

Inspection report on compliance with HTA licensing standards
Inspection dates: 20-21, 26, 28 February and 20 March 2024



CenoBiologics Ltd
HTA licensing number 22640

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

Licensed activities

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

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
CenoBiologics Ltd.		E	E	E	E	E	E

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.

Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Bone; Acellular Bone		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Bone; DBM		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Bone; Cancellous Bone Particles		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Bone; Ribs		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Bone; Other Skeletal Tissue		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Bone; Bone Struts		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal,		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised

Bone; Cartilage							
Musculoskeletal, Tendon and Ligament; Tendons		Authorised*	Authorised*	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Tendon and Ligament; Ligaments		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Musculoskeletal, Tendon and Ligament; Menisci		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Skin; Skin		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Membrane, Fascia Lata; Fascia Lata		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Membrane, Pericardium; Pericardium		Authorised	Authorised	Authorised	Authorised	Authorised	Authorised
Membrane, Amniotic; Amniotic Membrane		Authorised	Authorised*	Authorised	Authorised	Authorised	Authorised
Cardiovascular, Valves; Heart		Authorised*	Authorised*	Authorised	Authorised	Authorised	Authorised

Valves							
Cardiovascular, Valves; Pulmonary Patches		Authorised*	Authorised*	Authorised	Authorised	Authorised	Authorised
Cardiovascular, Vessels; Conduits		Authorised*	Authorised*	Authorised	Authorised	Authorised	Authorised
Cardiovascular, Vessels; Other Vessels (including Iliac)		Authorised*	Authorised*	Authorised	Authorised	Authorised	Authorised

Licensed activities – Human Tissue Act 2004

The establishment is licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose.

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 CenoBiologics Ltd (the establishment) had met most of the HTA's standards that were assessed during the inspection, one major and eight 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

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

Major 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.		
<p>n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.</p>	<p>The establishment imports tissues and cells from several third country suppliers (3CS) and it is expected that the DI has oversight of the activities undertaken prior to import.</p> <p>With regards to one of the 3CS, it was determined that the establishment did not have clearance to audit a laboratory undertaking mandatory serological testing linked to tissue imported from the 3CS. The establishment was therefore unable to provide sufficient assurance that testing undertaken by the laboratory met the requirements set out in Directions 001/2021.</p> <p>The DI had undertaken an audit of a second 3CS. This audit did not include a review of how serology samples are managed prior to testing to ensure the samples are handled in accordance with the serological test kit manufacturer's instructions or laboratory-validated parameters.</p> <p>A review of records associated with the aseptic processing of a tissue product imported from one of the establishment's 3CS did not list the</p>	<p>Major (cumulative)</p>

	<p>components of the antibiotic solution used during processing. Furthermore, at the time of the inspection the DI was unable to provide adequate assurance that the monitoring of the background environment was aligned with the requirements of Directions 001/2021.</p> <p>The establishment imports aseptically processed tissue from one of its 3CS. The establishment was unable to provide evidence demonstrating that antibiotics used during processing are effectively removed or neutralised before microbiological testing of the final product, to avoid the risk of inhibitory effects.</p>	
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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.	The establishment's documented procedure for operating an autoclave and reviewing autoclave cycle printouts does not provide clear instructions to staff on how to document their review and acceptance or rejection of a cycle.	Minor
r) Third party agreements specify the responsibilities of the third party and	The establishment's agreement with a third party responsible for undertaking terminal sterilisation of tissue products requires updating to reflect the requirement for the third party to report potential adverse events	Minor

meet the requirements set out in Directions 001/2021.	to the establishment within 24 hours of discovery or determination.	
GQ2 There is a documented system of quality management and audit.	During the inspection, examples were found where records had not been fully completed. This was not identified through the subsequent internal review and audit process.	Minor
b) There is an internal audit system for all licensable activities.	Furthermore, the establishment's audit schedule for activities at their UK premises did not include a review of temperature monitoring records to ensure they were complete and that any excursions are documented and investigated.	
GQ4 There is a systematic and planned approach to the management of records.	The frequency and scope of the establishment's internal audits require updating to ensure that records are completed properly at the time an activity is undertaken.	
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.		
GQ2 There is a documented system of quality management and audit.		
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.	Although the establishment had arranged for an independent audit of activities since the last inspection, the scope of the audit was not sufficient to demonstrate compliance with all applicable standards and did not include a vertical audit of representative tissue records.	Minor

GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.

<p>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.</p>	<p>During a review of records an example was identified in which the tissue entering a manufacturing event could not be fully reconciled against the applicable record of items imported from the establishment's 3CS. The establishment's approach to documenting tissue entering each processing run requires updating so that each tissue item used in the run is fully documented.</p>	<p>Minor</p>
<p>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.</p>		

PFE2 Environmental controls are in place to avoid potential contamination.

