



Site visit inspection report on compliance with HTA minimum standards

Cells4Life Group LLP

HTA licensing number 11083

Licensed for the

- **procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

5 - 6 June 2017

Summary of inspection findings

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

The HTA found that Cells4Life Group LLP (the establishment) had met the majority of the HTA standards; however, 11 shortfalls were found. One major shortfall was found in relation to Governance and Quality Systems. The shortfall relates to the need for the regular evaluation of processes affecting the quality and safety of tissues and/or cells. 10 further shortfalls were found in relation to Governance and Quality Systems and Premises and Facilities and Equipment standards. These relate to: providing clients with the correct information to make an informed decision; the requirement that standard operating procedures (SOPs) should accurately reflect current practices; the limited scope of internal and independent audits as well as risk assessments; the time and temperature in transit of blood samples prior to testing and how this relates to the validation of the testing kits; making adequate provisions in the event of termination of activities and ensuring that environmental controls are in place to avoid potential contamination.

Examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

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.

Licensable activities carried out by the establishment

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

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Umbilical cord blood (UCB)	TPA	E	E	E	E	E	E
Umbilical cord tissue (UCT)	TPA	E	E	E	E	E	E

Background to the establishment and description of inspection activities undertaken

This report refers to the activities undertaken by the private tissue bank Cells4Life Group LLP. The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Quality and Safety Regulations) for the procurement, testing, processing, storage, distribution, import and export of umbilical cord blood (UCB) and umbilical cord tissue (UCT). The establishment is also 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. The establishment has been inspected on a total of seven occasions since it was first licensed in September 2006. Since the last inspection a new Designated Individual (DI) has been appointed. The DI is also the Corporate Licence Holder contact on this licence.

In the UK, UCB and UCT procurement is undertaken on behalf of the establishment by a phlebotomy agency acting under the terms of a third party agreement (TPA). Prior to procuring for the establishment, all phlebotomists are trained on the establishment's collection procedure via an e-learning package. The establishment liaises with its international partner offices for the procurement of UCB and UCT units from all over the world. Representatives from the international offices, usually physicians, receive training in the use of the procurement kit and completion of consent forms and via a formal legal agreement with the establishment, take responsibility for ensuring compliance with all relevant HTA standards. Samples received from international partner offices are shipped using a validated transport boxes. Samples procured in the UK are expected to be delivered to the establishment within 24 hours. A temperature logging device is included within the procurement kit and a second is affixed to the outer packaging by the courier to alert staff at the establishment if the kit temperature deviates above the set upper limit. The establishment processes all samples regardless of time and temperature in transit. Clients are informed if their samples show less than the establishment's defined acceptable viability, and the client is specifically prompted in the correspondence to decide based on this information whether to bank or request disposal of their sample. If the establishment does not hear back from the client, then the establishment will make reasonable repeat attempts to get in touch. Where clients are not able to be reached, the samples are banked as per the terms of the agreement.

UCB and UCT units received into the establishment are processed in a dedicated clean area consisting of two biological safety cabinets within a soft wall clean room. All critical, open processing takes place within a Grade A environment and environmental monitoring is conducted throughout in accordance with the requirements of Directions 003/2010 and Annex I of the EU Guidelines to Good Manufacturing Practice. Plates and samples for microbiological testing, and blood samples taken for mandatory serology testing, are analysed in-house. Any positive microbiology or serology samples are sent to a local hospital pathology laboratory for confirmation. Following processing, the samples are placed in passive freeze boxes and kept at -80°C for a maximum of 12 hours before being transferred for long term, vapour-phase storage in dedicated liquid nitrogen tanks. Since the last inspection, the establishment has invested in a satellite storage site and has transferred all samples that had been previously stored at a licensed third party site to the new satellite site.

The establishment has agreements with two NHS hospitals for the procurement of UCB and UCT for research purposes. Upon receipt, research samples are stored in a monitored refrigerator located within the organisation's research laboratory which is distinct from the facility used to process tissues and cells for human application. The establishment has

additional liquid nitrogen storage tanks on-site for research samples that require long-term storage.

This report describes the routine site visit inspection which took place on 5-6 June 2017. The inspection included a visual inspection of the sample receipt, processing and cryostorage areas as well as a visit to the satellite site. Roundtable discussions were held with members of staff involved with sales/client operations, storage, processing and testing as well as the laboratory manager and the DI. Prior to the inspection the HTA requested information on all the samples received in the preceding two years. The data supplied included information on date of birth, date of collection, date of receipt, processing, microbiology testing results and serology testing results. Analysis of the data indicated that for in excess of eight percent of all samples received exceeded the transit time limits set by the establishment. The inspectors identified individual samples from this data to use for the traceability audits explained below.

