Site visit inspection report on compliance with HTA minimum standards

Poole Hospital NHS Foundation Trust

HTA licensing number 11133

Licensed for the

- **procurement, testing and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

11-12 March 2019

Summary of inspection findings

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

Although the HTA found that Poole Hospital NHS Foundation Trust (the establishment) had met the majority of the HTA standards, one major shortfall and four minor shortfalls were found in relation to governance and quality systems, premises, facilities and equipment standards. The major shortfall was related to an overall lack of oversight of the temperature monitoring in the apheresis room and the storage areas for the reagents and consumables. In addition to this, there were shortfalls found in relation to insufficient information for reporting serious adverse event and reactions (SAEARs) in agreements, the clarity of the requirement for traceability records to be kept for 30 years as required by the Directions 002/2018, lack of procedures for retention of traceability records in the event of termination of activities and labelling procedures not meeting the requirements of the Single European Code (SEC).

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; the establishment is licensed for this activity but another licensed establishment carries out the activity on their behalf.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, Peripheral Blood Stem Cells (PBSC); PBSC	**E**		**E* / SLA**		**E**		

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the Dorset Cancer Centre (DCC), which is based at the Poole Hospital NHS Foundation Trust. The establishment has been licensed since 2006 for the procurement and distribution of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). Although the establishment is also licensed for donor serology testing, this activity is currently undertaken by another licensed establishment under the terms of a service level agreement (SLA). The establishment procures peripheral blood stem cells (PBSC) from adult patients for autologous use.

Consent for the harvest and storage of stem cells is taken by haematology consultants. Two forms are used: one for collection of stem cells and one for the testing, storage and discard of stem cells. The completed forms are stored in the patient's medical notes. The establishment has an SLA in place with a neighbouring HTA-licensed establishment for donor serology testing and the processing and storage of the procured cells. The agreement also covers the release of the cells for transplant and disposal of cells that are no longer needed.

A request to process form is e-mailed to the processing laboratory providing details of the patient and the planned collection date. The Apheresis nurse and the processing establishment communicate during the lead up to the collection, and the processing establishment is informed when the harvest procedure has actually commenced. The processing laboratory provides labels with a unique identification number for the harvested cells and these are double-checked by the Apheresis nurse against patient details on receipt. Apheresis is carried out in a dedicated room within the oncology day unit and there are always two trained members of staff available during the harvest procedure. CD34 counts are measured using a blood sample taken before harvesting begins and are used to indicate the volume of product to be harvested. This approach allows the majority of patients to achieve their target dose to be collected in one day. At the end of the harvest procedure, all labelled harvested products are placed into a transport box with the accompanying paperwork. The establishment has an agreement with a taxi company to transport CD34 samples and cells to the processing and storage laboratory.

Samples for mandatory serological testing are taken not more than 30 days before the PBSC collection date. The samples are sent to the neighbouring HTA-licensed processing and storage establishment. They are then spun down within 72 hours and forwarded to another testing laboratory, operating under the same governance system as the processing and storage establishment, on the same day or the following day by courier.

This was the sixth routine site visit inspection of the establishment. The inspection included discussions with key members of staff involved in the carrying out of licensable activities, including the Programme Director, who is also the Designated Individual (DI), the Quality Manager, and a Clinical Nurse Specialist. A visual inspection of the wards and the storage areas where licensable activities take place was conducted. Roundtable discussions were carried out with the relevant staff in relation to the consent, donor selection and procurement procedures, and the governance and quality management systems. Policies, standard operating procedures (SOPs) and patient information were reviewed.

The testing laboratory was not inspected on this occasion because the testing activities are not currently taking place at the establishment. A traceability audit was performed with three sets of autologous patient records. The review included confirmation that the records contained all relevant documentation, including consent forms, apheresis worksheets, serology test results, request to collect and process forms, microbiology results, delivery records, summary of products issued for transplant records and a final report from the processing facility. There were a number of discrepancies found with temperature monitoring records.

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
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		**Major (cumulative)**
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Personnel carrying out routine temperature monitoring had not received adequate formal, documented training to complete the activity correctly and consistently.	
GQ4 There is a systematic and planned approach to the management 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.	Temperature monitoring is carried out in the reagent and consumables storage areas, and the room where cell collection takes place. During the document review, recurring discrepancies with the temperature records were found. Incorrect temperatures had been recorded in the room where the ACD-A was stored. Columns for recording the temperature and staff initials had not been completed properly, and some columns had been crossed out without explanation. There were missing temperature records on days that staff were not available due to annual leave.	
GQ7 There are systems to ensure that all adverse events 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.	During a review of the temperature records, it was found that temperature excursions had not been reported and there was no evidence of corrective actions taken.	

