Site visit inspection report on compliance with HTA minimum standards

Basingstoke and North Hampshire Hospital

HTA licensing number 11119

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**

23 February 2016

Summary of inspection findings

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

Basingstoke and North Hampshire Hospital (the establishment) was found to have met all HTA 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.

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

Background to the establishment and description of inspection activities undertaken

Basingstoke and North Hampshire Hospital is an acute hospital providing medical and surgical services to the population of Hampshire and West Berkshire. The establishment is licensed for procurement, donor testing, storage and distribution of tissues and cells for patient treatment. The Designated Individual (DI) is the Divisional Medical Director for Medical Services; Hampshire Hospitals NHS Foundation Trust is the corporate licence holder and the corporate licence holder contact is the Chief Executive Officer of the Trust.

The hospital's Bone Bank procures femoral heads from patients during hip replacement surgery. Patients who are scheduled for surgery attend 'Hip School' where they are provided with information about their upcoming surgery, recovery, and physiotherapy following surgery. Nurses who run the Hip School also provide potential donors with information about bone donation. Pre-assessment sisters follow up on patients who express an interest in donating bone and obtain their medical and social history including the use of intravenous drugs, travel history and sexual behaviour. A blood sample is also taken within 30 days before the scheduled date for surgery. The blood sample is sent for serology testing to the laboratory based within the hospital which has Clinical Pathology Accreditation. Following the previous HTA inspection in 2014, the establishment started screening for HTLV-1 in addition to the other mandatory tests. Repeat donor serology testing of successful donors is undertaken six months after they donate bone.

Completed consent forms are filed in the donor's clinical notes. The donor's details are recorded in the bone bank register which is also used to track the status of the donation and

details about the recipient. Each donation is assigned a unique bone bank number in order to ensure anonymity of the donor.

Procurement takes place in one of four laminar flow theatres. The surgeon removes the femoral head and takes a chip from the femur for histology. The procured femoral head is subjected to thermal disinfection in theatres using a proprietary heat disinfection device which is CE marked. The femoral head is placed in a pot with a one way valve supplied by the manufacturer. The pot is labelled with the bone bank number, filled with Hartman's saline solution and placed in the device. Trained scrub nurses and circulators are responsible for recording the lot number and the batch number of the Hartmann's solution. The disinfection device has only two settings – a heating profile for thermal disinfection and another setting which is used to thaw donated bone before it is implanted into the recipient. The heating cycle takes around 90min to complete and the manufacturer guarantees that the temperature in the centre of any femoral head up to 56mm in diameter, reaches 82.5^{0}C and is maintained at that temperature for 15 minutes. Upon completion, the device provides a printout which states that the procedure has been successfully completed. The printout is signed and filed together with other donor information.

Once the thermal disinfection process is completed, the pot containing the femoral head is inverted and the boiling fluid (Hartmann's solution) is drained out through a one way valve, under laminar flow conditions. The boiling fluid is sampled aseptically and 30ml is sent to the microbiology laboratory for testing, in order to detect any residual microbial contamination which may not have been removed during the disinfection process. The pot containing the femoral head is then placed within the outer container and stored in a -80^{0}C freezer.

Femoral heads are stored in two locked -80^{0}C freezers located in a room near theatres. The temperature of the freezers is continuously monitored using a proprietary temperature monitoring system. An alarm is triggered if the temperature of the freezers goes above -65^{0}C; switchboard staff are alerted who then inform designated staff. The quarantine freezer contains femoral heads, where repeat donor testing and microbial testing have not been completed; the ready to use freezer contains femoral heads for clinical use. Once repeat donor testing is undertaken, the files are signed off by the Bone Bank Director and the femoral heads are transferred from the quarantine freezer to the ready to use freezer. The Bone Bank uses two white boards to record the location of femoral heads within both freezers. Trained staff remove femoral heads from the ready to use freezer as required and take them to the theatres where they are defrosted using the proprietary thermal disinfection device.

The Theatre Nurse provides training to theatre staff. Staff are informed about incidents and any changes to procedures during regular theatre staff meetings.

The fourth routine inspection of the bone bank took place on 23 February 2016. The inspection team had discussions with the DI, Director of the Bone Bank, Quality Manager, the consent taker, Theatre Nurse and a Biomedical Scientist.

The establishment intends to stop the current practice of repeat donor testing after 180 days on the basis that femoral heads are disinfected, which reduces the risk of transmission of infections from donor to recipient. This planned change was discussed during the inspection and the establishment was advised to submit a Preparation Process Dossier to the HTA for consideration and apply to add the licensable activity of processing to their HTA licence.

In 2013, the establishment undertook a reconstruction of a child's anterior cruciate ligament (ACL) using the hamstring tendon donated by the parent. This inspection did not cover documentation or processes relating to this procedure

A document review was carried out. Documents reviewed included the Quality Manual, Trust's consent policy, and standard operating procedures (SOPs) relating to donor

assessment, harvesting of the femoral head, the use of the thermal disinfection device, microbial testing on the boiling fluid undertaken by the microbiology laboratory, storage and incident reporting. The bone bank register, cleaning and maintenance records for the thermal disinfection device, staff training records, disposal records, an adverse incident report and corrective actions relating to a freezer failure, audit calendar, management reviews, minutes of meetings and maintenance and service agreements for the freezers were reviewed.

