Site visit inspection report on compliance with HTA minimum standards

Russells Hall Hospital

HTA licensing number 12129

Licensed for the

- **Procurement and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**

19 June 2012

Summary of inspection findings

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

Although the HTA found that Russells Hall Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to the requirement to undertake audits under standards GQ2 and GQ4.

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 DI, Licence Holder, premises and practices are suitable.

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

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

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Licensable activities carried out by the establishment

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

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
PBSC	**E**				**E**		

Background to the establishment and description of inspection activities undertaken

Under this licence, Russells Hall Hospital's Haemopoietic Progenitor Cell Transplantation (HPCT) programme procures peripheral blood stem cells for autologous use only. Patients are consented by the HPCT Programme Director, the Collection Facility Director or the Clinical Fellow. A trust consent form is used to record consent to stem cell mobilisation, apheresis and data collection. For the testing, storage and discard of cells, the NHS Blood and Transplant 2b consent form is used.

Cells are procured using a COBE Spectra apheresis machine, which is stored, when not in use, in a temperature monitored area. Apheresis takes place in either the day case centre, the designated 'theatre' area, or in the isolation ward, all of which are within the Georgina Ward. The machine, along with a digital thermometer used to check the temperature of the procurement location is taken to each of these areas when required.

Donated cells are labelled while the donor is attached to the machine and are hand delivered by the Clinical Nurse Specialist to the blood bank within the hospital. Their arrival at the blood bank is logged onto the electronic Masterlab system and cells are packaged by blood bank staff using four cool bags and validated NHSBT packaging. Cells are couriered to NHSBT Birmingham by either Interserve (hospital transport) or a taxi courier company, and in both cases there are suitable agreements in place. The blood bank keeps a written log of collection times and a telephone call is made to the establishment by the courier to confirm the delivery of cells at NHSBT Birmingham.

NHSBT Birmingham processes and stores the cells for the establishment. On the day of transplantation, cells are transported by NHSBT directly to the ward where infusion takes place. A receipt form is signed to confirm that the paperwork accompanying the sample is correct. Two independent checks of identity and traceability are made against the recipient's hospital wristband, the transport paperwork, the sticker on the sample and the reinfusion records.

NHSBT also completes mandatory virology testing of donors and provides sets of barcodes and a log to the establishment, so that each donor can be assigned an individual barcode and an associated identification number. These are assigned in a non-sequential manner to avoid transcription errors. Superfluous labels are returned to NHSBT. Following difficulties in receiving results by fax, virology reports are now received electronically from NHSBT and a copy is put into the patient's notes prior to donation.

When required, NHSBT disposes of cells on behalf of the establishment. There is communication between the establishment and NHSBT each month to confirm which cells should be kept in storage and which can be disposed of. The DI gives permission to NHSBT to discard the samples of deceased donors. No donations from living donors are disposed of without prior discussion with the donor.

The establishment has a suitable agreement in place with NHSBT for testing, processing, storage and disposal.

This was a routine site-visit inspection, as the HTA has a statutory responsibility to inspect all establishments licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 every two years. The establishment has been licensed since 2008 and was previously inspected in July 2010, at which time no conditions were identified but a number of items of advice and guidance were offered to the establishment. During the course of the present inspection, there was evidence that the majority of this advice had been acted upon, with the exception of advice around audit and risk assessment.

The inspection timetable was developed in consideration of the previous inspection findings, the establishment's activity data and information provided by the establishment prior to the inspection.

During the site visit, interviews were conducted with key staff working under the licence, as well as a review of key documentation and a traceability audit (see below). A visual inspection was undertaken covering areas where consent is taken, the three areas where apheresis takes place, the storage area for the apheresis machine and other equipment and reagents, and the hospital blood bank.

A traceability audit was carried out by looking at three sets of patient notes and following the paper trail from initial consent through to testing, donation, transportation of cells and transplantation or disposal.

Records showed a complete, clear trail for all of the donations made by the three patients selected. This included consent for apheresis and treatment, and consent for testing, storage and discard of cells, pre harvest assessments, transportation documentation, and records of cell issue and infusion. All patient identification numbers corresponded and the infusion records were countersigned twice. Lot numbers and expiry dates for anticoagulant citrate dextrose solution and saline and the apheresis kit lot number were recorded in the patient notes. A central log with this information is also kept. It was noted that the consent form for testing, storage, and discard of stem cells was missing in one file (although entries made in the patient's record provided evidence that informed consent had been given). Advice was provided regarding the use of the patient pathway document as a checklist for completion of various elements of the procedure (see advice item 3 below).

