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Site visit inspection report on compliance with HTA minimum standards

Luton and Dunstable University Hospital

HTA licensing number 22605

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**

03 May 2017

Summary of inspection findings

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

Although the HTA found that Luton and Dunstable University Hospital (the establishment) had met the majority of the HTA standards, six minor shortfalls were found: five with regard to the Governance and Quality Systems (GQS) standards and one with regard to the Disposal (D) standards. The minor shortfalls were in relation to: (i) governance meetings; (ii) document control; (iii) a contingency plan for stored tissue in the event of licence revocation; (iv) an internal audit system; (v) an independent audit; and (vi) records of disposal. Advice has been given relating to the GQS and Premises, Facilities and Equipment standards, as well as to licence management.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual (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 type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Bone				**E**			
Tendons / ligaments				**E**			

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Luton and Dunstable University Hospital (the establishment). The establishment was issued an HTA licence in August 2010. This was the fourth HTA site visit inspection of the establishment (the last inspection was in May 2015). The current inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards.

Luton and Dunstable University Hospital is part of Luton and Dunstable University Hospital NHS Foundation Trust (FT). The Orthopaedic and Trauma Unit within the hospital (the 'Unit') performs over 5,000 orthopaedic surgical procedures for patients from the Bedfordshire and Hertfordshire area each year.

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 DI is a Consultant Orthopaedic Surgeon. The Corporate LH (CLH) is Luton and Dunstable University Hospital NHS FT and the CLH Contact (CLHC) is the Chief Executive of the Trust. There are three Persons Designated (PDs) on the licence: two Senior Theatre Sisters and the Theatre Clinical Risk Lead.

The establishment stores cryopreserved bone, tendons and ligaments from living and deceased donors. The tissue is purchased from an HTA-licensed supplier under a service level agreement. The supplier is responsible for donor selection, consent, procurement, serological testing and transportation. The tissue is used in adult hip replacement/revision procedures and in knee revision and foot and ankle reconstructive surgery. In 2016, the establishment performed 12 bone and two tendon/ligament allografts.

Tissue is received into the Unit by authorised personnel. 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 being transferred onto an electronic spreadsheet, which is backed up as part of the Trust Information Technology (IT) system (*see Advice item 7*).

The tissue is stored securely in a lockable freezer outside the operating theatre complex but the freezer is not labelled to indicate that it contains human tissue (*see Advice item 15*). At the time of the inspection the temperature was -32^{o}C. Non-conforming units are stored on a separate shelf in the freezer. The freezer is linked to a continuous temperature-monitoring unit that feeds into a wireless callout system. Temperature excursions outside the set ranges trigger both audible alarms and the callout system but the system is not tested routinely (*see Advice item 18*). The freezer is subject to an annual service and calibration under contract (*see Advice item 19*). A back-up freezer is available for contingency storage (*see Advice item 13*).

When required for engraftment, the tissue is removed and taken to the operating theatres for thawing before use. The date of removal and patient number of the recipient are entered into the tissue register (*see Advice item 8*).

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 (*see Shortfall under D2a*).

The establishment also purchases demineralised bone matrix and cancellous bone chips from two HTA-licensed suppliers. A spreadsheet is being set up of the quantities, batch numbers and expiry dates of the packs received and used (*see Advice item 7*). This 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 and the three PDs.

Audits of traceability were carried out:

- Three units of bone (two femoral heads and one cortical strut) were selected from the freezer and labelling details were compared to the records in the tissue register and on the dispatch sheets. There were no discrepancies noted.
- Three units of bone (one femoral head and two cortical struts) and one unit of tendon were chosen from the tissue register and allograft recipient details in the register were compared to the clinical notes. There were no discrepancies noted.

Inspection findings

The HTA found the DI and the CLH to be suitable in accordance with the requirements of the legislation. During the inspection, the removal of certain activities from the establishment's HTA licence was discussed (*see Advice item 1*).

