Site visit inspection report on compliance with HTA minimum standards

Castle Hill Hospital

HTA licensing number 12174

Licensed for the

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

21 – 22 October 2014

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.

Castle Hill Hospital (the establishment) was found to have met all HTA standards.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

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

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

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

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

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

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

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

Licensable activities carried out by the establishment

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

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

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

Background to the establishment and description of inspection activities undertaken

Castle Hill Hospital (the establishment) is licensed for the procurement, testing and storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Castle Hill Hospital is the hub premises under this licence, with licensable activities also taking place at two satellite premises located at the Spire Hull and East Riding Hospital and the Hull Royal Infirmary.

The hub establishment procures femoral heads from patients undergoing hip replacement surgery for allogeneic use. Consent for the donation of bone is sought by the bone bank coordinator prior to the donor being taken to theatres for their surgery. Advice has been given

to the DI regarding donor information leaflets that previously were given to donors during the consent process. The supply of leaflets, however, is now exhausted and no information other than a copy of the consent form is given to the donor.

Following removal of the femoral head, and once the orthopaedic surgeon is sure that bone from the patient's own femoral head will not be required during their surgery, bone chips and swabs are taken from the procured femoral head and are sent to the microbiology testing laboratory for analysis. The procured femoral head is placed into an inner container and then a secondary container by the scrub theatre person. The pots are purchased by the establishment for the purpose of bone storage and their batch numbers are recorded on the procurement paperwork. The containers are sealed and labelled with a unique bone bank number before being transferred to the bone bank quarantine freezer shelf for storage. A donor serology blood sample is taken prior to surgery by the anaesthetist which is then tested for the mandatory serological markers. Paperwork containing donor details, dates and time of surgery, batch numbers for the storage pots and serological testing results, once returned, are filed by the bone bank coordinator.

The bone bank coordinator undertakes home visits to bone donors so that a 180 day serological testing blood sample can be taken and returned to the establishment for testing. Once donor serological and microbiological tests are received and if they meet the establishment's acceptance criteria, bone is moved by the bone bank coordinator from the quarantine shelf of the freezer onto the 'end use' shelf of the freezer and become available for end use by the establishment's surgeons. The movement from quarantine to 'available for end use' is recorded in the paperwork associated with the tissue donation.

The establishment also occasionally purchases and receives other allogeneic bone products, such as strut grafts, from another HTA-licensed establishment and these are stored within the bone bank freezer.

The Spire Hull and East Riding Hospital satellite site also procures femoral heads on behalf of the hub establishment for allogeneic use.

Consent for procurement is sought during the pre-surgical assessment visit of the donor by a trained member of the clinical staff. The DI also undertakes home visits to the donor or coordinate with another clinic visit by the donor so that a 180 day serological testing blood sample can be taken and returned to the establishment for testing.

This satellite establishment has, in the past, procured femoral heads for autologous use. These tissues are appropriately labelled and are sent to the hub premises for storage until being returned to the satellite site for end use. When procuring femoral heads for allogeneic use, femoral heads removed during primary joint replacement surgery that are not needed for the surgery are procured and sent to the hub premises for storage and eventual end use. The satellite site uses storage pots and traceability paperwork provided by the hub establishment. Blood samples for serology testing are also sent to the hub premises with the femoral head as are bone chips and swabs for microbiological testing. Transport of the procured tissue is undertaken by the satellite hospital's portering and transport service, which undertakes a dedicated journey only used for transporting the procured tissue to the hub premises.

The Hull Royal Infirmary (HRI) satellite site procures cranial skull flaps during neurosurgery which are then used autologously in subsequent surgery. Cranial flaps are procured and packaged in pots similar but larger than the pots used to hold procured femoral heads. Again and as with the femoral heads, bone chips and swabs are taken from the procured bone and are sent to the microbiology testing laboratory for analysis. Pots are labelled with patient identifiers (name, date of birth and hospital number) using a patient addressograph label and are then transferred to the hub establishments storage facility. Neurology staff send the blood samples directly to the laboratory for serological testing. Transport is undertaken by the Trust's internal transport service. Donor paperwork accompanies the flaps which again is

used by the establishment as a means of traceability. Consent documentation, if sought prior to the procurement, is retained within the patient's medical file. On occasion, the donor is unconscious prior to surgery as a result of their injuries and, in these cases, the surgeon undertakes the procurement underthe provisions of the Mental Capacity Act 2005 and in accordance with professional guidance. Once recovered from surgery and capable of giving their consent, the donors are informed about the procurement procedure.

Skull flaps are returned to the HRI satellite site for end use via the Trust's own transport service and are delivered just in time for surgery, meaning no storage of the skull flaps prior to end use takes place at the satellite site. Records of use are again maintained in the patient's clinical notes and at the hub establishment.

