Site visit inspection report on compliance with HTA minimum standards

Great Western Hospitals NHS Foundation Trust

HTA licensing number 11014

Licensed for the

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

07 February 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 Great Western Hospitals NHS Foundation Trust (the establishment) had met the majority of the HTA standards, three minor shortfalls were found in relation to the Governance and Quality Systems standards. The minor shortfalls relate to the third party agreements, the independent audit against all applicable HTA standards and the retention of raw data for 10 years.

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	**E**		**E/ TPA**	**E**			
Musculoskeletal; Tendon & Ligament	**E***		**E*/TPA**	**E**			

Background to the establishment and description of inspection activities undertaken

The Great Western Hospitals NHS Foundation Trust has been licensed by the HTA since August 2006. The HTA licence includes the procurement, donor testing and storage of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The majority of licensable activities undertaken at this establishment relate to femoral heads procured from patients undergoing hip replacement surgery.

Potential donors are identified prior to their attendance at the pre-assessment clinic. Any patients with contraindications to bone donation are screened out. Those identified as suitable for bone donation are given an information sheet concerning bone donation. If the patient agrees to donate their femoral head, staff at the pre-assessment clinic will further assess the patient's suitability with a medical and behavioural history questionnaire and obtain consent. The patient is informed that they will be required to have blood taken for serological testing post-operatively, usually the following day, but no later than seven days post-donation and when they return in 12 months for their orthopaedic follow-up appointment. All the femoral heads procured at the establishment are for allogeneic use.

On the day of the harvest, a swab of the outer surface of the femoral head and a bone sample are taken for sterility testing. The femoral head is placed in a sterile inner pot, which, in turn, is placed in a larger sterile pot. The outer bone jar is allocated a unique bone bank number, date of donation, expiry date, a statement for single patient use, a red dot and a security seal. Shortly after, the femoral heads are placed in the -80°C quarantine freezer. Related notes are kept in the red folder of the Bone Bank filling trolley, located next to the freezers.

Donor testing for most of the mandatory serology markers and microbiological testing of tissues is carried out within the establishment's Microbiology/Pathology Department, which holds a Clinical Pathology Accreditation (CPA). Another HTA-licensed establishment undertakes HTLV-1 testing. Repeat serology testing is performed 12 months post-surgery for all the mandatory serology markers, except HTLV-1.

When available, the results of the initial and repeat serology tests, together with the results of the microbiology tests, are reviewed and recorded in the bone bank logbook and electronic database. If all the results are negative, the femoral head is released for clinical use. At this time, the red dot on the outside of the pot is replaced with a green dot and the bone jar is moved to the release freezer. The move is recorded in the logbook and the electronic database. The notes associated with the femoral head are also moved from the red folder in the top drawer of the bone bank trolley to the green folder in the second drawer of the trolley. If either set of test results is positive, the femoral heads are disposed of according to the Trust's disposal policy, following a two-person check of the unique jar number and donor addressograph.

The establishment also occasionally receives and stores tendons and ligaments from another HTA-licensed establishment, under the terms of a service level agreement (SLA). These are stored in the -80°C release freezer and records are maintained in the logbook and electronic database. Both freezers are temperature-monitored and linked to a wireless call-out system. Temperature excursions outside the set ranges alert the Trust's switchboard, and, in turn, nominated staff are notified, in and out of hours.

This report describes the establishment's sixth inspection, which took place on 7 February 2018. Discussions were held with the Designated Individual (DI), the Bone Bank Coordinator, the Theatre Bone Bank Coordinator and a member of the Planned Care Clinical Audit team. The inspection included a visual inspection of the areas where tissue storage and serology testing take place, and review of documentation relevant to the licensable activities of the establishment.

Audits of traceability were carried out and included the storage location of one tendon and two femoral heads; locations in the quarantine and release freezers were cross-checked against the bone bank register. A total of three donor and two recipient files were reviewed to ensure that they contained all relevant documentation, including serology and microbiology results. One discrepancy was identified in the clinical notes for one of the patient records provided (*see Advice, item 6*).

