



Licence application assessment visit report on compliance with HTA licensing standards

Tissue Regenix Ltd.

HTA reference number 22670

Establishment to be licensed for the

- **import, 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**

14 March 2018

Summary of inspection findings

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

Although the HTA found that Tissue Regenix Ltd. (the establishment) had met the majority of the HTA standards, nine minor shortfalls were found, in relation to the establishment's standard operating procedures (SOPs), agreements between the importing establishment and the third country supplier (3CS), export authorisation from the 3CS, third party agreements, contingency plans, documented risk assessments, storage of tissues and cells and temperature recording of the store room.

The HTA's regulatory requirements

Prior to the grant of the licence the HTA must assure itself that the proposed 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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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.

Activities to be carried out by the establishment

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

Tissue category; Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal; Bone				E	E	E	
Musculoskeletal, Tendon & ligament; Tendons				E	E	E	
Membrane, Amniotic; Amniotic Membrane				E	E	E	
Membrane; Fascia Lata				E	E	E	

Skin; Skin				E	E	E	
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Background to the establishment and description of inspection activities undertaken

This report describes the licence application assessment visit of Tissue Regenix Ltd., which took place on 14 March 2018. The establishment is based on a single site in Swillington, Leeds. The establishment applied for a licence for import, storage, distribution and export of human tissue and cell products for allogeneic use under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). Following the site visit the DI confirmed that the establishment will only distribute human tissue and cell products to establishments within the European Economic Area (EEA) and will not be needing an export licence in the immediate future.

All the material is procured from deceased donors by subcontractors (SCs) and processed at a 3CS based in the United States of America (USA). The 3CS is licensed by the FDA, accredited by the American Association of Tissue Banks (AATB) and carries out the mandatory testing of all the donors in accordance with the European Union Tissues and Cells Directives (EUTCDs). The 3CS is responsible for applying the Single European Code (SEC) on to the primary packaging of products and the accompanying documentation at the point of the release.

Tissue Regenix Ltd. will be responsible for ensuring that all material imported from the 3CS, stored and distributed to other establishments comply with all applicable HTA standards. The establishment employs five production operators that will be responsible for the receipt, packing and distribution of the products.

The licence application visit provided an opportunity for the HTA to review the establishment's premises and to assess the suitability of the systems that have been put in place to ensure that imported material meets equivalent standards of quality and safety to those set out in the EUTCDs.

The site visit comprised of:

- a visual inspection of the storage area including the goods-receipt and goods-out areas, the cold storage area, a locked cage for the ambient temperature storage of tissue and cell (T&C) products within the warehouse, and an area where non-conforming or damaged products will be stored before being sent for disposal. The establishment operates a no returns policy for cold chain products;
- review of documentation relevant to the establishment's licensable activities, including contingency arrangements, agreements, induction and on-going training of the staff;
- review of the processes related to sample receipt, including the input of traceability information (SEC);
- storage conditions including temperature monitoring and contingency arrangements for ambient temperature and cold chain T&C products;

- interviews with key members of staff.

The proposed DI confirmed that the establishment currently stores relevant material from three Research Ethics Committee (REC) approved research projects, which are still in date. As such, it was not deemed necessary to inspect the areas where the research material is stored. Following the site visit the proposed DI confirmed in writing that the establishment also wishes to include storage of relevant material under the licence as a contingency for when the REC approvals expire.

Inspection findings

The HTA found the proposed 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.	<p>Although the establishment has a number of SOPs, some procedures still need to be put in place.</p> <p><i>(see Advice, item 1)</i></p>	Minor
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.	<p>The agreement between the importing establishment and the 3CS does not include as a minimum the clauses set out in Annex IV, EC Directive 2015/566.</p> <p>At the time of the site visit there was not an up-to-date copy of export authorisation certificate covering each of the products, which the establishment has applied to import.</p> <p><i>Prior to the final report being issued the DI provided a copy of the 3CS's export authorisation certificate. The HTA therefore consider this aspect of the shortfall to have been addressed.</i></p>	Minor