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.	The fridge where the ACD-A was stored was not monitored properly. It was noted that staff had been recording the room temperature instead of the fridge on several occasions.	
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The establishment was unable to demonstrate that the temperature monitors had been calibrated in accordance to the manufacturer's instructions. The establishment was also unable to provide the maintenance records for the fridge where the ACD-A was stored.	

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.		
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	The establishment has various Third Party Agreements (TPAs) in place to provide courier and contingency apheresis services. However, these agreements do not specify the timeframe for reporting the SAEARS to the DI.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
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.	The establishment's Quality Management Plan [JACIE-QUAL-2] and SOP [JACIE-LAB-2] do not clearly state that the traceability records are kept for 30 years as required by Directions 002/2018.	**Minor**

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.	There was no documented procedure in place to ensure that in the event of termination of activities, records of traceability are maintained for 10 or 30 years as required after the use, expiry or disposal of tissues and/or cells.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment does not currently have procedures in place to ensure that the SEC-DI is applied after procurement as set out in Directions 002/2018.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1d	The DI is advised to ensure that the dates on the risk assessment forms match the Q-pulse active dates to ensure that the risk assessments are reviewed in a timely manner. The DI is also advised to review the risk assessments and include further details by carrying out a step-by-step review of the licensable activities from consent and procurement to end use.
2.	GQ1d	The DI is advised to review the three forms which have been assigned the same document number [JACIE-CLIN-38] to ensure that when the documents are updated that the correct version is used, and to remind staff to use only up-to-date controlled versions of documents.
3.	GQ2b	The DI is advised to include a review of temperature records in the documented procedures before procurement to ensure that that the storage temperatures of the reagents and consumables are satisfactorily met before use.
4.	GQ3f	The DI is advised to add the HTA regulatory context to the training programme for staff working under the licence.
5.	GQ3k	Currently the data manager post is vacant and the clinical staff are covering this role outside of their own workloads. The HTA have concerns about the sustainability of this arrangement. It was noted that the completed cell disposal forms were not always returned from the storage establishment, therefore the tracking of disposal is not consistent. The DI is advised to arrange for additional resource to fulfil the workload of the data manager, to ensure that the disposal of cells are fully tracked and that the annual review of patient's requirements is carried out to determine which cells can be disposed or used for research and development.
6.	GQ4b	The temperature records are kept in paper format on the wards and not within the oversight of the apheresis staff. The DI is advised to keep a back-up

		scan/photocopy of the temperature data in case of loss or destruction of these paper records.
7.	GQ4c	The DI is advised to implement training for good documentation practice for staff completing documents. Documents should not be completed using pencil or correction fluid, and the obliteration of entries and overwriting in fields should be avoided.
8.	GQ7a	The DI is advised to put controlled measures in place for the timely logging of variance forms onto Q-pulse in accordance with the establishment's procedures.
9.	PFE5f	The SOP for the operation and cleaning of the apheresis machine has recently been updated to include cleaning of the camera lens as advised by the service engineer. The DI is advised to update the cleaning form to capture this.
10.	PFE5j	The DI is advised to update the temperature monitoring form to include the serial number of the corresponding monitor used for each area so that this can be traced back to the calibration records.

Concluding comments

The HTA saw examples of strengths and good practice during the inspection. There are a range of meetings that cover the licensable activities, including staff haematology education meetings. Regular meetings are also held with the neighbouring establishments which focus on the sharing of regulatory and clinical issues and experience. The DI is a nominated approver of all of the relevant Q-Pulse documents which enables good oversight of the licensable activities. Despite currently being understaffed, the team have shown to be resilient and demonstrated strengths in good communication and teamwork. Staff were found to be experienced, knowledgeable, and actively engaged in providing continuous improvement to the quality systems.

There are a number of areas of practice that require improvement, including one major shortfall and four minor shortfalls which were found in relation to governance and quality systems, premises, facilities and equipment standards. The major shortfall was related to an overall lack of oversight of the temperature monitoring in the apheresis room and the storage areas for the reagents and consumables. In addition to this, there were shortfalls found in relation to insufficient information for reporting serious adverse event and reactions (SAEARs) in agreements, the clarity of the requirement for traceability records to be kept for 30 years as required by the Directions 002/2018, lack of procedures for retention of traceability records in the event of termination of activities and labelling procedures not meeting the requirements of the Single European Code (SEC).

The HTA has given advice to the Designated Individual with respect to risk assessments, document control, training, updating procedures to provide continuous improvement of the quality systems and providing additional resource to manage the workload.

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: 09 April 2019

Report returned from DI: 12 April 2019

Final report issued: 08 May 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.
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.
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.
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.
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.
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.
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.

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 002/2018.
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.