Site visit inspection report on compliance with HTA minimum standards

NHSBT Colindale

HTA licensing number 22600

Licensed for the

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

24-25 April 2019

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.

Although the HTA found that NHSBT Colindale (the establishment) had met the majority of the HTA standards, one shortfall was identified which related to a nucleic acid amplification technique (NAT) test being carried out on behalf of the establishment by a third party, without a formal agreement in place.

In addition to this, since the last inspection the establishment has procured cord tissue as a starting material for ATMP manufacture on a number of occasions, without prior notification to the HTA. The HTA considers this a breach of the standard condition of the establishment's licence, which requires it to seek approval from the HTA prior to it procuring a new type of tissue and/or cells. The HTA will consider the need for regulatory action in relation to this matter separately to the inspection findings reported below.

Particular 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.

'SLA' = Service level agreement. This activity is performed by another licensed establishment on behalf of the establishment.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cells, Haematopoietic, Cord Blood; Cord Blood	**E**		**E / SLA**				
Other; Cord Tissue	**E**		**E / SLA**				

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by National Health Service Blood and Transplant (NHSBT) Colindale (the establishment). The establishment has been licensed since 2010 under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, and

this was their first inspection since the amended Regulations came into force on 1 April 2018. The establishment is also licensed under the Human Tissue Act 2004 for the storage of relevant material for the scheduled purpose of research, but at present is not storing any material for this purpose.

Cord Blood

The establishment forms part of the NHSBT Cord Blood Bank (CBB), and under this remit undertakes allogeneic cord blood procurement and certain testing activities. Procured units which have met the establishment's initial acceptance criteria are sent to NHSBT Filton for subsequent processing, storage and distribution.

Establishment staff procure cord blood from five local hospitals. Parents are given information about cord blood donation at routine hospital visits during pregnancy. Shortly before delivery establishment staff seek consent for collection of cord blood, and this is captured on a pre-delivery 'mini' consent form.

Hospital midwives deliver the placenta and complete a placenta identification form, which captures information about the birth and the mother's details. If this information indicates the cord blood/tissue is suitable for procurement, establishment staff take the placenta and form to a dedicated, secure, temperature-monitored collection room. The room is also used to store the necessary kits, consumables, and the incubator and fridge used to temporarily store cord blood and tissue respectively prior to collection by the contracted courier.

Venipuncture sites undergo a two-stage cleaning process prior to collection, with staff changing their gloves in-between. A balance is used to weigh the collection bag and thereby determine the volume of cord blood collected. Information about the collection is recorded using a collection form. The cord sample is assigned a set of unique identification labels and the maternal samples are assigned a second set, in consecutive order. The cord is labelled first and the labels reconciled before the maternal labels are allocated. The two identification labels are linked in the records, ensuring traceability of cord and maternal samples.

If the volume collected meets the establishment's minimum acceptance criteria, the cells are stored at 20-24°C in a monitored incubator. Establishment staff seek further consent for the donation, serological testing, storage and use of the cells. A comprehensive donor screening questionnaire is also completed and used to identify the need for any additional tests. Maternal bloods for biological tests are also taken and sent to NHSBT Colindale at this time. Staff at the main NHSBT Colindale site are notified about procured donations ahead of receiving the cells, and initiate a record for each within the establishment's laboratory information management system (LIMS).

At the end of the working day procured cells are transferred to a validated transportation container along with a maximum-minimum temperature monitor, set to alarm if the temperature exceeds the required 20-24°C range. The container is collected the following morning by a courier and transported to the NHSBT Colindale site.

Staff receiving cord blood at NHSBT Colindale unpack the cells, check the temperature monitor and segregate each collection into a separate tray. The cell bag and labelling is checked using a receipting checklist, and a sample is taken from the cell bag bleed line. The remaining blood weight and total nucleated cell (TNC) count are determined and details of the donor, procurement and unit are entered onto the establishment's LIMS.

Acceptable units are repackaged along with the bleed line sample and collected by the courier later the same morning for delivery to NHSBT Filton. The establishment assigns a unique Single European Code Donor Identification Sequence (SEC-DI) to each unit, and this is recorded in the paperwork that accompanies the donation.

