Site visit inspection report on compliance with HTA minimum standards

Royal Devon and Exeter NHS Foundation Trust

HTA licensing number 11012

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 (as amended)**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

21 and 22 August 2018

Summary of inspection findings

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

Although the HTA found that the Royal Devon and Exeter NHS Foundation Trust (the establishment) had met the majority of the HTA standards, three minor shortfalls were found in relation to the governance of standard operating procedures (SOPs) and risk assessments, and the storage of critical consumable reagents under the Premises, Facilities and Equipment standards.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Licensable activities carried out by the establishment

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

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Musculoskeletal, Bone; Bone	**E**		**E**	**E**	**E***		
Musculoskeletal, Tendon & Ligament; Tendons				**E**	**E***		
Musculoskeletal, Cartilage; Other	**E**		**E**				

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at the Exeter Bone Bank, situated at the Royal Devon and Exeter NHS Foundation Trust. The establishment has been in operation since the late 1980s and has held an HTA licence since 2006. Activities carried out under the licence include procurement, donor testing and storage of femoral heads and other orthopaedic tissues (both allogeneic and occasionally autologous) for use at the establishment. In the past the establishment distributed femoral heads, under an agreement, to a neighboring private hospital for immediate use. The establishment has now ceased the distribution of tissues and will not undertake this activity in the future.

The establishment also undertakes the procurement of chondral tissue for use as a starting material for an advanced therapy medicinal product (ATMP) that is then used by the establishment to treat damaged knee cartilage by autologous chondrocyte transplant (ACT).

Potential donors of femoral heads are identified from patients undergoing hip surgery who are given literature and a confidential personal medical and behavioral history form to read. If the patient indicates that they still wish to be a donor, staff at the establishment hold a further discussion with the patient to ask about previous medical conditions, travel and sexual history, exposure to heavy metals and prior receipt of allografts. The identification of potential donors and subsequent seeking of consent for procurement is performed by one of three members of staff trained to seek consent. Subsequent to the inspection, an additional staff member has been fully trained in this process.

Theatre staff make up packs prior to the surgical procedure taking place to use during procurement. These include two unique labels, one to be used on the pot containing the procured femoral head and the second for the patient's clinical notes. A check is carried out to confirm that the patient has consented prior to the procurement of tissue. All paperwork is reviewed using a checklist on the back of the procurement form. A blood sample for mandatory serology screening is taken on the day of procurement. Femoral heads are procured in an operating theatre using aseptic techniques and under the control of an orthopaedic surgeon. Microbiology screening is performed on a bone chip and swab from each procured femoral head at the time of donation. These samples, along with the blood sample, are analysed at the hospital's in-house testing laboratory.

Upon receipt at the testing laboratory, the blood samples are labelled with a unique laboratory ID and are assayed for hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBc), hepatitis C (HepC), syphilis, human T-lymphotropic virus (HTLV) and HIV antibodies. Confirmatory testing for HepB, HepC and HIV are performed in-house whilst confirmatory testing for syphilis and HTLV are carried out at two separate HTA-licensed establishments. The blood test results are uploaded onto the laboratory's electronic database and a paper copy of the results is sent to the bone bank.

The procured femoral head is placed in a sterile pot, then placed in a second outer pot, weighed and adjustments made for the weight of the empty pots. A label is applied to the side of the outer pot stating the tissue type, date of donation, identification number, size in grams and expiry date. Occasionally the procured femoral head may be stored for future autologous use; in such cases the pot is labelled "for autologous use". The rhesus status is recorded in all donor's notes and rhesus status clearly labelled on the pots, both positive and negative. In cases where the recipient is a woman of childbearing age the establishment matches rhesus status, but in the event of status not being known only rhesus negative femoral heads are used. As a precaution to protect against loss of traceability if the label came off the pot, the unique identification number on the label is also hand written on the side of the pot using a permanent marker. After procurement, the femoral head is placed in the -80°C 'quarantine'

freezer labelled freezer A. Details of the stored tissue are entered into the bone bank logbook and femoral heads for autologous use are highlighted in green.

After 180 days, a letter is sent to donors that live locally to the establishment, and their GP, requesting a second blood sample for mandatory serology screening. Donors living further away from the establishment first receive a phone call to determine whether they are happy to proceed and, if so, a bio-bottle is sent to the donor to take to their GP. Blood samples taken by the GP are then sent to the establishment for testing. Once the results of the second screen are obtained, the results are entered onto the relevant paperwork as well as into the establishment's electronic database. The DI will review the serology and microbiology results and if all of the results are negative, the femoral head will be removed from quarantine and placed in one of two other -80°C freezers. Rhesus positive tissue is stored in freezer B while Rhesus negative tissue, and tissue marked for autologous use, is stored in freezer C. Femoral heads are stored on different shelves in the freezers based on their size.

A whiteboard located next to the freezers is used to record the location of individual femoral heads that have been released for use. Establishment staff review the freezer contents monthly and perform a quarterly audit of the tissue. In addition, two members of staff are always involved in accessing material within the freezer and they 'check' the adjacent 'pots' every time material is accessed. Surgeons request femoral heads according to size, and two members of staff cross-check the details of all tissue issued and ensure that all paperwork has been completed appropriately. The freezers are connected to an alarm which triggers in the event of a deviation in temperature from the expected range. The alarm is linked to the switchboard, which will notify the bone bank staff both in and out of hours if the alarm is triggered. Access to the bone bank is restricted and the freezers are locked.