Sample traceability audits

- (1) One client sample that has tested positive for Hepatitis B was audited for appropriate actions taken with regard to the positive status. No anomalies were found relating to environmental monitoring records, storage location or client communication. In this instance, the client had known Hepatitis B positive status before procurement and had made this known to the establishment. The sample was banked.
- (2) One client sample that had tested positive for E.coli contamination was audited for appropriate actions taken with regard to the positive status. No anomalies were found relating to environmental monitoring records, storage location or client communication.
- (3) Four client samples for which transit time limits were exceeded, and which showed viability levels below the threshold set by the establishment were audited for appropriate actions taken with regard to the deviation. Client communication and any disposal records were examined for all samples. All appropriate records were in place and no anomalies were found relating to client communication. One client had opted to dispose of their sample rather than continue storing and for this sample the statement of disposal was in place and the establishment's records indicated that the sample had been disposed.

The inspection of activities being undertaken under the research licence was limited to correlating the consent information for three samples that were being used in various research projects. No anomalies were found.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
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) 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, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice.	<p>The sales team's model answers routinely used in some of their correspondence with clients is incorrect with regard to an explanation of public banking. Although the establishment confirmed that this information has not been relayed to clients, the model answer states that a cord blood unit banked in a public banks 'is prohibited' from being used to treat the donor, even if it is still available. This statement is directly contradictory to public banking practice.</p> <p>Following the inspection, the establishment informed the HTA that they have re-issued their model answer document to reflect this.</p>	<p>Minor</p> <p><i>The establishment took action to address this shortfall before the issue of the final report. The HTA now assess this standard as fully met.</i></p>
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	<p>Although the staff were able to describe the procedures for receipt and cryopreservation of samples it was noted that the SOPs had been revised and considerably shortened with the consequence some of the detail described by staff was missing in the documents. The procedures for the validation of the passive freeze boxes were not accurately reflected in the establishment's documentation.</p>	<p>Minor</p>

<p>g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.</p>	<p>The automated LIMS system alerts staff according to the validated transport parameters. However, policies and procedures relating to the transport of samples are inconsistent with regard to the definition of "transit time", this is described in documents as either the time between procurement and receipt; or the time between procurement and processing.</p>	<p>Minor</p>
<p>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</p>	<p>The establishment's policy is not to store any HIV positive samples. However, it was unclear how this policy was being implemented.</p>	<p>Minor</p>
<p>GQ2 There is a documented system of quality management and audit.</p>		
<p>b) There is an internal audit system for all licensable activities.</p>	<p>The establishment uses their electronic tracking and monitoring system for their internal audit processes. However, this not sufficient as a means of auditing all licensable activities for example during processing ensuring that the settle plates are placed in the correct position or undertaking a visual inspection of the premises.</p>	<p>Minor</p>
<p>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.</p>	<p>Independent audits were conducted last year and just prior to the inspection; however, these did not cover all the relevant HTA standards.</p>	<p>Minor</p>
<p>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.</p>	<p>Following the inspection, the establishment provided evidence of on-going evaluation of the UCT banking service. However, data was only available for 2017. The establishment confirmed that no on-going evaluation of this service had been conducted since the previous inspection. The establishment has not been able to provide the necessary assurance that UCT banked over that period of time continued to achieve the intended results.</p>	<p>Major</p>

GQ4 There is a systematic and planned approach to the management of records.		
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.	The establishment is in the process of putting an agreement in place for the transfer of samples to another licensed establishment in the event of termination of licensable activities. However, no provision has been made with this licensed establishment to transfer traceability records and raw data. Instead the records will be retained by the establishment's Chief Executive Officer on unlicensed premises.	Minor
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.	The serology testing kits used by the establishment requires that the blood samples, if stored at room temperature, are tested within 24 hours. Alternatively the serum may be stored at 2-8°C and tested up to six days later. The establishment's practices does not ensure that samples held for serological testing are transported or stored in accordance with these requirements.	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.	The establishment has in place risk assessments; however, these were limited in scope and do not fully capture all the risks associated with activities that may affect the quality and safety of tissues and cells.	Minor

Premises, Facilities and Equipment

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.	The establishment has commenced in-house temperature mapping of its fridges and freezers. The validation procedures are not sufficiently detailed nor the acceptance criteria adequately defined.	Minor
--	---	--------------