Units that are not acceptable are visually identified via an additional red label, and may be sent to an establishment that has requested fresh cord blood for research, providing appropriate consent is in place. Otherwise, units not meeting the establishment's acceptance criteria are disposed of.

Cord Tissue

Recently the establishment has begun to procure cord tissue and dispatch it to two other NHSBT sites as a starting material for ATMP manufacture. Establishment pre- and post-delivery consent forms have been updated to include consent for procurement of tissue for this purpose. Cord tissue can be procured without concurrent cord blood procurement, provided the appropriate consent is in place and selection criteria met.

The surface of the procured length of cord is wiped with alcohol disinfectant, then stored in transportation solution in a sterile pot. This pot is enclosed within a secondary labelled pot, which is further enclosed within a self-seal bag.

The tissue is then held at 2-8°C in a monitored refrigerator whilst an ad-hoc courier collection is arranged by the establishment. The cold chain is maintained during transportation to NHSBT Colindale using gel packs and a validated transport container. Upon receipt it is checked, logged and repackaged for dispatch to one of the two NHSBT ATMP manufacturing sites. The establishment takes responsibility for the onward transport of the tissue by a contracted courier.

Donated placentas from which the cord blood does not meet the establishment's volume and TNC criteria may still be accepted for cord tissue procurement, and establishment procedures document the requirement for equivalent follow-up consent, screening, serological testing and review steps to be completed in such circumstances.

Cord Bank Team Managers based at NHSBT Colindale regularly visit each hospital site to monitor the facilities, equipment, collection kits, procedures and training. Medical staff involved in the collection of the placenta are made aware of the regulations relating to this work and of expectations in terms of handling the placenta before it is given to the NHSBT collection staff and record keeping. Collection staff have a full induction programme and are signed-off once competent. Sampling of the cord units for microbiological testing is carried out at NHSBT Filton; tests are carried out at National Bacteriology lab at NHSBT Colindale. The results of the microbiology tests are trended and investigated internally if a pre-assigned threshold is exceeded.

NTMRL

The National Transfusion Microbiology Reference Laboratory (NTMRL) is based at the NHSBT Colindale site. This laboratory carries out biological testing on samples from deceased tissue donors, confirmatory tests and tests on samples that are non-routine e.g. small volume samples. This testing is carried out on behalf of a number of HTA-licensed establishments, internal and external to NHSBT, under a series of service level agreements.

Inspection Activities

The establishment has been licensed since January 2010 and this was the fifth routine site inspection. The inspection team conducted visual inspections of the areas for cord blood and tissue receipt, consumable storage, serology sample receipt, the NTMRL and associated sample archive areas. The inspection also included a visit to the H&I laboratory which carries out human leukocyte antigen (HLA) typing of procured tissue and cells.

Round table discussions were performed in which the records for four sets of procurements were examined, two of which included the procurement of cord tissue. Further round table discussions examined the establishment's governance procedures relating to the NTMRL and the cord blood and tissue procurement activities. Records and associated procedures for

audits, risk assessments, incident reporting, equipment maintenance, change control processes, agreements with other parties, contingency arrangements and procedures for the allocation of the SEC-DI were examined.

Inspection findings

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

However, since the last inspection the establishment has procured cord tissue as a starting material for ATMP manufacture on a number of occasions, without prior notification to the HTA. The HTA considers this a breach of the standard condition of the establishment's licence, which requires it to seek approval from the HTA prior to it procuring a new type of tissue and/or cells. The HTA will consider the need for regulatory action in relation to this matter separately to the inspection findings reported below.

Compliance with HTA standards

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

Governance and Quality

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) 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.	The establishment procures cord tissue as a starting material for ATMP manufacture. A NAT test for Epstein Barr virus (EBV) is performed by a third party as part of this work. At the time of the inspection there was no formal agreement in place with the third party carrying out this additional testing.	**Minor**