<p>r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.</p>	<p>The establishment has written agreements with third parties whenever an activity takes place. These need to be reviewed to include, where applicable, the responsibilities for each party in relation to:</p> <ul style="list-style-type: none"> • the retention of critical traceability records (for 30 years) and raw data (for 10 years); and • the disposal of tissues and cells. <p>(see Advice, item 2)</p>	<p>Minor</p>
<p>s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.</p>	<p>The agreements need to be reviewed to include, where applicable, the responsibilities for each party in relation to serious adverse event and reaction (SAEARs) reporting. In particular this should include reporting to the establishment immediately and no later than within 24 hours of discovery.</p> <p>(see Advice, item 2)</p>	<p>Minor</p>
<p>GQ4 There is a systematic and planned approach to the management of records.</p>		
<p>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.</p>	<p>Contingency plans are not in place that will ensure that records of traceability and raw data are maintained in the event of termination of activities.</p>	<p>Minor</p>
<p>GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.</p>		
<p>a) There are documented risk assessments for all practices and processes.</p>	<p>Although the establishment has documented risk assessments, these do not capture all the risks associated with the activities being carried out under the licence and the full range of control measures in place, which help to mitigate identified risks.</p> <p>(see Advice, item 4)</p>	<p>Minor</p>

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.	At the time of the site visit there was no risk assessment carried out of the premises to ensure they are fit for purpose.	Minor
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.	<p>The establishment has an additional freezer that can be used as a contingency in the event of the main freezer malfunctioning. However, this freezer is currently used for temporary storage of xenografts before they are processed in the lab.</p> <p>The establishment's procedures and risk assessments do not include adequate provisions to ensure that if the contingency plans are enacted T&C products are appropriately segregated to minimise the risk of contamination.</p>	Minor
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
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.	<p>At the time of the site visit there was no minimum-maximum temperature recording of the storeroom where the ambient temperature products are to be stored.</p> <p><i>(see Advice, item 5)</i></p>	Minor

Advice

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

No.	Standard	Advice
1.	GQ1(b)	<p>With reference to shortfall against GQ1(b), the proposed DI is advised to formalise and record:</p> <ul style="list-style-type: none"> the acceptance criteria for cold chain products including, should it be required, arrangements for the quarantine of these products; the processes around sample receipt including the input of the traceability information such as the product code/ batch number and the SEC in the spreadsheet and the checks to be carried out for possible transcription

		<p>errors and loss of traceability; and</p> <ul style="list-style-type: none"> the release of tissues and cells to end users procedure, setting out the requirements for data retention and SAEARs reporting.
2.	GQ1(r),(s)	<p>With reference to shortfalls against GQ1(r) and (s), the proposed DI is advised to create a template End User Agreement (EUA), which covers the responsibilities of the end user and reporting of SAEARs to the establishment.</p> <p>The proposed DI is also advised to include in the requirements of the EUA that establishments that receive and intend to distribute products to other end users must hold an HTA licence as required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).</p>
3.	GQ2(b),(c)	<p>The proposed DI is advised that the results of all audit findings, and actions taken, should be formally recorded and discussed at governance meetings, to ensure continuing improvement of processes and practices.</p> <p>The proposed DI is also advised to schedule the independent audit to occur in the intervening year between HTA inspections.</p>
4.	GQ6 (c)	<p>Once operational the establishment intends to input the SEC manually into a spreadsheet. This step will be performed by a single member of staff.</p> <p>The proposed DI is advised to consider the use of an electronic system or a second person verification to minimise the risk of transcription errors that may result in loss of traceability.</p>
5.	GQ8(a)	<p>The establishment has carried out a number of risk assessments covering activities such as the import, storage and distribution of human tissue.</p> <p>With reference to shortfall against GQ8(a), the proposed DI is advised to consider expanding the scope of the risk assessments to include:</p> <ul style="list-style-type: none"> transcription errors in the input of the SEC in the spreadsheet by a single person to ensure all of the risks are identified and appropriately assessed. the storage of T&C products in the contingency freezer and their segregation from xenografts to minimise the risk of contamination. <p>The proposed DI is also advised to document the full range of control measures in place, which help to mitigate identified risks. This will help ensure that the impact on risk is appropriately reassessed when working practices or the facilities change.</p>
6.	PFE5(c)	<p>With reference to shortfall against PFE5(c), the proposed DI is advised to adapt the minimum - maximum temperature and list it on the records sheets to reflect the requirements of the T&C products as set out by the manufacturer.</p>

Concluding comments

Nine areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. The HTA has given advice to the Designated Individual with respect to the development of SOPs, the EUA, internal and independent audits, traceability of T&C products, the risk assessments and the minimum – maximum temperature limits for the T&C products.

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: 2018-04-13

Report returned from DI: 2018-04-16

Final report issued: 2018-04-20

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: 2018-10-15

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
C2 Information about the consent process is provided and in a variety of formats.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.

g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
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 003/2010.
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.
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 003/2010, is collected and maintained.
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.
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 003/2010.

b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
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.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
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.
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.
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 003/2010.
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 licensing standards (Research sector)

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.