Site visit inspection report on compliance with HTA minimum standards

St George's Hospital

HTA licensing number 12462

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**

24-25 July 2017

Summary of inspection findings

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

Although the HTA found that St George's Hospital (the establishment) had met the majority of the HTA standards, one major and one minor shortfall were found with regard to the Consent and Governance and Quality Systems standards. The major shortfall relates to the establishment's procedures for donor testing and consent for skin procurement and the minor shortfall relates to the independent audit.

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.

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

'SLA' = Service level agreement; another licensed establishment carries out the activity on behalf of the establishment.

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

Tissue category; Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Hematopoietic, PBSC; PBSC	**E**	**SLA**	**E**	**SLA**	**SLA**		
Progenitor Cell, Hematopoietic, Bone Marrow; Bone Marrow	**E***		**E***	**E***	**E***		
Mature Cell, T Cell (DLI); DLI	**E**	**SLA**	**E**	**SLA**	**TPA**		
Musculoskeletal, Tendon & Ligament; Tendons & Ligaments				**E**			
Skin; Skin	**E**		**E**	**E**			

Background to the establishment and description of inspection activities undertaken

St George's Hospital has been licensed by the HTA since 2007. The HTA licence includes the procurement, donor testing, storage and distribution of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The majority of licensable activities undertaken at this establishment relate to stem cell collections procured for autologous or allogeneic patient treatment.

Consultants undertake donor assessment and seek consent for procurement of peripheral blood stem cells (PBSC) from autologous or allogeneic donors. Blood samples for the mandatory serology testing are taken on the day of the consent and no earlier than 30 days before procurement of stem cells. Mandatory donor testing, including testing for HTLV, takes place at the onsite laboratory.

Procurement of PBSC takes place in dedicated areas in the adult wards. On the day of the procurement, donors are monitored to ensure that the target CD34 counts are reached and consultants seek consent for the procedure before apheresis commences. There are four apheresis machines maintained under a service contract and staff cleans them after each apheresis session and once a month on a rota. Consumables such as the anticoagulant Acid-Citrate-Dextrose Formula A (ACD-A) are stored in a separate room, which is temperature-monitored and checked daily, including weekends.

Each collection is assigned a unique code, which ensures traceability from procurement through to processing, storage, distribution and end-use or disposal. During the last year the establishment has signed an SLA with another HTA-licensed establishment for processing and storage of stem cell harvests on their behalf. The labels with the unique code are provided from the other licensed establishment, are pre-printed and placed in the transplant folder of the establishment. The stem cell collection is placed in an insulated transport box along with five pre-chilled ice packs, together with relevant documentation. The temperature is monitored with a temperature strip. The courier picking up the stem cell collection signs the driver record logbook. Following this, the stem cell collection is delivered by the courier to the other licensed establishment for processing and storage. Although the establishment is licensed for distribution of PBSC this activity is overseen by the other licensed establishment.

Bone marrow harvests take place infrequently; Since 2015, the establishment has not procured any bone marrow harvests. The establishment also purchases and stores frozen femoral heads and tendons for use in orthopaedic surgery, as and when required.

In the past, the establishment procured and stored skin and vessel/artery samples for longer than 48 hours, in a refrigerator, for potential use in surgery. Where tissue is being stored for more than 48 hours for use in a patient, donor serology testing of the donor's blood sample must be performed in accordance with the requirements of Directions 003/2010. The establishment has recently decided to no longer store vessel/artery samples and is in the process of evaluating whether it will continue to procure and store skin in the future.

This report describes the establishment's sixth routine inspection, which took place over a day and a half on the 24-25 July 2017. Discussions were held with the Designated Individual (DI), the Consultant Haematologist, the Apheresis Nurses, the Theatre Team Leaders for Plastic Surgery and Cardiothoracic Surgery and the Quality Manager. A review of documentation relevant to the establishment's licensable activities and a visual inspection of the premises where tissue procurement and storage take place, were also included as part of the inspection.

An audit of records of the cells collected at apheresis was undertaken. A total of two matched related donor files and two recipient files of stem cell harvests were reviewed to ensure they contained all the relevant documentation. The audit covered the donor consent, the Adult Patient Consent to Apheresis Procedure form, the cell collection records, the consumables

used, the record of transfer of product for processing and storage, seal tag numbers, the transplant request and subsequent transfer back to the establishment for infusion into the patient. There were a few discrepancies in the completion of the consent forms (see advice item 1 below).

Audits of traceability included two femoral heads and three tendons cross-checked against the order sheets and the bone bank register. There were a few inconsistencies in the filling-in of the register (See advice item 4 below). No skin samples were being stored on site at the time of the inspection, which was reflected in the storage records. The records indicated that since the last HTA inspection skin had been stored for more than 48 hours without mandatory donor serology testing being performed (see shortfall under GQ5b). No vessel/ artery samples were being stored on site at the time of the inspection.

