Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: 18 June 2024

Health Medical Bank Ltd (Uvence)

Proposed HTA licensing number 22719

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

Licensable activities applied to be carried out by the establishment
Proposed licensed activities
'E' = Establishment applied to be licensed to carry out this activity and will carry it out.
'E*' = Establishment applied to be licensed to carry out this activity but will not carry it out.
'TPA' = Third party agreement; the establishment applied to be licensed for this activity but another establishment (not licensed by the HTA) will carry out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Health Medical Bank Ltd (Uvence)	TPA	E		E	E*/TPA		

Tissue types applied to be authorised for licensed activities

Applied to be authorised = Establishment to be authorised to carry out this activity and will currently be carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Adipose; Adipose	Applied to be authorised	Applied to be authorised		Applied to be authorised	Applied to be authorised		

Summary of visit findings

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

Although the HTA found that Health Medical Bank Ltd (Uvence) (the establishment) had met the majority of the HTA's standards, three major shortfalls and seven minor shortfalls against standards for Governance and Quality, and Premises, Facilities and Equipment were found.

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	Visit 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.	The establishment's standard operating procedures (SOPs) do not contain sufficient detail and in some cases related forms are not aligned with the SOP. For example: • Not all consumables listed in SOP-005 "Receiving, Washing and Freezing of Human Tissue" are listed in the "Sample Receipt, Washing and Freezing" form. • SOP-003 "Storage Conditions for Human Tissue" describes the process for storage of human tissue, "per Human Tissue Act (HTA) guidelines" rather than referencing The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). • SOP-006 "Thawing and Emulsification of Human Microfat" does not describe what happens to the microbiological quality control samples and cell viability samples. Nor does it outline how many samples may be thawed at the same time and where thawed samples will be stored.	**Major (cumulative)**

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.	The establishment's risk assessments are limited in scope and do not cover all intended practices and processes relating to the quality and safety of the tissue. For example, consideration has not been given to: • The establishment's proposed practice of reusing laboratory coats, not wearing shoe covers or use of sticky mats before accessing the processing room. • The reuse of reagents for the processing and cryopreservation of the adipose tissue.	
PFE1 The premises are fit for purpose.		
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	The scope of the procurement centre's premises risk assessment is limited and does not cover all the risks and mitigating actions taken to maintain the quality and safety of the tissue.	

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.	The establishment intends to store reagents and consumables in the processing room. This room is not temperature monitored. The establishment cannot be assured that reagents and consumables will be stored in accordance with the manufacturer's required storage temperature.	**Major (cumulative)**

PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.	The establishment does not have an appropriate system in place for the return of the tissue to the clinic. When required for end use, the cryopreserved tissue will be thawed, emulsified and transported to the clinic at the specified temperature of 2 - 8°C. The establishment has determined that the transit time will be approximately two hours. The transport box, on activation, takes more than two hours to achieve a temperature of 8°C or lower. Furthermore, the clinics require the product to be at a higher temperature before use.	
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.	Before tissue is stored, the proposed DI must ensure that there is a temperature monitoring procedure in place which stipulates the upper and lower storage temperature limits, provides detail on how to challenge and test the alarms, describes how to respond to an alarm out of normal business hours, and ensures temperature monitoring data is reviewed and stored for the required period.	

Standard	Visit findings	Level of shortfall
PFE2 Environmental controls are in place to avoid potential contamination.		
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriately monitored environment as required by Directions 001/2021.	The establishment intends to process adipose tissue in a Class II Bio-safety cabinet in a Grade A environment against a Grade D background. The establishment does not have plans in place to undertake continuous non-viable particle monitoring for the duration of critical processing, as required by Directions 001/2021. The establishment has not developed an environmental monitoring programme to provide assurance that the processing area and personnel undertaking processing activities will be monitored in accordance with cleanroom environmental standards, and that there will be an effective process to detect excursions from environmental limits triggering investigation and assessment of risk to product quality. The procedure for processing tissue does not describe any decontamination steps, such as the spraying of or changing of gloves, when the operator moves in and out of the Grade A cabinet. The establishment does not have plans in place for the use biocides on a rotational basis for the cleaning and disinfection of the laminar flow cabinets used to process tissue.	**Major**

Minor Shortfalls

Standard	Visit 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.		
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.	Procurement of adipose tissue will be undertaken at an unlicensed organisation. The establishment does not currently have a TPA with this organisation.	**Minor**
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.	The establishment's agreement with the third party that will undertake mandatory serology testing does not set out the third party's responsibilities for the retention of raw data which are critical to the safety and quality of tissues and cells.	**Minor**

GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	The establishment does not have a Quality Manual.	**Minor**

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.		
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.	The establishment's SOP for the reporting and management of serious adverse events and reactions (SAEARs) does not detail how end users should contact the establishment nor what provisions will be in place to respond to SAEARs notifications outside of normal business hours.	**Minor**

PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.	The establishment has yet to enter into an agreement with a courier company for the transportation of samples from the procurement centre to the processing facility, and from the processing facility to end users.	**Minor**

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
j) For each critical process, the materials, equipment and personnel are identified and documented.	There is no documented procedure specifying the expiry dates of the reagents.	**Minor**
k) There are contingency plans for equipment failure.	The establishment currently has one controlled-rate freezer (CRF). There is no documented procedure that sets out what action should be taken in the event that the CRF fails.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1h	On receipt, the procured adipose tissue will be placed in a fridge where reagents are also stored. The DI is advised to define where receipted adipose tissue will be stored within the fridge and also to ensure that there is a separate shelf for the storage of any tissue that has been quarantined or specified for disposal.
1.	GQ1l and GQ4m	The DI is advised to ensure that, following the granting of a licence, procedures are put in place to ensure that in the event of termination of activities, stored tissues and records are transferred to another licensed establishment.
2.	GQ4e	Procured tissue will be transported from the clinic in temperature-controlled transport boxes. Written instructions are provided for the activation of the transport box. To ensure that the samples are transported within the validated temperature range, the DI is advised to demonstrate to staff, at the clinic, the correct way to activate the cooling engine.
3.	GQ4g	Patient data will be stored on the DI's laptop as well as in the Cloud. The DI is advised that the laptop should only be used to securely access patient data and that a patient database is not maintained on any laptop that may be taken away from the establishment.
4.	GQ6a	The establishment will generate labels for the procured tissue and blood samples. The DI is advised to put in place a process to reconcile the number of labels issued and used to avoid any unused labels being used for another patient.
5.	PFE2a	The establishment does not intend to separate the storage of processed samples where serology or sterility test results are pending. Samples will be placed in an overwrap and a cassette for cryopreservation and final storage. The DI is advised to document in a risk assessment the steps

		undertaken to protect the quality and safety of the processed adipose tissue whilst the samples are awaiting test results.
6.	PFE3c	Cryopreserved tissue will be stored in racks in the -150°C freezer. When required, the samples will be removed for thawing and processing. To minimise the time the freezer is kept open the DI is advised to consider maintaining an inventory checklist near to the freezer to facilitate storage and retrieval of tissue.

Background

Health Medical Bank Ltd (Uvence) (the establishment) has applied to be licensed for the procurement, processing, storage and distribution of adipose under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended).

The establishment has applied for a licence to procure autologous adipose tissue via a third party. The procured adipose tissue will then be couriered in a transport box to the establishment for receipt, processing and storage. Mandatory serology testing of client bloods will be undertaken by an establishment holding a human application licence for testing, under a service level agreement. The treating clinician will inform the establishment when the client requires the cryopreserved adipose tissue. The cryopreserved tissue will be emulsified at the establishment, loaded into syringes and couriered to the clinic for end use.

Description of activities undertaken during visit

The HTA's regulatory requirements are set out in Appendix 1. A desk-based assessment of the documents submitted as part of the licence application was conducted, followed by an on-site visit.

Standards assessed against during the desk-based assessment.

Standards covered in this assessment are listed in Appendix 3. Any standards that did not apply to the establishment have been deleted from this table. Any applicable standards that were not covered during the assessment have been highlighted in grey.

Review of governance documentation
Documentation was reviewed relating to the licensable activities. This included procedures, agreements with third parties, and risk assessments. In addition, a Preparation Process Dossier (PPD) and validation report to support the proposed processing activity was reviewed by the PPD Working Group.

The Regulation Manager team covered the following areas during the visit:

Visual inspection
A visual inspection of the establishment's facility was conducted. A walk through of the process from the proposed delivery point of the procured adipose, the receipt, processing and storage of the cryopreserved tissue and final thawing and preparation of the product for end use was undertaken.

Meetings with establishment staff
The assessment included a meeting with the following staff: proposed DI, the Chief Executive Officer and Chief Scientific Officer.

Report sent to proposed DI for factual accuracy: 16 July 2024

Report returned from proposed DI: 17 July 2024

Final report issued: 23 July 2024

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: 23 December 2024

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, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), 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:

   - 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, or;
   - 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 (as amended) 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 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, or;
- follow up at next routine site-visit inspection.

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

Appendix 3: 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 (as amended)

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and 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 Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) 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.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.

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 001/2021 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on 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.

e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
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 Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).
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 001/2021.
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.
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.
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
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 001/2021 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.

k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
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 is in place to ensure raw data and records of traceability are maintained for 10 or 30 years respectively, 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 001/2021.
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 001/2021.
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 UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021.
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.

b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 001/2021.
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.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
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 001/2021.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
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.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
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.