Site visit inspection report on compliance with HTA minimum standards

Broomfield Hospital

HTA licensing number 12404

Licensed for the

- **procurement and storage 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**

19 April 2018

Summary of inspection findings

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

Although the HTA found that Broomfield Hospital (the establishment) had met the majority of the HTA's standards, seven minor shortfalls were found in relation to: (i) an incomplete audit schedule; (ii) an absence of an independent audit; (iii) an absence of a documented plan for retention of raw data; (iv) a lack of availability of risk assessments, for staff, for HTA-licensed activities; (v) an absence of full temperature monitoring and testing of the freezer alarm system; (vi) an absence of a disposal procedure for human tissue; and (vii) incomplete tissue disposal records.

Advice has been given relating to the Governance and Quality Systems and Premises, Facilities and Equipment standards.

Particular examples of 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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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 licenses against four groups of standards:

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

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

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

Licensable activities carried out by the establishment

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

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

Tissue Category; Tissue Type	Procurement	Storage
Skin; Skin	**E***	**E**

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Broomfield Hospital (the establishment). The establishment was issued an HTA licence in February 2007. This was the sixth HTA site visit inspection of the establishment (the last inspection was in January 2016). The current inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards.

Licensed activities take place in the St Andrew's Centre for Plastic Surgery and Burns at Broomfield Hospital, part of Mid Essex Hospital Services NHS Trust. The St Andrew's Centre is a regional referral centre for plastic surgery and burns patients. The Burns Service (Burns

Intensive Care Unit - ITU, Adult and Children's Burns Wards) covers a population of 9.8 million from London and the South East of England.

The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended; Q&S Regulations) for the procurement and storage of tissues and cells for human application. The establishment is also licensed for the storage of relevant material for use for a scheduled purpose under the Human Tissue Act 2004 (HT Act). Although licensed for this activity, the establishment does not currently store relevant material for use for a scheduled purpose.

The DI is the Clinical Director of the Burns Service, the Corporate LH (CLH) is Mid Essex Hospital Services NHS Trust and the CLH Contact (CLHC) is the Trust Medical Director. There is one Person Designated (PD) working under the licence - the Burns and Plastics Theatre Sister.

Procurement

The establishment previously procured skin biopsies from selected patients and these were expanded and cultured by a separate HTA-licensed establishment into an advanced therapy medicinal product (ATMP) for use in autologous treatment. This activity is not currently taking place.

Storage

The establishment stores cryopreserved skin from cadaveric donors. The tissue is purchased from another HTA-licensed supplier under the terms of a service level agreement (SLA). The supplier is responsible for donor selection, consent, procurement, serological testing and transportation. The skin is used in burns surgery and, in 2017, the establishment performed 52 skin allografts.

Packaged, cryopreserved split skin is received into the secure storage room next to the Burns Operating Theatre by authorised personnel (one of six trained clinical personnel). The area is staffed at all times, allowing for round the clock cover. The allograft details are entered into the tissue register and paper copies of dispatch sheets are kept separately. The details from the tissue register are transferred onto an electronic spreadsheet, which is backed-up as part of the Trust Information Technology (IT) system.

The skin is stored securely in a lockable -80^{o}C freezer. At the time of the inspection, the freezer temperature was -78^{o}C. Non-conforming units are stored on a separate shelf in the freezer. There is daily visual check of the freezer digital display and twice-daily manual recording of the temperature on log sheets (see *Advice*, items 12 and 13). The freezer has an audible alarm system and there is a work instruction on the freezer door summarising procedures to follow when the audible temperature alarm is activated. However, there is no system where the maximum and minimum temperatures are recorded and the alarm system is not tested routinely [see shortfall against standard PFE3(c)].

The freezer is subject to an annual service and calibration under contract and a back-up freezer in the Orthopaedic Department is available for contingency storage (see *Advice*, item 14).

When required for engraftment, the skin is removed and taken to the Operating Theatre for thawing before use. The date of removal and patient number of the recipient are entered into the tissue register and on the electronic spreadsheet (see *Advice*, item 9).

Tissue is disposed of by incineration and is bagged separately from other clinical waste but the details, including date and method of disposal, are not recorded in the tissue register or on the electronic spreadsheet [see shortfall against standard D2(a)]. In addition, there is no procedure for the disposal of human tissue [see shortfall against standard D1(a)].

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection reports, communications with the HTA since the last inspection and annual activity data. The inspection included a visual inspection of the storage area and the contingency freezer in the Orthopaedic Department. Discussions and interviews were held with key staff and documentation was reviewed. Interviews were held with the DI, CLHC, PD, a Burns and Plastics Staff Nurse and the Quality Manager.

Audits of traceability were carried out:

- Two units of skin were selected at random from the freezer and labelling details were compared to the records in the tissue register, on the electronic spreadsheet and on the dispatch sheets. There was one minor discrepancy noted where the label of one of the units had been incorrectly transcribed into the tissue register. The allograft recipient details in the tissue register and on the electronic spreadsheet were compared to the allograft continuation sheet and the Trust's clinical notes. All allograft details were recorded in the patient notes and there were no discrepancies noted.
- Two units of skin were selected at random from the tissue register. The units were identified in the freezer and their labels were checked against the register. There were no discrepancies noted.
- Two units that had been disposed of were traced from the tissue register/electronic spreadsheet to the disposal paperwork. Minor discrepancies were noted in each case; the discard form for each unit did not contain a date or method of disposal.
- Four sets of clinical notes for allograft recipients were reviewed and the labelling details of the units of skin in the notes were compared to records in the tissue register, on the electronic spreadsheet, on the dispatch sheets and on the allograft continuation sheet. There were no discrepancies noted.