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

Consent / 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.		**Major (cumulative)**
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.	The establishment was unable to provide evidence for appropriate arrangements for consent for the procurement and subsequent storage of a unit of skin for longer than 48 hours.	
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.	Directions 003/2010 require that where tissues or cells from autologous donors are stored for periods longer than 48 hours, the same minimum set of biological testing requirements must apply as for an allogeneic living donor. Such testing was not carried out in relation to the skin sample referred to above. *See advice item 6*	

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	Although internal audits cover the range of activities carried out under the licence, no independent audit was conducted to verify compliance with protocols and all relevant HTA standards. *See advice item 3*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1d	Although the donor information leaflet includes information on all mandatory serology tests as set out in Annex B in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment, the 'Adult Patient Consent to Apheresis' form does not cover all the relevant tests. The DI is advised to update the 'Adult Patient Consent to Apheresis' form to also include HTLV testing.
2.	GQ1d	The DI is advised to review the establishment's standard operating procedures (SOPs) to ensure they reflect current practices and include up-to-date references. Examples of inconsistencies include: • the SOP on packing and transportation is not accurate as the receiving establishment does not carry out testing; • the SOP on labeling contains no information on what to do if labels are wrong or not available; and

		• the SOP on audits of femoral heads in the freezer does not include the procedure for stock-taking and managing disposal so that expired grafts do not remain in the freezer post expiry. The DI is also advised to update the SOP entitled 'JACIE 01/JA S5 Nursing 24', as it is out of date.
3.	GQ2b,c	With reference to the above shortfall, the DI is advised to formalise and record the processes involved in internal and independent audits in an SOP. This will ensure that new and existing members of staff are consistent in their approach to audits. The DI is also advised to review the establishment's approach to the audit of records. Consideration should be given to the extent and scope of the establishment's internal audits to ensure that records are completed accurately. The results of all audit findings, and actions taken, should be formally recorded and discussed at governance meetings, to ensure continuing improvement of processes and practices.
4.	GQ4b	A number of discrepancies were noted during the audit of the establishment's patient forms. Examples include: • A number of fields within the 'Adult Patient Consent to Apheresis' and the 'Traceability' forms were not always filled in. The DI is advised to review the content of the forms to ensure there is no duplication of information. The DI is also advised to include these forms in the annual audits. • The 'Adult Patient Consent to Apheresis' form contained routine entries in the margins. The DI is advised to review the format, updating it with specific fields with sufficient space into which the relevant information can be recorded.
5.	GQ4c	The inspection team noted that there was not a consistent approach to the amendment of the tissue register that would facilitate audit. The DI is advised to implement a consistent approach to the amendment of written records; for example, errors could be struck through with a single line, and the corrections dated and signed by the member of staff responsible for making the changes.
6.	GQ5b	The DI is advised to ensure all staff involved in the procurement, storage and management of skin have received the appropriate training.
7.	GQ8a	The DI is advised to review the risk assessment(s) developed for the procurement, testing and storage of skin, and ensure that they are sufficiently robust to identify and mitigate all relevant risks.
8.	PFE3b	The DI is advised to test and record the switchboard's response to unannounced freezer alarms to ensure that the correct notification procedures are being followed.

Assessment of existing shortfalls against standards

During the inspection, it was noted that a unit of skin had been stored for longer than 48 hours without the appropriate arrangements for consent and testing of the donor blood in accordance with the requirements of Directions 003/2010. This issue was also identified in the last HTA inspection and appropriate steps have not been taken to address this shortfall.

Concluding comments

The HTA observed a number of good practices during the course of the inspection.

Staff at the establishment work well together to provide a well-organised and co-ordinated service for patients. Scenario-based learning takes place in the apheresis unit, where staff have carried out a practice run on a “pretend” patient, including filling in all the relevant forms required, before sending off the product for processing and storage.

The establishment uses a spreadsheet that contains information on all stem cell collections from 2008 onwards including patient outcomes. The spreadsheet is a useful tool as part of the audits of engraftment to ensure that the procedures remain effective.

The establishment has a comprehensive training programme, which includes a proprietary e-learning system in the Trust and yearly refresher training. Members of staff at the establishment have further designed and developed a competence based, e-learning material to support the training of the bone bank staff. The establishment intends to use this e-learning material to cover all aspects of the work the staff undertake as part of their posts including the requirements under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Two areas of practice were identified during the inspection that require improvement, resulting in one major shortfall and one minor shortfall. The HTA has given advice to the DI with respect to a number of the establishment’s procedures, documents, quality management system, donor testing, internal and independent audits with a view to helping the establishment further develop its working practices.

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: 16 August 2017

Report returned from DI: 23 August 2017

Final report issued: 5 September 2017

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: 15 June 2018

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 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.
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.
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.

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.