Site visit inspection report on compliance with HTA minimum standards

Royal National Orthopaedic Hospital

HTA licensing number 11135

Licensed for the

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

11 January 2018

Summary of inspection findings

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

Although the HTA found that The Royal National Orthopaedic Hospital (the establishment) had met the majority of the HTA's standards, one major and three minor shortfalls were found. The major shortfall was in relation to tissue processing activities taking place in the absence of a processing licence. The minor shortfalls were in relation to: (i) an absence of governance meetings; (ii) an absence of a contingency plan for stored tissue in the event of licence revocation; and (iii) incomplete tissue disposal records.

Advice has been given relating to the Governance and Quality systems and Premises, Facilities and Equipment standards.

Particular examples of strength 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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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 licenses 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 Category; Tissue Type	Procurement	Testing	Storage	Distribution
Musculoskeletal, Bone; Bone			**E**	**E**
Musculoskeletal, Tendon & Ligament; Ligaments			**E**	
Musculoskeletal, Tendon & Ligament; Tendons			**E**	
Other; Nerve			**E**	

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by The Royal National Orthopaedic Hospital (RNOH; the establishment). The establishment was issued an HTA licence in February 2007. This was the fifth HTA site visit inspection of the establishment (the last inspection was in January 2016). The current inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards.

The Royal National Orthopaedic Hospital NHS Trust is the largest orthopaedic hospital in the UK. It provides neuro-musculoskeletal health care ranging from acute spinal injury or complex bone tumour treatment to orthopaedic medicine and specialist rehabilitation for chronic back pain sufferers. The RNOH treats patients from across the UK, many of whom have been referred by other hospital consultants for second opinions or for the treatment of complex or rare conditions.

The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) for the procurement, testing, storage and distribution of tissues and cells for human application. The establishment is not currently licensed for processing (see shortfall against standard GQ2(d)). The establishment is not licensed for the storage of relevant material for use for a scheduled purpose under the Human Tissue Act 2004 (HT Act). Relevant material consented and stored for research in various research institutes and research centres within the hospital is under the governance of the University College London (UCL) Cancer Institute research licence (HTA licensing number 12055).

The DI is a consultant anaesthetist, the Corporate LH (CLH) is RNOH and the CLH Contact (CLHC) is the Director of Nursing, Quality and Patient Experience. There is one Person Designated (PD) working under the licence - the Critical Care, Clinical Audit and Service Manager.

The establishment stores cryopreserved bone, ligaments, tendons and peripheral nerves from cadaveric donors. The tissue is purchased from two HTA-licensed suppliers under the terms of a service level agreement (SLA). The suppliers are responsible for donor selection, consent, procurement, serological testing and transportation.

Bone, ligaments and tendons are used in adult hip replacement and revision procedures, as well as in knee revision and reconstructive foot and ankle surgery. Peripheral nerve allografts are used in the reconstruction of adult peripheral nerve discontinuities caused by traumatic injury or surgical intervention.

In 2017, the establishment performed 44 bone, 15 tendon/ligament and four peripheral nerve allografts.

Tissue is received into the secure storage room adjacent to the operating theatre complex by authorised personnel (one of five 'tissue co-ordinators'). The allograft details are entered into the tissue register and paper copies of dispatch sheets are kept separately. The details from the tissue register are transferred onto an electronic spreadsheet, which is backed-up as part of the Trust Information Technology (IT) system.

The tissue is stored securely in a lockable -80^{o}C freezer. At the time of the inspection, the freezer temperature was -72^{o}C. Non-conforming units are stored on a separate shelf in the freezer. The freezer is linked into a wired alarm system which contacts the establishment's security team. Temperature excursions outside the set ranges trigger both an audible alarm and the security team. The security team then contacts the nominated tissue co-ordinator. The system is tested routinely but this is not recorded (see *Advice*, item 12). The freezer's

temperature is also monitored daily and recorded by staff during normal working days on a temperature log sheet on the wall outside the storage room. There are inconsistencies in this procedure (see *Advice*, item 13).

