Site visit inspection report on compliance with HTA minimum standards

London Bridge hospital

HTA licensing number 11069

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**

20-22 January 2016

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 London Bridge Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls were found with regard to the Governance and Quality Systems (GQS) standards The shortfalls were in relation to the actions required before procurement of haematopoietic stem cells can commence at the Harley Street Clinic and the recording of expiry dates of tissues supplied to the establishment.

Since the previous inspection, the licensing arrangements have been changed at the request of the establishment. London Bridge Hospital is now the 'hub' site with associated licensed activities taking place at a number of satellite sites, including the Princess Grace Hospital, which was previously the hub.

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
PBSC	**E***		**E**				
Bone				**E**			
Tendons/ Ligaments				**E**			
Skin				**E**			
Chondro-cytes	**E**						

Background to the establishment and description of inspection activities undertaken

London Bridge Hospital (the establishment) has been licensed by the HTA since December 2006. It was re-licensed in 2007, when the Quality and Safety for Human Application Regulations came into force. It carries out procurement, donor testing and storage of tissues and cells for human application.

Licensable activities also take place at five satellite sites. They are the Harley Street Clinic, which is licensed for procurement; Wellington Hospital and Prince Grace Hospital, which are

licensed for procurement and storage and two HCA (Hospital Corporation of America) laboratories at Shropshire House and Wimpole Street, which are licensed for donor testing.

Procurement of peripheral blood stem cells (PBSCs) from paediatric patients took place at the Harley Street Clinic until late 2014. These stem cell harvests for autologous use were transported to another HTA-licensed establishment for processing and storage. Due to staff shortages, this activity has not taken place for over a year. The establishment recently recruited new members of staff and intends to recommence activities once the procedures have been reviewed and new members of staff have completed their training programme. All clinical procedures relating to adult patients take place at another HTA-licensed establishment under a service level agreement.

In March 2014, a knee biopsy was procured at Princess Grace Hospital for autologous patient treatment. The biopsy was transported to an establishment in another country in the EU which is accredited under the EU Tissues and Cells Directives. The chondrocytes were isolated, expanded and returned to Princess Grace Hospital for reimplantation in August 2014. The HTA only regulates the procurement and donor testing of this process; all other steps are regulated by the Medicine and Healthcare Products Regulatory Agency (MHRA), as the expanded chondrocytes are designated as Advanced Therapy Medicinal Products (ATMPs).

Donor testing is undertaken at the HCA laboratories, which are accredited by the United Kingdom Accreditation Service (UKAS). Blood samples are barcoded, tracked and test results are recorded and provided to clinical staff at the relevant hospitals.

London Bridge Hospital, Princess Grace Hospital and the Wellington Hospital store bone, tendons, ligaments and skin for end use within the respective hospital. These tissues are supplied by other HTA-licensed establishments. Each of these sites has a dedicated human tissue freezer where tissues are stored. The locked freezers are located in secure areas close to the operating theatres. Named staff who have received training have access to the keys and are responsible for placing and removing tissues from the freezers. Each freezer contains a probe which communicates with a control panel linked to an independent proprietary wireless temperature monitoring system. The system can be checked remotely and triggers an alarm which alerts key members of staff whenever the temperature goes above -25^0C or below -45^0C. There are back up freezers in the event of a freezer failure.

Details of tissues received at each site, including date received, donor ID number, serial number, expiry date and name of the person placing it in storage are entered into a tissue register. The establishment's policy states that tissues can only be stored for three months in the freezers and must be disposed of if it is not used within that period. A tissue tracker form is used to record tissues removed from freezers and transferred to theatres. Details of tissues used are also recorded in the proprietary computerised traceability system used in theatres and is saved in the recipient's electronic patient record.

Regular audits are undertaken, which include cross-site audits. Audit reports are issued and actions, as appropriate, are taken to address findings. Whenever an untoward occurrence takes place, staff use proprietary incident management software to report, investigate and monitor corrective actions. The DI attends weekly governance meetings where all incidents are discussed and is responsible for escalating the incidents and reporting serious adverse events and reactions (SAEARs) to the HTA as required.

The establishment intends to validate a procedure to irradiate pelvic bone removed from a patient and then re-implant the irradiated bone into the donor. The DI must submit a

Preparation Process Dossier which covers the irradiation process to the HTA for authorisation and to add the licensable activity of processing to the HTA licence before it undertakes this activity.

This was the fifth routine site visit inspection of London Bridge Hospital and included a visual inspection of the hub site and all the satellite sites. This was the first inspection of the satellites sites where donor testing is undertaken, since they were first licensed as satellite sites in April 2014. Discussions were held with the Chief Nursing Officer who is the DI, the Head of Governance and Risk who is the Corporate Licence Holder Contact, a Consultant Orthopaedic Surgeon, Persons Designated at each site and staff responsible for temperature monitoring.

