Site visit inspection report on compliance with HTA licensing standards
Inspection date: **21 and 22 October 2019**

Birmingham and Midland Eye Centre

HTA licensing number 11061

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

and

Licensed under the Human Tissue Act 2004

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

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

Licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Birmingham and Midland Eye Centre				E	E*		

Tissue types authorised for licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Ocular; Cornea				Authorised	Authorised		
Ocular; Sclera				Authorised	Authorised		

Membrane, Amniotic; Amniotic Membrane				Authorised	Authorised		

Licensed activities – Human Tissue Act 2004

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose
Birmingham and Midland Eye Centre	Licensed

Summary of inspection findings

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

Although the HTA found that the Birmingham and Midland Eye Centre (the establishment) had met the majority of the HTA's standards, one major (cumulative) and seven minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

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.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	Although there are defined procedures for dealing with incidents, a review of the incident log identified a number of potential serious adverse events that were not reported to the HTA. These included incidents where: • ocular tissue was cloudy and was returned to the supplier. The scheduled surgery was postponed; • the supplier informed the establishment that an ocular tissue product was contaminated. The surgery was rescheduled; • a tissue graft was lost when the container was dropped, delaying surgery; and • a patient underwent prolonged hospitalisation when their ocular tissue graft was damaged during preparation as a result of the fact that the required DSAEK equipment was not available and staff were not suitably trained.	**Major (cumulative)**
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.		

Minor Shortfalls

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.	Establishment SOPs do not provide sufficient detail or cover all licensable activities. For example: • the establishment has generated tissue-specific SOPs, however it was noted that a SOP for one tissue type was not available; • SOPs related to the use of cornea and amniotic membrane do not detail who is responsible for liaising with the supplier during a product recall; • the -80°C freezer is kept locked and accessed using a key. The relevant SOP does not specify that the key is signed in and out as is the current procedure; • the SOP detailing the usage of sclera described how tissue is prepared but does not provide specific details (lot number, volume, dilution instructions, storage location etc.) for reagents and consumables, how to label the prepared product, or who is responsible for preparing the tissue; and • if needed, sclera may be split for use in two different patients. SOPs do not provide sufficient detail on how to split the tissue. Furthermore, the SOP does not reflect discussions undertaken with the supplier about the suitability of the sclera for splitting, and for the assignment of a unique ID.	**Minor**

GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	While the establishment has undertaken an audit of all tissue products held at the establishment, there is no audit schedule. Internal audits did not cover the processes associated with all licensable activities. For example, there was no evidence of audits of the following records and documents: • product storage conditions (e.g. temperature) and associated records; • SOPs, policies and risk assessments; and • delivery records and tissue log books (i.e. the theatre log).	**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.	While an independent audit was conducted prior to the site visit inspection, establishment records did not clearly set out the scope of the audit.	**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.	SOPs related to the storage of data do not specify that raw data critical to the safety and quality of tissues and cells need to be retained for 10 years after the use, expiry date or disposal of tissues and / or cells. In addition, the SOPs related to the storage of the minimum data to ensure traceability from donor to	**Minor**

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.	recipient specify that data should be kept for 30 years from 'receipt' of the tissues and / or cells rather than from the 'use, expiry or disposal' of the tissues and / or cells, as required by Directions 003/2010. ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to this shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be now met.***	
j) Records are kept of products and material coming into contact with the tissues and / or cells.	The establishment prepares some tissue products the day prior to a scheduled surgical procedure. Details of products and material coming into contact with the tissue are not recorded.	**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.	While the establishment had a number of risk assessments in place they did not cover all activities. For example, there is no risk assessment of: • the premises to ensure they are fit for purpose; and • the ambient storage conditions/storage location to provide an assurance that the available air conditioning is sufficient to maintain the temperature range required. A review of the manual temperature logs identified several days over the summer months where the temperature exceeded the maximum storage temperature for one of the products by up to 2°C.	**Minor**
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.		