The establishment also stores tendons and other bone allografts in freezer C; another HTA-licensed establishment supplies these tissues. Receipt and end use of these allografts is also recorded in the bone bank logbook and on the whiteboard. The establishment also stores acellular products for end use.

Kits for the procurement of cartilage are ordered from a company based in Germany, which is authorized to manufacture autologous chondrocyte transplants (ACT) according to the German Medicines Act. The treating clinician in day surgery, who provides the patient with relevant information sheets, seeks the consent of the patient undergoing cartilage procurement. Procurement of chondral tissue is undertaken in orthopaedic theatres under laminar air flow. Blood samples are taken at the time of procurement for mandatory serological testing. Cartilage biopsies are placed in transport vials containing liquid culture medium that has been stored at 4-10°C. Immediately following procurement, the blood samples and procured material are transported to Germany in a validated shipper, provided by the German establishment, for testing and processing respectively. In order to ensure all mandatory tests are carried out donors of cartilage undergo the same standard serological testing as used for femoral head donors.

This was the sixth routine inspection of the establishment. The site visit included a visual inspection of the freezer storage area, a review of the establishment's documentation and roundtable discussions with the bone bank staff and the DI. The audit undertaken during the inspection included consent forms for procurement, testing records, and records relating to the subsequent use of the femoral heads. In addition, the location and details for three femoral heads (one selected randomly from each freezer) were confirmed. Patient records (donor and/or recipient) for a further six femoral heads were also reviewed. In addition, the patient records for two chondrocyte donors were reviewed. No discrepancies were found. At the time of inspection, the establishment were also storing an amniotic membrane patch for use in ocular surgery, which had been purchased for a scheduled surgery that was postponed for clinical reasons. The amniotic membrane patch was stored in freezer C, and

recorded using the standard bone bank system, the tissue was fully traceable and no discrepancies were found.

At the time of the inspection, relevant material was not being stored under this licence for use in a scheduled purpose as defined by the Human Tissue Act 2004. Consequently, the establishment's systems relating to the storage and use of such material were not assessed during this inspection.

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.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	Standard operating procedures (SOPs) do not include details of procedures relating to the transportation of blood samples to the testing laboratory, receipt of samples at the testing laboratory, or the provision of testing results to the bone bank.	**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.	There are no risk assessments addressing the potential loss of material during internal transfer, such as between the bone bank and serology testing laboratory, within the establishment, or the risks associated with donor follow-up for the 180-day repeat serology testing. Many of the risk assessments assessed focused on health and safety issues, or the risk of material becoming contaminated and causing an infection in the recipient or staff, rather than the risks to the tissue itself becoming damaged, lost, or unusable.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.	Culture broth for bone chips and swabs is stored at ambient temperature in the theatres; the storage areas are not temperature monitored. This does not provide an assurance that the broth has been stored within the required 2-26°C temperature range. Transport media (TM) for cartilage culture is stored in an unmonitored fridge in the theatre. This does not provide an assurance that the TM has been kept within the required 4-10°C temperature range.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1b	The establishment does not currently record how long products, purchased from another HTA-licensed establishment, have been in transit. The DI is advised to develop a process where this time is recorded to ensure that products have been dispatched, and received, within the recommended period.
2.	GQ4a	The establishment maintain a logbook of batches of femoral heads that have been discarded, including the date of disposal and reason for disposal. This is in addition to details being recorded in the bone bank database, which is regularly backed up. The DI is advised to periodically scan, or copy, the logbook to ensure these hand written 'batch' records are not lost in the event of an incident with the paper logbook, such as loss or damage.
3.	GQ5b	The consent forms used for cartilage procurement are provided by the ATMP manufacturer. The forms describe the serological testing undertaken but do not reference HTLV testing. While the staff seeking consent explain that HTLV testing is included in the assessment panel, the DI is advised to have this added to the consent form itself, and to retain a physical copy of the signed consent form at the establishment after the sample is shipped.
4.	GQ8c	Hard copies of risk assessments are filed within the establishment office area. The DI is advised to make the risk assessments more accessible to individuals working under the licence who may not be based in the office.

Concluding comments

Several areas of good practice were observed during the inspection. The establishment collaborates with another HTA licensed department within the hospital, performing independent audits on each other's facility, facilitating independent audits against the HTA standards.

Bone bank staff and establishment surgeons are engaged with the collection, storage and end use femoral heads procured under the licence, allowing for close interactions and feedback on the whole process, from individual procuring the sample to the end user. In addition the bone bank has initiated a process where donors receive a thank you letter once the femoral head has been used, ensuring the donor is aware that their donated tissue has been used clinically and promoting engagement with the public.

Three minor shortfalls were identified during the inspection that related to SOPs, risk assessments, and the storage of critical consumables. There are some areas of practice that may benefit from further improvement and HTA has given advice to the Designated Individual with respect to these.

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: 18 September 2018

Report returned from DI: 27 September 2018

Final report issued: 04 October 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: 02 January 2019

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.

b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
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.
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.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.

g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
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 002/2018.
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 002/2018.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.

h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

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

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.