<p>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.</p>	<p>The area within the establishment's laboratory where microbiological plates are incubated is not continuously monitored to provide assurance that the required temperature range is maintained throughout each incubation period.</p> <p>The establishment undertakes continuous non-viable particle monitoring for the duration of critical processing, as required by Directions 001/2021. However, the particle monitor inlet faces the cabinet bench where work is being undertaken, rather than towards the source of filtered air within the cabinet. The current placement is not aligned with the equipment</p>	<p>Minor</p>
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	manufacturer's guidance and does not allow the monitor to properly measure the quality of the filtered air flowing over the tissue during the aseptic processing steps.	
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.	The establishment stores some reagents in a corridor within the processing suite. The area is not monitored to ensure the manufacturer's required storage temperature range for the reagents is maintained.	Minor
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The establishment undertakes tissue processing in clean room facility that is maintained at grade A with a grade C background. The establishment ensures that the clean room facility is routinely requalified by an external contractor. However, the records of a recent requalification that were reviewed during the inspection did not include confirmation that the integrity of final filters had been checked to confirm suitable performance. <i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised</i>	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.	GQ2b	The DI is advised to update SOP Q-82-1 relating to customer complaints to reflect that potential adverse events should be reported by customers within 24 hours of discovery or determination, to allow onward reporting to the HTA in line with regulatory requirements.
2.	GQ3e	The DI is advised to update training procedures to capture decision making about when staff absent from the organisation for a period of time would require refresher training upon their return.
3.	GQ4b	The DI is advised to update procedures to require staff to indicate where a data entry is not required, through writing 'N/A' or similar. This may make it easier to identify which tissues were processed in a given run, and to distinguish fields that were deliberately not used from those that may have been left blank in error.
4.	GQ5a	The DI is advised to update the English translation of the donor selection form produced by one of the establishment's 3CS to ensure that the response to the question regarding xenotransplantation can be clearly evidenced.
5.	PFE3a	The establishment's final product storage area is monitored using a continuous temperature monitoring system. The probe used to measure the current temperature is located close to a door and some distance from tissue that is stored near a window. The DI is advised to map the temperature of the room to determine whether the current probe location is representative of the worst-case temperature ranges within the room, and to relocate the probe if the mapping exercise indicates that this is not the case.

6.	PFE3a	Packages of tissue awaiting collection may be temporarily stored in the establishment's lobby area, where access is not restricted. The DI is advised to either store packages awaiting collection within the nearby secure reception area, or to restrict access to the lobby in order to maintain the security of this tissue.
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Background

The establishment imports a range of tissues from three third country suppliers (3CS). Imported tissue falls into three categories: unprocessed tissue which is processed into irradiated final product under the establishment's licence, partially processed tissue products for which processing and irradiation is completed under the establishment's licence, and processed grafts that are aseptically produced at one of the 3CS prior to import. The establishment has been licensed by the HTA since June 2012. This was the establishment's seventh routine inspection; the last routine inspection took place in February 2022.

Description of inspection activities undertaken

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

Review of governance documentation

The inspection included a review of policies and procedural documents relating to licensed activities, servicing records, clean room maintenance and environmental monitoring records, audits, incidents, temperature monitoring records, and staff training records.

Visual inspection

The inspection team visited areas where tissue is received and dispatched, and areas where tissue is stored pre- and post-processing, including quarantine storage arrangements. Areas where freeze drying, packaging and labelling are undertaken were visited, including the laboratory where tissue quality is assessed and microbiological plates are incubated. The team also visited the clean room suite and observed some of the establishment's processing activities.

Audit of records

The inspection included a review of records of donor consent, selection, serological testing, tissue traceability, tissue processing (either at the 3CS or the establishment's premises), packaging, terminal sterilisation or environmental monitoring, as applicable, final labelling and packing and, where applicable, distribution for the following examples:

- two terminally sterilised bone products;
- a membrane product; and,
- an aseptically processed heart valve, imported as a final product.

In addition to the above, the inspection included a detailed review of traceability arrangements for two shipments of tissue received from two of the establishment's three 3CS.

Meetings with establishment staff

The inspection team met with the DI, who is also the corporate licence holder contact, and staff undertaking processing and quality assurance activities under the licence, including the oversight of third country suppliers and the review of tissue imported under the licence.

The establishment is also licensed for the storage of relevant material for use in a Scheduled Purpose. This activity was not reviewed as part of this inspection.

Report sent to DI for factual accuracy: 07 June 2024

Report returned from DI: 17 June 2024

Final report issued: 30 July 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

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
- 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 on-site 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments 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)

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.
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.
n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.
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.

d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.

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.

Human Tissue Act 2004 standards

Consent

Standard
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) 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.
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

Standard
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

Standard
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

Standard
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.