A document review was undertaken. SOPs covering all licensable activities, staff training records, audits, risk assessments and records of cleaning of freezers and monitoring of freezer temperatures were reviewed. In adition, agreements between the establishment and providers of the following services were reviewed: supply of tissues for human application; provision of wireless temperature monitoring; service freezer maintenance; and calibration services.

Audit trails were undertaken on two tissue samples stored in the freezers at each site and two tissue samples received at each site and used for human application. The tissues were traced from receipt at each site, freezer registers, tissue tracker forms, implantation registers and patient electronic records as appropriate. Records of disposal of tissue stored for more than three months were reviewed. Consent forms, donor serology and nucleic acid test results and re-infustion records relating to three PBSC procurements from paediatric patients which were undertaken before this activity was temporarily suspended, were reviewed. Consent documentation and donor virology testing results relating to one adult patient from whom PBSCs were procured at another HTA licensed establishment were also reviewed. No discrepancies were noted.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	In 2014, the Harley Street Clinic ceased procurement of PBSCs from paediatric donors. The Harley Street Clinic recently employed new members of staff who are receiving training. The establishment intends to re-commence apheresis once training and competency assessments and a review of documented procedures have been completed. The establishment does not have a change management plan which covers staff training, review of documented procedures, completion of risk assessments and other relevant actions before the re-commencement of this service takes place.	**Minor**
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.		
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.		
GQ4 There is a systematic and planned approach to the management of records.consumables and 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.	Staff do not always record the correct date of expiry for tissues received and stored at -40^{0}C . The expiry date of these tissues is dependant on the storage temperature and documented procedures state that all tissues will only be stored for three months.. There is the risk that recording the incorrect expiry date could result in tissues being stored for longer than three months as staff will not be aware of the correct date for disposal of these tissues.	**Minor**

Advice

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

No.	Standard	Advice
1.	C2c	The DI is advised to provide age-appropriate information on mobilisation of stem cells and the apheresis procedure to paediatric patients when seeking consent for procurement. The information which has been prepared is suitable for adults, *i.e.* the child's parents, and is not child friendly.
2.	GQ1b	In some cases, tissues are received in the Materials Department before they are transferred to theatres where they are stored in freezers. The DI is advised to ensure that there are formal procedures in place to ensure that the Materials Department transfers all tissues to the theatres as soon as they are received. The DI is advised to review the SOP for procurement of knee biopsies for isolating chondrocytes for autologous use if the establishment intends to undertake this procedure in the future as the SOP is out of date.
3.	GQ1h	The DI is advised to amend the SOP which covers the handling of human tissues (CCP.HTA.SOP.009) to include the procedure to be followed if the tissues received do not meet requirements. The procedure for handling any non-conforming consignments should cover proper storage, re-packaging, return or disposal as appropriate, in order to prevent cross contamination of other tissues being stored by the establishment. The DI should consider clearly marking or labelling any non-conforming consignments in order to prevent inadvertent use of those products.
4.	GQ3e	The DI is advised to increase awareness of incidents which are reportable to the HTA (SAEARs) by providing information about SAEARs during training presentations provided to staff, incuding persons designated and surgeons who work under the licence.
5.	GQ4c	The DI is advised to remind staff that when making amendments to written records, the person making the amendment must cross out the incorrect record with a single line and date and sign next to the amendment.
6.	PFE3c	The DI is advised to review the temperatures of the freezers over the course of each month in order to identify any trends and take appropriate action as required.
7.	PFE5e	The DI is advised to amend the agreement with the company which provides temperature monitoring services to include replacing batteries in each temperature probe as part of the annual servicing and calibration of equipment.

Concluding comments

There were many areas of good practice including good lines of communication between the DI and all staff who work at the hub site and satellite sites. Staff at the establishment informed the HTA team that senior management responded quickly to any concerns raised.

Corporate policies, corporate SOPs, local SOPs which reflect minor local variations to procedures, and information published by the HTA are saved in the intranet and easily accessible to all staff. Comprehensive training programmes and competency assessments are in place for new members of staff and experienced staff, including staff responsible for donor testing. There is a dedicated training programme for Persons Designated under the HTA licence, which helps to ensure that they understand their role. The Wellington Hospital has devised flow diagrams which cover removal of tissue from the freezer, defrosting of the freezer, actions to be taken in the event of freezer failure and recording of disposal details; these are displayed near the freezer for easy access by staff. Cross-site audits are used as an opportunity to share good practices and learning with new members of staff.

The Princess Grace Hospital uses a 'HTA tissue product traceability form' which is completed by one member of staff and audited by another member of staff before it is filed. The form details the movement of tissue from the freezer to the theatre, thawing and rinsing of the tissue and implantation into the recipient along with the names of staff responsible for each step.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to providing age-appropriate literature to paediatric patients who receive treatement at the Harley Street Clinic, reviewing an SOP, further improving annual training provided to consultants who work on site and trending freezer temperatures.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 18 February 2016

Report returned from DI: 1 March 2016

Final report issued: 11 March 2016

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: 21 December 2017

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
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.
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.
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.
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.
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.
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.
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.
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.