The freezer is subject to an annual service and calibration under contract and a back-up freezer is available for contingency storage.

When required for engraftment, the tissue is removed and taken to the operating theatres for thawing before use. The date and time of removal and patient number of the recipient are entered into the tissue register and on the electronic spreadsheet (see *Advice*, item 6).

Tissue is disposed of by incineration and is bagged separately from other clinical waste but the details, including date and method of disposal, or reason for disposal, are not recorded in the tissue register or on the electronic spreadsheet (see shortfall against standard D2(a)).

The establishment purchases demineralised bone matrix and cancellous bone chips from two HTA-licensed suppliers. A comprehensive log is maintained of the quantities, batch numbers and expiry dates of the packs received and used. The material is stored securely at room temperature.

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection reports, communications with the HTA since the last inspection and annual activity data. The inspection included a visual inspection of the storage area outside the operating theatre complex. Discussions and interviews were held with key staff and documentation was reviewed. Interviews were held with the DI, CLHC, PD, two consultant orthopaedic surgeons and a senior Theatre Staff member.

Audits of traceability were carried out:

- Four units of bone (two femoral heads and two units of ground bone) were selected at random from the freezer and labelling details were compared to the records in the tissue register, on the electronic spreadsheet and on the dispatch sheets. There were no discrepancies noted. The allograft recipient details in the tissue register and on the electronic spreadsheet were compared to the Trust's electronic patient notes. All allograft details were recorded in the patient notes and there were no discrepancies identified.
- Two units of tendon were selected from the freezer and labelling details were compared to paper and electronic records as described above. There were no discrepancies noted. The allograft recipient details in the paper and electronic records were compared to the Trust's electronic patient notes. There were no discrepancies identified.
- Two units of peripheral nerve were selected at random from the freezer as described above. There were no discrepancies noted. The allograft recipient details in paper and electronic records were compared to the Trust's electronic patient notes. There were no discrepancies identified.

Inspection findings

The HTA found the DI and the CLH 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.	The DI meets informally with staff working under the licence to discuss matters relating to HTA-licensed activities but there are no documented, regular governance meetings to discuss such matters. See *Advice,* item 2.	**Minor**
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.	The DI has informally discussed contingency plans for the termination of activities with other licensed establishments but no final plan and agreement is in place. See *Advice*, item 7.	**Minor**

GQ2 There is a documented system of quality management and audit.		
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.	In the past, the establishment has occasionally carried out a procedure involving the surgical resection of cancerous bone, which is packaged and transferred to another hospital (unlicensed) to be irradiated. The irradiated bone is then returned to the establishment to be surgically re-implanted into its original anatomical location. The irradiation of bone is considered to be 'processing' under the Q&S Regulations. The DI was advised during the last inspection that, before this procedure happened again, the establishment would need to add the activity of 'processing' to its suite of HTA licences. In addition, it was advised that a preparation process dossier (PPD) must be sent to the HTA. A PPD describes the procedure and provides evidence that it attains the desired results, and does not render the tissue clinically ineffective. Only if the PPD is approved by the HTA, and the licence is amended to include processing, could the procedure take place. During the current inspection, it became clear that this activity had recently taken place again. In addition, the establishment had not applied for 'processing' to be added to its HTA licence and had not submitted a PPD.	**Major**

