where relevant, storage arrangements ensure the dignity of the deceased. c) Storage conditions are monitored, recorded and acted on when required. d) There are documented contingency plans in place in case of failure in storage area.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. b) Users have access to instructions for equipment and are aware of how to report an equipment problem. c) Staff are provided with suitable personal protective equipment.

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

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

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

1. **Critical shortfall:**

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

   Or

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

   Or

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

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

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall.

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

of a donor or a recipient

or

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

or

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

or

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

or

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

or

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

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

3. **Minor shortfall:**

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

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

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

Follow up actions

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

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

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

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