Virology reports were not easy to locate within the patient files. However, the HTA acknowledges that the establishment has recently changed its procedures so that virology results are now received electronically and a printout put into the section of the patient's notes containing apheresis documentation. (See shortfall below relating to the auditing of this process).

Inspection findings

The HTA found the DI 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**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	The establishment does not have an active internal audit calendar or a fully developed audit plan. Audits are restricted to consent, multidisciplinary team and apheresis records, and the patient satisfaction survey, and are usually conducted by the DI. This means that there is not currently an audit system for all licensable activities which comprises both horizontal and vertical audits. The traceability audit conducted as part of the inspection highlighted the benefits of audits to check the usefulness of and adherence to new systems and documents, such as the use of the patient pathway document and the electronic receipt of virology results from NHSBT. They will also help ensure the consistency of record keeping and filing of important documentation such as consent forms and virology reports. While it is noted that the DI has made plans for an audit to be conducted every two years in an independent manner by a referring hospital to verify compliance with protocols and HTA standards, there is no evidence that such an audit has been conducted at the establishment since the licence was first issued in 2008.	**Minor**
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.		
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.		

Advice

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

No.	Standard	Advice
1.	GQ1q	The DI is advised to ensure that all technical agreements for the procurement of stem cells in the event of collection facility failure reference the Human Tissue (Quality and Safety for Human Application) Regulations 2007, under which the establishment is licensed, rather than the Human Tissue Act 2004. The DI is advised that the technical agreement between Dudley Group of Hospitals HPCT programme and referring hospitals has gone beyond its review date, and should ensure that this is promptly reviewed.
2.	GQ3e	The DI is advised to keep the competency assessment documentation of apheresis nurses up to date by ensuring that records are kept when nurses carry out observed apheresis procedures as part of ongoing assessment.
3.	GQ4c	The DI is advised to ensure that amendments to documents and patient notes are neatly crossed out and signed so that original entries remain legible. It was noted that where there were no entries in the 'check and initial' column of the patient pathway document, which is used to ensure that all stages and checks of the process are completed, it was unclear whether the check had been carried out or whether this was not applicable. The DI is advised to ensure that records are fully completed indicating 'not applicable' where necessary.
4.	GQ4h	The DI is advised to archive raw data (e.g. temperature monitoring records) periodically in order to minimise risk of loss of data, in the event of accidental destruction or loss of record logs.
5.	GQ4h GQ4i	Currently the establishment is keeping records indefinitely and ensures that records are kept by using 'Do not destroy' stickers. The DI is advised to develop a record retention schedule so that raw data which are critical to the safety and quality of tissues and cells are kept for ten years after the use, expiry or disposal of tissues and/ or cells, and 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.
6.	GQ7c	The DI is advised to develop the SOP 'Managing Errors, Variances, and Improvements' (SOP/HPCT/Misc/002) so that it is clear that there is a requirement for notification to be given to the HTA within 24 hours of discovery or determination of serious adverse events and reactions. The SOP should also more clearly define who is responsible for reporting to the HTA and the lines of internal communication of reportable events and reactions.
7.	PFE1a	The DI is advised to carry out a risk assessment of the premises, which is specific to the licensable activities being undertaken on them. In particular, the three areas where apheresis takes place should be risk assessed so that the DI can assure himself that the premises are fit for purpose.
8.	PFE5b	The DI is advised to ensure that digital thermometers used for temperature monitoring are calibrated regularly in accordance with manufacturer's instructions.

Concluding comments

There appears to be good communication between the DI and staff working under the licence at Russells Hall Hospital. Regular formal meetings of staff associated with licensable activities provide a platform for discussion and dissemination of information about near misses, corrective and preventative actions, complaints, audits and training. This helps to assure the DI that practices are suitable.

Donors are provided with very clear written information and a DVD explaining stem cell collection. They are also given the opportunity to be shown around the ward prior to harvest. This helps them in preparing for their treatment. They are also invited to complete a survey after every harvest and transplant and the HTA saw evidence of improvements made as a result of survey feedback. Overall, the staff and practices at the establishment demonstrated a particularly patient focused approach to the activities for which they are licensed.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the DI with respect to technical agreements, competency assessments, amendments to documents, the storage of raw data and record retention. Advice has also been given around the SOP for reporting serious adverse events and reactions to the HTA, risk assessment of the premises and equipment calibration.

The HTA requires that the DI 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 16 July 2012

Report returned from DI: 23 July 2012

Final report issued: 27 July 2012

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: 12 December 2012

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.

s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.

e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured,

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

Premises, Facilities and Equipment

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

d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.

i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

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.