Site visit inspection report on compliance with HTA minimum standards

The Derby Bone Bank

HTA licensing number [11029]

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 March 2017

Summary of inspection findings

Although the HTA found that the Derby Bone Bank (the establishment) has met the majority of the HTA standards, shortfalls were found, particularly in relation to governance and quality systems. The shortfalls relate to the documentation of training provided, lack of recorded governance meetings, the recording and investigation of incidents and the lack of risk assessments and legal agreement for the chondrocyte work.

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.

Tissue type	Procurement	Testing	Storage
Bone	**E**	**E**	**E**
Cartilage	**E**	**E**	
Tendons and Ligaments			**E**

Background to the establishment and description of inspection activities undertaken

The Derby Bone bank has been operational since 1994 and has been licenced by the HTA since 2007. The HTA licence includes the procurement, donor testing and storage of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The majority of licensable activities undertaken at this establishment relate to femoral heads procured from patients undergoing total hip replacement surgery.

At the pre-assessment visit all patients about to undergo this operation are given an information sheet concerning bone donation. If the patient agrees to donate their femoral head, the pre-assessment nurse takes consent along with their medical and social history and the blood samples required for the mandatory serological testing. The pre-assessment visit usually happens three weeks prior to the hip replacement surgery and staff routinely check the consent form to ensure no more than thirty days from the day of the surgery have elapsed since the mandatory serology bloods were taken.

In addition to the blood samples for the serological testing a swab of the outer surface of the femoral head and a bone sample are taken for sterility testing. Donor testing for most of the mandatory serology markers and microbiological testing of tissues is carried out within the Clinical Microbiology Department at the Royal Derby Hospital. Another licenced establishment undertakes HTLV-1 testing. Repeat serology testing is performed 180 days post-surgery.

On the day of the procurement the femoral head is washed with saline and placed in a sterile inner pot, which in turn is placed in a larger sterile pot. The bone jars are placed in a clear

plastic bag and a unique jar number is allocated to each femoral head from the bone bank folder along with the donor's addressograph label that is affixed to the outer pot. Following procurement, femoral heads are placed in the -80°C quarantine freezer and the notes are kept on the quarantine cabinet drawer, located next to the freezers. The whiteboard charts, also located next to the freezers, are updated with the position of the femoral heads in the quarantine freezer.

Once the initial and the 180-day serology, and microbiology test results are reviewed the results are recorded on the bone bank folder and the electronic register. If the results are negative, the clear plastic bag containing the bone jars is changed on transfer and the donor patient details form is updated along with the date the bone is moved to the release freezer. The move is also recorded on the whiteboard charts and the notes are moved from the quarantine to the release cabinet drawer. Any samples with positive results are confirmed by the reference laboratory. If both sets of results are positive, the femoral heads are disposed of according to the Trust's disposal policy, following a two-person check of the unique jar number and donor addressograph.

The majority of femoral heads stored at the establishment are for allogeneic use. Occasionally, femoral heads are also procured for autologous use and stored in a separate drawer of the -80°C release freezer at the establishment, until they are needed for use. The establishment also stores tendons and ligaments, which are purchased from another HTA licensed establishment. These are stored on a separate drawer in the -80°C release freezer and records are maintained in the bone bank register.

The -80°C freezers are plugged into a power socket, but are not hard wired to the wall. The temperature is monitored by a wheel chart, which is reviewed and replaced weekly. The freezers are alarmed to the switchboard, which will notify nominated staff in and out of hours in the event of deviation from the required temperature.

More recently, the establishment is undertaking procurement of cartilage tissue as a starting material for an advanced therapy medicinal product (ATMP) that is used in autologous chondrocyte implantation (ACI) surgery to treat damaged knee cartilage. In the past year the establishment carried out one ACI procedure.

Consent for the procedure is taken by the consultant surgeon, prior to the surgery. There are two consent forms to be completed; the Derby Bone Bank donor patient details form for ACI and the second form supplied by the ATMP manufacturer.

On the day of the procedure theatre staff check the patient consent and donor patient details. The biopsy kit unique reference number and lot number of the jar are recorded to ensure continued traceability. The bone bank register and donor's notes are updated with the consent form, unique reference number and jar number and retained in the locked filing cabinet next to the freezers.

Immediately following procurement of the cartilage, the tissue sample and blood samples are placed in the biopsy transfer box and the patient addressograph is affixed to the pot. The procured tissue sample is distributed to Belgium for serology testing to be processed into an ATMP. The ATMP manufacturer undertakes serology testing for HIV1 and 2, Hepatitis B and C, and Syphilis, but no HTLV testing. The establishment also takes a second blood sample to screen for the above tests including HTLV testing, as required by Directions 003/2010. Distribution to Belgium and processing into an ATMP is not taking place under the establishment's licence and falls outside the remit of the HTA. Once processed the final product is returned to the establishment for autologous administration into the patient.

This report describes the establishment's fifth inspection, which took place on the 21 March 2017. Discussions were held with the designated individual (DI), the quality assurance staff nurse and the pre-assessment senior nurse. The inspection included a visual inspection of

the areas where tissue storage and serology testing take place and review of documentation relevant to the licensable activities of the establishment.

Audits of traceability were carried out and included storage location of one tendon and of three femoral heads for allogeneic or autologous use, at both the quarantine and release freezers, cross-checked against the bone bank register. A total of five donor and two recipient files were reviewed to ensure that they contained all relevant documentation, including serology and microbiology results. There were a few inconsistencies in the completion of the forms (*see advice below*).