Advice

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

No.	Standard	Advice
1	GQ1c	The DI should ensure that findings and actions arising from the audits and incidents are well-documented and discussed at HTA governance meetings. Minutes from these meetings should be disseminated to all staff to raise awareness of incidents. This will also help ensure that follow up action plans are completed.
2	GQ1r	The annual TPA renewal with phlebotomists is a simple form requiring their signature. The DI is advised to include the TPA itself in full, as a reminder of the responsibilities of the each party and the regulatory requirements as set out in Directions 003/2010. The DI is also advised to ensure that the TPAs with the courier company, and the NHS hospital, providing confirmatory results, reference the current HTA Directions 003/2010 instead of the Directions which have since been revoked.
3	GQ2a	The DI is advised to update the establishment's quality manual to refer to the HTA's new Codes of Practice.
4	GQ3e	The DI is advised to formalise and document all aspects of sales team consent and information provision training, for example scenario training and observing calls.
5	GQ7a	The DI is advised to appoint Persons Designated who are able to report serious adverse events and reactions (SAEARs) to the HTA in the DI's absence. Staff training programmes should ensure that all staff are made aware of their responsibility to report incidents. Staff directly involved in reporting SAEARs in the absence of the DI should receive additional training in assessing and reporting SAEARs to the HTA.
6	PFE2d	The DI is advised to review and risk assess the practice of not changing sharps bin between client samples and only disposing of the sharps bin when it is full.

Concluding comments

A number of good practices were observed during this inspection. As part of their training, new members of the sales team role play various client-related scenarios and are gradually allowed to take on more complex customer enquiries. The in-house software system ensures that there is good traceability of samples and that the samples are processed in a timely manner.

There are a number of areas of practice that require improvement, including one major shortfall and 10 minor shortfalls. The HTA has given advice to the Designated Individual with respect to fully documenting all the training undertaken by staff; renewal TPAs should contain reminders of the obligations and requirements of the third party and findings from audits are actioned and discussed with staff and minutes of meeting disseminated; simplifying the letter sent to clients when samples test positive for microbial contamination and to consider appointing Persons Designated who are able to report SAEARS.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection

Report sent to DI for factual accuracy: 3 July 2017

Report returned from DI: 3 January 2018

Final report issued: 8 January 2018

Completion of corrective and preventative actions (CAPA) plan

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

Date: 23 November 2022

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
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 (Q&S Regulations) 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 Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
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 003/2010 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 003/2010 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 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.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.

t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
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 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
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 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.

c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

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

e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
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 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.

j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
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 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
<p>a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.</p> <p>b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.</p> <p>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.</p> <p>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.</p> <p>e) Language translations are available when appropriate.</p> <p>f) Information is available in formats appropriate to the situation.</p>
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
<p>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.</p> <p>b) Records demonstrate up-to-date staff training.</p> <p>c) Competency is assessed and maintained.</p>
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
<p>a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.</p> <p>b) There is a document control system.</p> <p>c) There are change control mechanisms for the implementation of new operational procedures.</p> <p>d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.</p> <p>e) There is a system for managing complaints.</p>
GQ2 There is a documented system of audit
<p>a) There is a documented schedule of audits covering licensable activities.</p> <p>b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.</p>

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- a) Qualifications of staff and all training are recorded, records showing attendance at training.
- b) There are documented induction training programmes for new staff.
- c) Training provisions include those for visiting staff.
- d) Staff have appraisals and personal development plans.

GQ4 There is a systematic and planned approach to the management of records

- a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
- b) There are provisions for back-up / recovery in the event of loss of records.
- c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).

GQ5 There are systems to ensure that all adverse events are investigated promptly

- a) Staff are instructed in how to use incident reporting systems.
- b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

- a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.
- b) Risk assessments are reviewed regularly.
- c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail

- a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
- b) A register of donated material, and the associated products where relevant, is maintained.
- c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
- d) A system is in place to ensure that traceability of relevant material is maintained during transport.
- e) Records of transportation and delivery are kept.
- f) Records of any agreements with courier or transport companies are kept.
- g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner

- a) Disposal is carried out in accordance with the HTA's Codes of Practice.
- b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards

PFE1 The premises are secure and fit for purpose

- a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
- b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
- c) There are documented cleaning and decontamination procedures.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

- a) There is sufficient storage capacity.
- b) Where relevant, storage arrangements ensure the dignity of the deceased.
- c) Storage conditions are monitored, recorded and acted on when required.
- d) There are documented contingency plans in place in case of failure in storage area.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

- a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
- b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
- c) Staff are provided with suitable personal protective equipment.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

Or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

- (1) A notice of proposal being issued to revoke the licence
- (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- (3) A notice of suspension of licensable activities
- (4) Additional conditions being proposed
- (5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

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