An audit of tissue being stored in the establishment's freezer was undertaken during the inspection. Details of a femoral head, cranial flap and strut graft all being stored for allogeneic use were reviewed. Tissue identifiers (and donor details in the case of the cranial flap) and records pertaining to procurement, testing and, where applicable, expiry, were cross checked. In addition, records relating to an autologous use of a skull flap that was procured and implanted were reviewed. No anomalies were found during any of the audits.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C2(c)	The establishment's consent procedure refers to donor information leaflets which should be given to donors of femoral heads during the consent process. It was learned on inspection, however, that the establishment has exhausted its current supply of these leaflets. The DI is advised to source further leaflets regarding bone donation so that they may be provided to potential bone donors during the consent process.
2.	C2(d) C3(a)	The Di is advised to deliver refresher consent training for staff at both the hub and Spire Hull and East Riding Hospital satellite sites so that he may assure himself that donor consent is being sought as he intends and in accordance with the HT Act, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and HTA Code of Practice.
3.	GQ1(b)	During a review of the establishment's procedural documentation (standard operating procedure; SOPs) it was noted that some documents require minor updates to reflect changes in practice or other supporting documentation. These include, but are not limited to : • Some SOPs refer to marking unused tissue identifying labels as 'not for use' and do not reflect the current practice where unused labels are struck out with a single line through them before being filed in donor

		files. • The consent seeking SOP for the procurement of cranial flaps references a previous and out of date version of the Trust's consent policy. • The use of femoral heads SOP (SOP11) does not include detail of the requirement that femoral heads that have been removed from the storage freezer and subsequently are not used in theatre must be returned within four hours or discarded. • Additionally, the SOP on taking a medical history does not define an 'at risk' donor in the context of suitability for donation. The DI is advised to review all of the establishment's documentation to ensure that it remains current and reflects current practice.
4.	GQ1(k)	The establishment described the procedure that it would undertake if any tissue removed from storage was not used and had been returned within a timeframe that would allow it to be returned to storage. The procedure was however not documented. The DI is advised to document the procedure which would be followed in the event of tissue being returned to the establishment.
5.	GQ1(l) GQ4(m)	The DI described how any tissue that was being stored at the establishment would be dealt with in the event that the establishment revoked its licence and ceased licensable activities. In addition, the DI described that he would approach other neighbouring HTA Human Application Licence Holders and DIs with a view to transferring the associated traceability and raw data records. The procedure was, however, not documented. The DI is advised to formalise and document an outline of the procedures which would be followed in the event of the establishment ceasing licensable activity and revoking its licence.
6.	GQ2(c)	The establishment has organised an audit in an independent manner which reviewed traceability records relating to tissues and some procedural documentation. The independent audit did not, however, include a review of the establishment's compliance with the HTA licensing standards. The DI is advised to include an audit of compliance with the HTA licensing standards in the next independent audit that is undertaken.
7.	GQ2(b)	A range of internal audits of consent and traceability documentation and its completeness are undertaken regularly by the establishment. The DI is advised to ensure that all internal audits of tissues that have been procured record details of the tissue identifiers that have been reviewed and include checks on traceability information, such as the tissue identifiers. This will provide the DI with a record of all tissues that have been subject to an internal audit.
8.	GQ7(e) GQ7(f)	In addition to procuring tissue for end use, the establishment purchases tissue from other licensed establishments. The DI is advised to develop and document the procedure which would be followed in the event that the other licensed establishment issued a tissue recall or advisory notice.
9.	GQ8(b)	One example of a risk assessment which had not been reviewed during the required 12 month period was found during the inspection. The DI is advised to review all risk assessments to ensure that they have been, and continue to be, reviewed every twelve months.
10.	PFE5(c)	The establishment's estates department undertakes a test of the alarm and the external alert to a freezer alarm condition during routine maintenance of the storage freezer. During these tests, the Trust's switchboard, where the external alarm sounds, is made aware of a test about to take place. The DI is advised to

		periodically perform an alarm test without notifying the Trust's switchboard so that he may assure himself that alarm conditions are responded to appropriately by switchboard. It was noted that the alarm does sound occasionally during routine de-icing of the freezer doors by establishment staff and on these occasions, the Trust's switchboard staff do respond to the alarm and contact relevant staff. The DI is advised to document these occasions when an unexpected alarm is responded to by switchboard as they provide an unexpected alarm test as described above.
11.	PFE4(g)	Although transport methods and conditions have been deemed suitable by the establishment's clinical staff, they have not been formally defined within the establishment's documentation. The DI is advised to document the required transport conditions for tissue so that it may be reviewed during the regular document reviews taking place. This will provide a means by which the transport conditions are also reviewed and give the opportunity for the DI to assure himself that they remain suitable.

Concluding comments

Areas of good practice were observed during the inspection. The establishment continues to demonstrate good working relationships between the various staff working under the licence.

The bone bank coordinator often carries out home visits to obtain blood samples for mandatory repeat testing. By doing so the risk of valuable tissues being discarded as a result of failure to obtain repeat samples is minimised.

The HTA has given advice to the Designated Individual with respect to consent, governance and quality systems and premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 14 November 2014

Report returned from DI: No comments received

Final report issued: 24 December 2014

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.