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
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	Although the DI meets with the persons designate (PD) under the licence on an individual basis, there is no existing minuted, governance meeting which covers HTA issues for all staff working under the licence. *See advice item below*	**Minor**
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.	At the time of the inspection there was no written agreement between the Trust and the manufacturer of the chondrocyte-derived ATMP that sets out the roles and responsibilities of each party.	**Minor**
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.		

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Although training is provided to new and existing members of staff, this is not always captured in the training records, including the competency of the staff to carry out a procedure. For example, during the inspection it was noted that on a number of occasions the freezers were left unlocked by members of staff accessing and/ or handling tissue. The corrective action involved refresher training, but the records did not evidence what thte training involved, which members of staff received it and when. *See advice item below*	**Minor**
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.	Although the establishment has a range of risk assessments in place relating to the work carried out by the bone bank, comparable documents are not in place for the ACI work. *See advice item* below	**Minor**

Advice

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

No.	Standard	Advice
1.	C1d GQ5a	A number of discrepancies were noted during the audit of the establishment's donor patients forms. Examples include: • although the medical history form includes all the donor exclusion criteria as set out in Annex A of the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment, the donor patients' form does not. • the establishment does not routinely assess the Rhesus status of the donors, as a result this section on the form was not completed.
2.	GQ1c	The DI is advised to include in the agenda for the governance meetings the ACI work undertaken by the establishment and any issues that may arise.

		This will help raise awareness among staff involved in this work of the associated regulatory requirements, and facilitate the integration of this activity into the governance and quality management system used by the bone bank. The DI is also advised to consider nominating a PD for the ACI programme.
3.	GQ2b,c	The DI is advised to review the establishment's approach to the audit of records. Consideration should be given to the extent by increasing the number of samples audited and scope of the establishment's internal audits to include audits of the testing laboratory. The DI could consider dividing this work in small, manageable tasks and nominating it to the PDs under the licence. The DI is advised to expand the scope of the independent audits to include the overall findings, the content of what was audited for all licensable acitvities, including chondral procurement. The DI is advised to schedule the independent audit to occur in the intervening year between HTA inspections. The results of all audit findings, and actions taken, should be formally recorded and discussed at governance meetings, to ensure continuing improvement of processes and practices.
4.	GQ3e C3a,b	The establishment provides training of new staff and refresher training to existing members of staff. Signing off of staff involves the staff acknowledging on the training matrix that they have read and understood the establishment SOPs. The DI is advised to record and capture on the training matrix which documents must be read and understood, the procedure for competency sign off together with the names and signatures of the trainer and trainees. The DI is advised to formalise training processes for consent in an SOP, to ensure that new and existing members of staff are kept current with all working practices and that this is reflected in the establishment's records.
5.	GQ4f,h,i	The Derby bone bank collects the documentation related to the donors and recipients of the tissue for the required 30 years. The DI is advised to include a copy of the consent forms of the patients as part of the records as currently the consent forms are filled independently along with the medical notes. The establishment collects raw data, including the temperature discs from the -80°C freezers for the required 10 years. The DI is advised to scan the temperature discs as with time they can fade.
6.	GQ7a	The establishment has documented procedures for managing and recording serious adverse events and reactions, but comparable procedures are not as robust for the management of non-reportable incidents. The DI is advised to formalise the process for the management of non-reportable incidents in an SOP to ensure that all members of staff understand the process and what it involves.

		The DI is advised to record all incidents in the incident log including, but not limited to: bone bank freezer temperature deviation, freezers left unlocked, femoral heads being dropped or wrongly disposed of. The DI is also advised to include the corrective actions taken and when the incidents were addressed and closed. The DI is also advised to discuss the corrective actions and closure of reportable and non-reportable incidents at governance meetings to raise staff awareness.
7.	GQ8a	The activities under the licence have been risked assessed and systems have been put in place to mitigate the risks. However, this has not been fully documented. The DI is advised to document in the risk assessments the full range of control measures in place to prevent the disposal of the wrong sample. The DI is also advised to review the risk assessment on donor testing, as it does not consider all the risks associated with this licensable activity.
8.	PFE3b	The DI is advised to test and record the switchboard's response to unannounced freezer alarms to ensure that the correct notification procedures are being followed.
9.	D2	The DI is advised to document in the disposal records the details of the anatomical waste bin used to dispose of femoral heads to ensure full traceability.
10.	N/A	The DI is advised to consider nominating a PD for the Testing Laboratory.

Concluding comments

The HTA observed a number of good practices during the course of the inspection. The establishment uses two whiteboard charts to record the location of the femoral heads both at the quarantine and release freezers, which minimises the risk of femoral heads being misplaced. When the femoral heads are moved from the quarantine to the release freezer the donor notes, containing all the traceability information, are updated with the 180 days serology results and moved to a separate drawer in the cabinet.

In case where the mandatory serology samples were taken longer than thirty days prior to the hip replacement surgery than arrangements are made for the bloods to be repeated on the day of the surgery. If this is during the weekends than pre-printed serology blood request forms are available for theatre staff to use. Systems are in place to ensure that the patients involved in the ACI programme are additionally tested for HTLV at the establishment in addition to the testing performed by the ATMP manufacturer.

Four areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. The HTA has given advice to the DI with respect to a number of the establishment's procedures, documents, quality management system, training, incident

reporting, internal and independent audits with a view to helping the establishment further develop its working practices.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: [2017/04/18]

Report returned from DI: [2017/04/28]

Final report issued: [2017/05/23]

Appendix 1: HTA standards

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

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

Consent

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

Governance and Quality

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

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

f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
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.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.

c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
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.
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.

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.