Inspection findings

The HTA found the DI 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.		
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.	The establishment has written agreements with third parties whenever an activity takes place. These need to be reviewed to include all the responsibilities of each party in relation to: • serious adverse events and reactions (SAEARs) reporting procedure and the procedures to follow in the event of an incident. • retention of critical traceability records (30 years) and raw data (for 10 years).	**Minor**
GQ2 There is a documented system of quality management and audit.		
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.	Although an independent audit had been conducted since the last inspection, it did not verify compliance with protocols and all applicable HTA standards. *Refer also to Advice, item 2*.	**Minor**

GQ4 There is a systematic and planned approach to the management of records.		
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.	The establishment has a policy for the retention of records. However, staff were not able to provide evidence that raw data, such as temperature records, were being retained for 10 years after the use, expiry date or disposal of cells.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(d)	The establishment uses a document control system for the majority of the Bone Bank documentation. During the document review, it was noted that the Quality Manual and a few of the risk assessments were not version controlled. The DI is advised to review all the standard operating procedures (SOPs), risk assessments, forms and the Quality Manual and include, where required, revision history, pagination, date of approval and implementation and the names of both the author and reviewer as relevant.
2.	GQ2(b), (c)	The Microbiology/Pathology Department has recently migrated documentation and audits to a new version of a quality management system. With reference to the shortfall against GQ2 (c) the DI is advised to review the results of all audit findings and actions taken to ensure these are formally recorded and completed. The DI is also advised to formally record and discuss these at governance meetings to ensure clarity and continuing improvement of processes and practices. The DI is also advised to formalise and record the processes involved in internal and independent audits in an SOP. This will ensure that new and existing members of staff are consistent in their approach to audits.
3.	GQ7(a)	Although the establishment has procedures in place at a Trust level for incident management and within the Bone Bank for the management and reporting of SAEARs to the HTA, there is no incident log for incidents of a lower seriousness. For example, the establishment has recently experienced an increase in the number of procured femoral heads with positive microbiology test results. These incidents have been discussed with a microbiology specialist but no root cause was identified. The investigations were subsequently closed, but they were not recorded anywhere to facilitate trend analysis and ensure the establishment is able to follow up any corrective actions taken. The DI is advised to create an event/ incident log for recording reportable and non-reportable incidents. The use of an incident log will ensure that in the future the following information is recorded for each event/incident:

		• the event/ incident, • action taken, • the impact, • the investigation • when the incident was closed • whether or not the incident was reported to the HTA and rationale for this The DI is also advised to formalise the process for the management of non-reportable incidents in an SOP to ensure that all members of staff understand the process and what it involves. The DI is advised to discuss the corrective actions and closure of reportable and non-reportable incidents at governance meetings to raise staff awareness.
4.	GQ8(a)	The activities under the licence have been risk assessed and systems have been put in place to mitigate the risks. However, this has not been fully documented. The DI is advised to document in the risk assessments the full range of control measures, which help to mitigate identified risks.
5.	GQ8(b)	Current practice is for the establishment to review the risk assessments annually. The DI is advised to document this in the relevant SOPs and the Quality Manual.
6.	N/A	Current practice is for the establishment to affix a label in the clinical notes of patients to indicate that the patient was a donor or recipient of human tissue. During the traceability audit, one of the patient records did not have this label. The DI is advised to audit clinical notes to ensure that the label is present.
7.	N/A	The DI is advised to review the establishment's documentation to ensure it includes up-to-date references to the new HTA Codes of Practice.

Concluding comments

The HTA observed a number of good practices during the course of the inspection.

The establishment uses a red-green colour "traffic light" system to record the location of the femoral heads and makes use of specific shelves in each the quarantine and release freezers. This minimises the risk of femoral heads being issued incorrectly or being misplaced. When the femoral heads are moved from the quarantine to the release freezer the documentation, containing all the traceability information, is updated with the final serology results and moved from the red to the green folder in the filing trolley.

The establishment also routinely makes use of two-person check procedures for labeling, issuing for clinical use and for discard of femoral heads that have expired or had positive serology or microbiology results. In addition to the routine swab during harvest for assessing any microbiological contamination of the bone, staff also routinely swab the outer surface of the femoral head prior to implantation.

There is an effective system of monitoring each of the freezers with two probes, one used to monitor the temperature in the air surrounding the femoral heads and the other the temperature in the bone.

Establishment staff have developed a dashboard that provides information regarding tissue retrieval and revision bone audits, the calibration, defrosting and service of the freezers, and training undertaken by members of staff. The dashboard is a useful and comprehensive tool that ensures information is disseminated among key members of staff involved in the operation of the Bone Bank.

During the inspection, three areas of practice were identified that require improvement, resulting in three minor shortfalls. The HTA has also given advice to the Designated Individual with respect to the establishment's documents, the internal and independent audits, the recording, management and closure of reportable and non-reportable incidents, risk assessments, the use of up-to-date references of the new HTA Codes of Practice and the use of labels within the clinical notes of graft donors and recipients.

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: 2018-03-07

Report returned from DI: 2018-03-21

Final report issued: 2018-03-28

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: 2018-11-07

Appendix 1: HTA standards

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

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

Consent

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

Governance and Quality

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

GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.

g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.

b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
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.
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.

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.
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.