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. **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.	Tissue that is kept at ambient temperature is stored in a locked safe in the theatre storage area. The temperature inside the safe is manually recorded on weekdays, and on weekends if staff are present at the establishment. A review of the temperature records identified a number of occasions where the temperature had not been recorded, including weekdays. In addition, several days were noted in summer where the temperature recorded exceeded the maximum temperature allowed for one of the products stored in the safe (by up to 2°C). These deviations were not recorded as incidents and the establishment had not followed-up with the supplier to determine if the deviations affected the quality or safety of the product. In addition, the establishment does not record the temperature ranges reached between individual readings. This does not provide an assurance that an acceptable temperature range has been maintained between the recorded daily temperature readings. The establishment has recently purchased a new -80°C freezer with an attached chart recorder. However, establishment staff manually record the temperature on a daily basis on weekdays, and weekends if staff are present. A review of the records during periods when product was stored in the freezer identified a number of days, including weekdays, when no temperature had been recorded. See *Advice*, item 9.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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.

Advice

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

Number	Standard	Advice
1.	GQ1a	The theatre waiting list officer (WLO) liaises with consultants to ensure that required product is ordered in advance of scheduled procedures. Once ordered from suppliers, the WLO adds the product to the shared E-Calendar to alert the HTA Licence Support Manager to the expected delivery. As the WLO is the primary point of contact with the supplier and plays a pivotal role in the process, the DI is advised to consider adding her, and her team, to the HTA Organisational Framework organisational chart.
2.	GQ1b	The DI is advised to review SOPs and other documentation to ensure that the information they contain is up to date, relevant and correct. For example, the draft policy related to the HTA subcommittee referenced another establishment and all policies and SOPs discussed the Human Tissue Act 2004, but contained no reference to the European Union Tissues and Cells Directives or the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). In addition, several SOPs indicated that after tissue preparation excess tissue could be used for research, while the product information sheets indicated the tissue could not be used for research purposes.
3.	GQ1c	The establishment holds quarterly directorate governance meetings that have a ‘HTA update’ agenda item. In addition, the establishment undertakes monthly, minuted HTA subcommittee meetings for staff working under the licence. During the inspection it was noted that the subcommittee had not met for a prolonged period from February to September 2019. The DI is advised to ensure the subcommittee holds regular meetings as intended.

4.	GQ3e	Staff at the establishment had no awareness of the Single European Code (SEC) or the need to retain the SEC within patient records. However, as the SEC was present on all product labels the SEC was retained in the documentation as required. The DI is advised to develop documented procedures related to the use and retention of the SEC, and ensure that all staff are trained accordingly. In addition, when reviewing training records it was noted that the trainee signs the training record to confirm that they are competent in the process. The DI is advised to amend the training process so that the trainer signs the records to confirm that the trainee is competent.
5.	GQ3f	The DI is advised to develop training into the background and requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) for all staff working under the licence, and to document training attendance.
6.	GQ7c	The DI is advised to identify and appoint additional Persons Designate to assist in the reporting of serious adverse events and serious adverse reactions, to provide assurance that there will always be staff available to report such incidents to the HTA within 24 hours as required.
7.	GQ7g	While the establishment is licensed for the activity of distribution, staff have not undertaken this for several years. Since staff indicated that there is no intention to continue distributing for end use, the DI is advised to consider removing this activity from the licence.
8.	GQ8a	The DI is advised to formally risk assess the processes involved with the preparation of sclera for a scheduled surgery. In addition, the majority of tissue stored at the establishment is assigned to a specific patient. The DI is advised to risk assess the steps involved in releasing pre-assigned tissue to ensure there is minimal risk of using tissue that has been assigned to a different patient during a procedure as, should this occur, it would potentially result in a loss of traceability.