Inspection findings

The HTA found the DI and the CLH 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
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	An internal audit system encompassing the full range of licensed activities has not been implemented. The establishment performs regular checks to ensure that tissue identifiers and usage in the tissue register match records in the clinical notes, on the dispatch sheets and on the allograft continuation sheet. However, this does not constitute an internal audit aimed at assessing the establishment's compliance against the full range of licensed activities. See *Advice*, item 3.	**Minor**
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.	There is currently no independent audit to verify compliance against HTA standards under the Q&S Regulations.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
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.	There is no documented plan or standard operating procedure (SOP) for the retention of raw data for 10 years after the use, expiry date or disposal of tissues and cells.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
c) Staff can access risk assessments and are made aware of local hazards at training.	Although there are risk assessments these are not currently available to staff.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	During the inspection, the inspection team were informed that the manual set temperature ranges for the freezer alarm system were -60^{o}C and -90^{o}C but these ranges were not documented. This alarm system is not tested routinely. In addition, there is no system for recording maximum and minimum temperatures within the freezer in between temperature monitoring times.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human body parts and tissues.		
a) The disposal policy complies with HTA's Codes of Practice.	There is a 'Waste Management Policy' but there is no specific procedure for the disposal of human tissue.	**Minor**
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.	The establishment does not routinely record the date and method of disposal for each unit of tissue.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(c)	There are regular local meetings of the Burns Service Team. The DI is advised to consider the inclusion of representatives from other departments (e.g. Clinical Governance, IT) to help develop the establishment's working practices. In addition, joint governance meetings, involving DIs across different sectors, are a feature in several other organisations that hold more than one HTA licence. The Trust is the CLH on two HTA licences. There are currently no meetings

		between DIs and individuals named on these licences. The DI and CLHCs are advised to consider setting up joint governance meetings involving staff on both these licences as an opportunity for shared learning.
2.	GQ1(k)	Tissue removed from the freezer that is not subsequently used is disposed of. The DI is advised to consider documenting this in the Quality Manual, for consistency.
3.	GQ2(b)	The DI is advised to extend the audit schedule to include: (i) audits of documentation (forms, notices) to ensure accuracy and consistency; and (ii) procedural audits of the establishment's activities to help assure the DI that the current practices being followed by establishment staff adequately reflect the content of SOPs.
4.	GQ3(e)	The DI is advised to introduce a system whereby staff 'sign-off' that they have read and are familiar with SOPs.
5.	GQ3(f)	The PD gives a presentation to new staff covering the regulatory framework underlying the work of the Burns Service. However, this currently covers only the Human Tissue Act 2004. The DI is advised to extend this training to include the Q&S Regulations.
6.	GQ4(e)	The DI is advised to consider adding the following to the tissue register and the electronic spreadsheet: the time from release of tissue by the supplier to placement in the freezer; the details of disposal [see shortfall against standard D2(a)].
7.	GQ4(e)	The DI is advised to consider using a two-person checking system to cover allograft retrieval from storage.
8.	GQ7(a)	All adverse events and corrective and preventative actions are reported through the Trust incident reporting system. However, there is no local oversight or review of such incidents. The DI is advised to ensure that incidents and follow-up procedures are reviewed at meetings of the governance committee.
9.	GQ7(b)	The DI is advised to ensure that the Quality Manual includes the types of incident which are classified as SAEARs. The DI is referred to the HTA's website page for further information: https://www.hta.gov.uk/policies/human-application-adverse-event-and-reaction-saears-reporting
10.	GQ8(a)	The DI is advised to consider adding the following to the suite of risk assessments: • Temperature variation outside of the set ranges • Freezer failure • Loss of samples • Sample mix-up or loss of traceability; • Incorrect disposal. Further risk assessments will be identified following an analysis of any incidents which have occurred.

		Where appropriate, risk assessments should include the identified mitigating actions and the level of residual risk remaining.
11.	PFE3(c)	During the inspection, it was noted that there were inconsistencies in the completion of the temperature log sheets. Specifically: - There were some incomplete fields. - There were signatures in the name box rather than in the signature box. - There were signatures alone with no corresponding name. The DI is advised to consider reviewing the temperature logging procedure to ensure that it conforms to Good Documentation Practice (GDocP) and to consider including temperature log records as part of the audit schedule.
12.	PFE5(e)	The DI is advised to consider keeping local records of service visits and maintenance agreements for critical equipment to ensure that such equipment is maintained on a regular basis.

Concluding comments

During the inspection, areas of good practice were noted:

- There is an annual Burns Educational Study Day for clinicians and other professionals based in the region.
- The document control system is overseen by Clinical Governance. This ensures consistency in style and content of SOPs, forms and notices.
- There is an HTA notice board adjacent to the Operating Theatre. This contains the organisational chart, details of the licences and associated notices.
- There are detailed and clear notices for staff on how to put allografts into the freezer, remove allografts from the freezer, and what to do if the audible temperature alarm is sounded.

There are a number of areas of practice that require improvement, including seven minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality Systems and Premises, Facilities and Equipment standards.

The HTA requires that the DI 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: 29 June 2018

Report returned from DI: 13 July 2018

Final report issued: 27 July 2018

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: 06 April 2020

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 002/2018 is included.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and

clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).

e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
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.
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.
j) Records are kept of products and material coming into contact with the 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.
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 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.
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.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.

c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
d) Records are kept of transportation and delivery.
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.

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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to 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 represents a systemic failure and therefore is 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 straight away.

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