Compliance with HTA standards

Human Tissue (Quality and Safety for Human Application) Regulations 2007 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**
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.	During the inspection there were several discrepancies noted in documentation, reflecting inconsistencies in the document control system: - The freezer temperature alarm trigger points are set at -25°C and -38°C but they are documented in the standard operating procedure (SOP) as -28°C and -38°C - The full list of personnel notified by the temperature callout system is not included in the SOP. - 'The establishment's Quality Manual lists all the 'relevant material' under the Human Tissue Act 2004 ('HT Act'), rather than the list of tissues and cells under the Q&S Regulations (the establishment is not licensed under the HT Act). - The Trust's 'Policy for Adverse Incident Reporting and Investigation of Incidents' makes no reference to serious adverse events and serious adverse reactions (SAEARs) and their reporting requirements. *See Advice item 12.*	**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 11.*	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	An internal audit system encompassing the full range of licensed activities has not been implemented. The establishment performs regular checks to ensure that tissue identifiers in the tissue register match those in patient and theatre records. However, this does not constitute an internal audit aimed at assessing the establishment's compliance against the full range of licensed activities.	**Minor**
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	The establishment has had two independent audits conducted by DIs on two separate post mortem licences. In both cases, the audits were (incorrectly) against the standards under the HT Act and not against the applicable standards under the Q&S Regulations.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
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, of each unit of tissue.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI is advised to consider removing the activities of procurement, testing and distribution from the establishment's licence as these are not currently taking place.
2.	GQ1c	The DI is advised to ensure that governance meetings identified in the shortfall 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 whether to include representatives from other departments (e.g. Clinical Governance, IT) to help develop the establishment's working practices.
3.	GQ2b, 4b	The DI is advised to consider developing a schedule that will allow different team members to carry out selected audits. This should include horizontal audits to ensure that SOPs accurately reflect current practices and vertical traceability audits, from records of receipt to engraftment or disposal. 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	The DI is advised to consider expanding the competence training templates for staff who receive and retrieve allograft tissue from storage. This could be of the form of a three-stage process where: the trainee observes the trainer carrying out the activity; the trainer observes the trainee; and the trainee performs the activity alone.
5.	GQ3f	The DI is advised to consider setting up 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. This could be of the form of a presentation for all relevant staff members and should include a background to the Q&S Regulations.
6.	GQ3g	The DI is advised to ensure that staff understand the quality systems used within the establishment; this could be of the form of a presentation. A system that records that relevant staff have read and are familiar with the Quality Manual, SOPs and risk assessments should also be set up.
7.	GQ4d, 4e	To date, only recipient details have been entered onto the electronic spreadsheet. The DI is advised to ensure that full records from receipt to engraftment (or disposal) are entered and that access to the document is granted to the relevant staff.
8.	GQ4e	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.
9.	GQ4e	The DI is advised to consider adding into the tissue register the time from release of tissue by the supplier to placement in the freezer.
10.	GQ4i	For allograft recipients, the DI is advised to consider highlighting that the electronic patient file needs to be retained for 30 years after use, expiry or disposal of tissue.
11.	GQ4m	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 records need to be labelled appropriately and stored in the Trust archives.

12.	GQ7b	The DI is advised to ensure that the Trust's 'Policy for Adverse Incident Reporting and Investigation of Incidents' and the establishment's 'SOP for the Management of Human Tissue in Theatres' (CG358, Appendix B) includes the types of incident which are classified as SAEARs. The DI is referred to the HTA's website page for further information: https://www.hta.gov.uk/policies/human-application-adverse-event-and-reaction-saears-reporting
13.	GQ8a	The establishment has a risk assessment for tissue storage. The DI is advised to consider expanding this to cover the requirement for freezer cleaning and decontamination. The establishment has a risk assessment for freezer failure. As the contingency freezer is in a separate department within the Trust, the DI is advised to consider creating a detailed contingency plan and to test this plan on a regular basis, to ensure that it works smoothly.
14.	GQ8c	The DI is advised to ensure that relevant staff can access risk assessments. The DI may wish to consider including risk assessments in staff competency folders.
15.	PFE3a	The DI is advised to consider labelling the freezer to indicate that it contains human tissue. This will ensure that staff are aware of the need to manage tissue in the freezer in line with health and safety and regulatory requirements.
16.	PFE3b	The DI is advised to consider hard wiring the freezer into the Trust power supply to prevent accidental disruption of the power supply.
17.	PFE3c	The DI is advised to consider placing a document-controlled label on the freezer to summarise procedures to take when the audible temperature alarm is activated.
18.	PFE3c	The DI is advised to consider carrying out regular testing of the continuous temperature-monitoring system to ensure that the callout procedure is functioning correctly.
19.	PFE5a	The freezer is under maintenance contract and there are regular service visits. During the inspection, it was noted that the service sheet did not fully record the actions taken during the service visit. The DI is advised to consider creating a service visit checklist. Items included in the checklist could be validation of the temperature probe and correct use of graph paper in the freezer's chart recorder.

Concluding comments

During the inspection, areas of good practice were noted:

- Nursing staff have good working relationships and communicate well with the DI.
- The Unit has recently set up regular contact with staff working under the HTA Post Mortem licence at Luton and Dunstable University Hospital, to share HTA-related knowledge and experience.

There are a number of areas of practice that require improvement, including six minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality Systems and Premises, Facilities and Equipment standards, as well as to licence management.

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: 01 June 2017

Report returned from DI: N/A

Final report issued: 29 June 2017

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: 07 June 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 that 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.
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.
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.
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.