Disposal

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.	The establishment does not record the date and method of disposal, or reason for disposal, for each unit of tissue.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(b)	The establishment has a wide range of policies and standard operating procedures (SOPs) covering licensed activities but there is repetition and duplication. The DI is advised to consider reviewing current policies and SOPs, rationalising this documentation where possible.
2.	GQ1(c)	The DI is advised to ensure that governance meetings identified in the shortfall against standard GQ1(c) regularly include items such as: standardisation of documents, changes to SOPs, audits and their findings, competence and training, management of incidents, risk assessments, equipment maintenance, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). The meetings should be governed by an agenda and minutes should be recorded and circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings. The DI may also wish to consider the inclusion of representatives from other departments (e.g. Clinical Governance, IT) to help develop the establishment's working practices.
3.	GQ1(k)	Tissue removed from the freezer that is not subsequently used but is placed back in the freezer is considered a 'returned product'. There are differences in the procedures for managing returned products depending upon the tissue type. Bone, tendons and ligaments are discarded if removed from the freezer and not used. For nerve grafts, there are inconsistencies in the procedure. In some cases the graft is returned within 15 minutes if not used; in other cases the graft is discarded automatically if not used. The DI is advised to standardise the procedure for returned products.
4.	GQ2(b)	Internal audits are usually conducted by one member of staff. The DI is advised to consider scheduling some of the planned internal audits as a two-person audit so that there can be greater scrutiny and quality control of both the data being audited and the audit data itself. The DI is also advised to consider developing a schedule that will allow different team members to carry out selected audits.
5.	GQ4(e)	The DI is advised to consider adding the following details to the tissue register and the electronic database: the time from release of tissue by the supplier to placement in the freezer (this should be less than 24 hours); the details of disposal (see shortfall against standard D2(a)).
6.	GQ4(e)	The DI is advised to consider using a two-person checking system to cover allograft placement into storage, retrieval from storage and confirmation of identity prior to thawing.

7.	GQ4(m)	As part of the contingency plan for termination, the DI is advised to be aware of the arrangements for contingency storage of records of traceability (for 30 years) and raw data (10 years). The electronic patient notes need to be highlighted appropriately and stored in the Trust archives. The raw data should be stored securely.
8.	GQ7(b)	The documented timelines for reporting serious adverse events and adverse reactions (SAEARs) to the HTA are inconsistent across policies, SOPs and the Quality Manual. The DI is advised to ensure that all documentation relating to SAEARs contains information stating that they should be reported to the HTA within 24 hours of discovery.
9.	GQ8(a)	The establishment has a risk assessment for tissue storage. The DI is advised to consider expanding this to cover the areas of freezer cleaning and decontamination.
10.	GQ8(c)	The DI is advised to ensure that relevant staff can access risk assessments, this could be achieved by including risk assessments in staff competency folders.
11.	PFE3(b)	The DI is advised to consider rationalising the notices on the freezer door. A document-controlled notice should be placed on the door summarising procedures to take when the audible temperature alarm is activated and providing staff contact details.
12.	PFE3(c)	The DI is advised to consider recording the dates and times when the temperature-monitoring system is tested.
13.	PFE3(c)	During the inspection, it was noted that there were inconsistencies in the completion of the temperature logs. Specifically: - There were some incomplete fields. - There were signatures in the name box rather than in the signature box. - There were signatures alone with no corresponding name. The DI is advised to consider reviewing the temperature logging procedure to ensure that it conforms to Good Documentation Practice (GDocP) and to consider including temperature log records as part of the audit schedule.

Concluding comments

During the inspection, areas of strength and good practice were noted:

- There is a dedicated team with good lines of communication between staff performing licensed activities. The use of five tissue co-ordinators, who train about 40 nursing scrub staff, streamlines the staff training system and the freezer callout system.
- The internal audit programme is detailed, thorough, and includes vertical audits and procedural audits. The establishment has identified appropriate people for external audit and has a good follow up of audits, with actions assigned to appropriate staff and findings distributed throughout the team.

- The establishment has developed and implemented competency assessments and quizzes following training, which help staff to evaluate their understanding of the training content.
- There is restricted access to the storage room. The tissue co-ordinators provide access to staff who need to enter the room.
- There are separate compartments within the tissue storage freezer for each tissue type. This assists staff when locating a specific tissue type and reduces the potential for mix ups.

There are a number of areas of practice that require improvement, including one major and three minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality systems and Premises, Facilities and Equipment standards.

The HTA requires that the DI 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: 3 May 2018

Report returned from DI: 17 May 2018

Final report issued: 24 May 2018

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: 26 October 2018

Appendix 1: HTA standards

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

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

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.
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.
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.
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.
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.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.

b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.

d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.

d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to 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 represents a systemic failure and therefore is 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 straight away.

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 the proposed action plan the establishment will be notified of the follow-up approach the HTA will take.