9.	PFE3c	The establishment currently manually records the temperature of the -80°C freezer unit and the ambient storage safe. The DI is advised to institute a process where the records are annotated to explain days when the temperatures have not been recorded, or have deviated from the expected storage ranges. Moving forward the establishment will use the attached chart recorder to monitor the temperature of the -80°C freezer unit. The DI is advised to implement a process whereby the chart is manually annotated to explain any temperature deviations.
10.	PFE5c	The -80°C freezer storage unit has an audible alarm and is connected to the establishment switchboard to allow an out of hours response. The DI is advised to consider implementing a system to regularly test and challenge the alarm system to ensure that it remains functional and allows an adequate out of hours response.
11.	PFE5d	The establishment has recently purchased a new -80°C freezer unit. The DI is advised to retain copies of the installation documents for its records, including copies of the Installation Qualification and Performance Qualification (if available).
12.	D2a	The establishment completes a Tissue Tracking Form (TTF) for every tissue product received. The TTF currently has a section to detail the use of any residual tissue after preparation for therapeutic use. A review of this section indicated it was rarely completed. The DI is therefore advised to review the section to ensure it remains fit for purpose.

Background

The Birmingham and Midland Eye Centre has been licensed by the HTA since 2006. This was the seventh site visit inspection of the establishment; the most recent previous inspection took place in October 2017. The establishment is licensed for storage and distribution of ocular tissue (cornea and sclera) and amniotic membrane supplied by other licensed establishments for use in ocular surgery.

Since the previous inspection, there has been a change in almost all staff working under the HTA licence at the Birmingham and Midland Eye Centre. This includes both the DI and CLHc who started their roles under the licence in September 2019. The previous DI left their post at the end of January 2019, and there was no DI in place to oversee licensable activities at the establishment until the appointment of the new DI in September 2019. The lack of a DI, and failure to notify the HTA, is a breach of the standard licensing conditions and the requirements of the Human Tissue Act 2004. The circumstances leading to the lack of a DI were investigated during the site visit investigation and the matter will be considered by the HTA outside of this inspection report.

Since the last inspection the establishment has removed the licensable activity of import from its licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

Standards covered at this inspection are listed in appendix 3. Any standards that were not applicable to the establishment have been deleted from this table. Any standards that were applicable, but were not covered during the inspection have been highlighted in grey.

The establishment is licensed for the 'Storage of relevant material which has come from a human body for use for a scheduled purpose' under the Human Tissue Act 2004 (HT Act). As the establishment was not storing material under the HT Act at the time of the inspection and had not previously done so, the 47 standards for this activity were not assessed.

Review of governance documentation

The inspection team undertook a review of documentation relevant to the establishment's licensable activities. Documentation reviewed included policies and procedural documents relating to licensed activities, receipt records, contracts relating to equipment servicing and servicing records, storage temperature monitoring records, minutes of governance meetings, incident logs, adverse events, audits, risk assessments, and training records for establishment staff.

Visual inspection

The inspection team undertook a visual inspection of all areas where licensable activity is undertaken. This included the areas where products are received, stored, and released for use, and the office where tissue tracking forms are stored.

Audit of records

The inspection team reviewed the product receipt records, storage logs and temperature records for the -80°C freezer unit and ambient storage safe. Three products in ambient storage, and two products in the -80°C freezer unit were physically checked against the storage inventories. In addition, all relevant records for five products (comprising amniotic membrane, cornea and sclera) were reviewed. This included records of receipt, storage and use logs, and the corresponding theatre log entries, tissue tracking forms and entry into the electronic patient records. One minor issue was found with a cornea product that had not been logged as being used in the receipt/storage log book. However, there was a record of the use of the tissue in the relevant theatre log book, and the issue had been identified in an internal product audit. Therefore, this was not deemed sufficient to amount to a shortfall but oral advice was provided to the establishment at the time of inspection.

Meetings with establishment staff

One to one discussions were held with the DI and CLHc. In addition, round table discussions included all staff working under the licence.

Report sent to DI for factual accuracy: 18 November 2019

Report returned from DI: 8 December 2019

Final report issued: 23 December 2019

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 18 August 2020

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, 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 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.

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 (HT Act), Human Tissue (Quality and Safety for Human Application) Regulations 2007, 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 HT Act or associated Directions,

   Or

   A number of 'major' shortfalls, none of which are 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Practice, 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 the final inspection report. Establishments 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 routine site-visit inspection.

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

Appendix 3: Applicable HTA Standards

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

Governance and Quality
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.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.

l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 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.
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.
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.
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.
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.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.

Premises, Facilities and Equipment
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.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 002/2018.
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.
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.
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
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Human Tissue Act 2004 Standards

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.