Advice

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

No.	Standard	Advice
1.	General	The establishment is licensed for the storage of storage of relevant material which has come from a human body for use for a scheduled purpose, but has not carried out this activity for some time. The DI is advised to consider removing this activity from the licence.
2.	GQ1p	The NTMRL performs a range of serological and NAT assays under agreement with other establishments. The laboratory provides clients with

		documentation specifying their requirements for sample storage from the point of bleed to testing, and sample shipping requirements. Samples must be handled according to these requirements in order to comply with the validated parameters of the NTMRL assays. Various options are provided, but the storage and shipping requirements are not entirely aligned. For example, storage requirements for serology samples specify storage at 2-8^{o}C only, but shipping requirements allow for the shipping of previously frozen samples. The DI is advised to review and update the table to ensure clients are clear on the permitted handling procedures for samples sent for analysis at the NTMRL.
3.	GQ6d	During the traceability audit, two records relating to cord tissue procured as the starting material for ATMP manufacture were reviewed. In both records the Single European Code Donor Identification Sequence (SEC-DI) contained one additional character in the unique donation number section. The DI is advised to implement procedures ensuring that the SEC-DI allocated to such tissue is compliant with the requirements of Directive EU 2015/565.
4.	GQ7a	The establishment trend microbiological results and have assigned a threshold which, if exceeded, would trigger internal reporting and investigation. The DI is advised to consider also introducing a threshold above which positive microbiological results would be reported to the HTA, and document this in establishment procedures.
5.	GQ8a	A comprehensive risk assessment is in place which considers the risks relating to licensable activities performed by the NTMRL. The DI is advised to consider updating this assessment to adopt the quantitative approach used elsewhere in the organisation, in order to quantify the potential severity of each risk and the efficacy of existing mitigating steps.

Concluding comments

Several areas of strength and good practice were noted during the inspection.

- There is a strong emphasis on quality management and all activities on site are overseen by a single quality assurance (QA) team. This enables interdependencies between the various activities to be taken into consideration as part of the QA process.
- The establishment is fully integrated within the national NHSBT governance structure, enabling consistency with the processing and storage establishment and the sharing of best practices.
- Staff involved in root cause analysis receive training in a range of standard techniques. These techniques are embedded within the incident reporting systems, to help ensure root causes are accurately identified and enable effective steps to be put in place to prevent recurrence.

Although the HTA found that the establishment had met the majority of the HTA standards, one shortfall was identified. This related to a NAT test being carried out on behalf of the establishment by a third party without a formal agreement in place for this activity.

The HTA has given advice to the Designated Individual with respect to the establishment's licensable activities, storage and shipping instructions supplied to clients of the NTMRL, the allocation of the SEC-DI to cord tissue procured for ATMP manufacture, and the update of

the risk assessment of NTMRL activities to a quantitative structure consistent with that used elsewhere at the establishment.

The HTA requires that the Designated Individual addresses the shortfall 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: 23 May 2019

Report returned from DI: 04 June 2019

Final report issued: 21 June 2019

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
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 002/2018 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.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.

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 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.

i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.

d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.

b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
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
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice. b) Consent forms are available to those using or releasing relevant material for a scheduled purpose. c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice. d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice. e) Language translations are available when appropriate. f) Information is available in formats appropriate to the situation.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice. b) Records demonstrate up-to-date staff training. c) Competency is assessed and maintained.

Governance and quality system standards
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities. b) There is a document control system. c) There are change control mechanisms for the implementation of new operational procedures. d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff. e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities. b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training. b) There are documented induction training programmes for new staff. c) Training provisions include those for visiting staff. d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records. b) There are provisions for back-up / recovery in the event of loss of records. c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.

b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. b) Risk assessments are reviewed regularly. c) Staff can access risk assessments and are made aware of risks during training.

Traceability standards
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it. b) A register of donated material, and the associated products where relevant, is maintained. c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom. d) A system is in place to ensure that traceability of relevant material is maintained during transport. e) Records of transportation and delivery are kept. f) Records of any agreements with courier or transport companies are kept. g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA's Codes of Practice. b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment standards
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose. b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained. c) There are documented cleaning and decontamination procedures.

PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity. b) Where relevant, storage arrangements ensure the dignity of the deceased. c) Storage conditions are monitored, recorded and acted on when required. d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept. b) Users have access to instructions for equipment and are aware of how to report an equipment problem. c) Staff are provided with suitable personal protective equipment.

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

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

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the 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 shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

   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 breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

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

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall.

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

3. Minor shortfall:

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

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

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

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with 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.