The freezer location of bone procured on site and a tendon supplied by an HTA licensed supplier were checked against the record noted on the white board. Records in two donor and recipient clinical notes were reviewed. Donor records filed in the bone bank contained consent forms, pre-operation donor test results, records of procurement, batch numbers of the Hartmann's solution and pot used, the thermal disinfection profile, histology report on the bone, microbial test result of the sample of boiling fluid, repeat donor test results, sign off by the Bone Bank Director and the bone implant date. Records in the bone bank register were checked. There were no discrepancies.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ2d	The laboratory reports negative microbiology test results on the boiling fluid surrounding the femoral head using the phrase 'no growth'. The DI is advised to consider including information which accurately conveys the comprehensive suite of tests and controls carried out by the microbiology laboratory. The laboratory undertakes a range of tests to detect aerobic and anaerobic bacteria as well as a growth promotion test in order to ensure that negative results are not due to inhibition of bacterial growth by chemicals present in the boiling fluid. These tests help to assure the establishment that the thermal disinfection procedure is effective.
2.	GQ4	The DI is advised to consider marking the outside of bone donor files with a clearly visible sticker when donated bone is used for implantation into in a recipient. The sticker will help to alert clinical staff in other areas, to inform the DI in the event that the donor develops a malignancy or other medical conditions which may have implications for the recipient of donated bone.
3.	GQ6	The DI is advised to ensure that staff in theatres receive regular reminders to attach labels with the bone bank unique number and information such as expiry date on the inner pot containing femoral heads. These pots are placed inside an outer pot before they are placed in the quarantine freezer. The HTA team observed that labels are sometimes placed on the outside pot and there is a risk that these labels fall off during storage.

4.	GQ7	The DI is advised to ensure that staff in theatres and the microbiology laboratory are reminded of the requirement to report SAEARs to the HTA and provided with examples of SAEARs in relation to licensable activities such as incidents relating to defective test kits, mixup of samples, and freezer failures which could result in loss of a significant amount of bone. The DI is also advised to formally document the requirement for DI and PDs to report SAEARs to the HTA within 24 hours of discovery. Staff are aware of this requirement but the documentation states that SAEARs must be reported as soon as possible.
5.	PFE2	The DI is advised to review and update the maintenance contract with the service provider responsible for maintaining the freezers. The establishment has contingency arrangements in place as femoral heads are moved to another freezer in the event of a freezer breakdown. The DI should consider including a 24 hour on-call service in the contract in order to ensure that any freezer breakdown is attended to as a matter of urgency. A recent incident where the ready to use freezer broke down highlights the need to ensure prompt service by the maintenance provider The DI is also advised to liaise with other Departments which use -80^{0}C freezers in order to formalise the use of these freezers in the event of a freezer failure. The DI is advised to set up a system to trend the temperature of freezers in order to detect any drift in the freezer temperature so that there is early warning of potential freezer failure. The freezer temperature is collected and saved by the monitoring system and can be downloaded and reviewed at regular intervals.

Concluding comments

There is good communication between staff undertaking licensable activities. The Quality Manager plays a key role in facilitating effective links between theatre staff, consent nurses, surgeons and staff in the microbiology laboratory. Staff are well supported by the DI who, as Director of Medical Services, has put systems in place to ensure that he has oversight of licensable activities and is able to effect changes as required.

The Bone Bank Director, who is a consultant orthopaedic surgeon, effectively supervises all activities. Dedicated consent nurses actively encourage bone donation and seek consent from potential donors. The theatre lead takes care to ensure that all staff involved in procurement and storage are suitably trained and that the thermal disinfection device is maintained as required.

The establishment keeps at least one shelf in the quarantine freezer and the ready to use freezer empty, so that bone can be moved between freezers in the event that one of them breaks down. The establishment stores records relating to the disinfection device, such as run times and heating profiles used to disinfect donated bone.

The establishment has plans to increase the availability of bone for patients undergoing orthopaedic procedures. A surgeon, with extensive experience in bone banking has recently been appointed in order to take on the role of Deputy Bone Bank Manager. The establishment is looking into stopping the current procedure, where they contact donors in order to ask them to return to the hospital for repeat donor testing six months after they have donated bone on the basis that donated bone is thermally disinfected following procurement. This will reduce the amount of bone which has to be disposed of because some donors do not return for these tests. The establishment also intends to divide femoral heads and subject each part to thermal disinfection so as to reduce waste as all of the femoral head is not used during surgery.

The HTA has given advice to the Designated Individual with respect to increasing staff awareness of SAEARs, reviewing the service contract for the freezers, trending freezer temperature, attaching labels on the inner pot containing femoral heads, updating the wording used to report microbial test results and attaching a sticker on donor files to alert other clinicians to inform the DI in the event that the donor develops a medical condition which may have implications for the recipient.

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

Report sent to DI for factual accuracy: 16 March 2016

Report returned from DI: 28 March 2016

Final report issued: 29 March 2016

Appendix 1: HTA standards

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

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

Consent

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

Governance and Quality

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

b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
o) There is a complaints system in place.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.

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

Premises, Facilities and Equipment

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

d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.

j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

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

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

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

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

1. **Critical shortfall:**

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

   Or

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

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

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

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

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall.

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

or

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

or

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

or

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

or

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

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

3. Minor shortfall:

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

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

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

Follow up actions

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

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

- a follow-up site-visit inspection

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

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