Site visit inspection report on compliance with HTA minimum standards

London Centre for Aesthetic Surgery

HTA licensing number 11112

Licensed for the

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

10 August 2017

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.

Although the HTA found that the London Centre for Aesthetic Surgery (the establishment) had met the majority of the HTA standards, ten shortfalls were found in relation to Governance and Quality, and Premises Facilities and Equipment. There were five major shortfalls which relate to the absence of procedures for microbial testing, systems to monitor temperatures and alert staff to temperature deviations, recording of temperatures, contingency plans and procedures to identify tissues that deviate from the required quality and safety standards. The additional five minor shortfalls relate to the absence of internal audits against the full scope of licensable activities, retention of raw data, governance meetings, records of material coming in contact with tissue and transfer of records in the event of a termination of activities.

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.

Tissue category; Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Adipose; adipose	**E**			**E**			

Background to the establishment and description of inspection activities undertaken

This report refers to activities carried out by the London Centre for Aesthetic Surgery (LCAS) (the establishment) which is licensed for procurement and storage under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. This was a routine site visit to assess whether the establishment is continuing to meet the required HTA standards.

The establishment procures adipose tissue from patients for autologous use in cosmetic surgical procedures. Two consultant surgeons, one of whom is the Designated Individual, provide information to patients and obtain consent for the procedure, which includes consent for storage, conditions under which the tissue will be disposed and consent for taking blood samples for mandatory serological tests. Blood for serological testing is taken on the day of the initial consultation and again on the day of procurement. The testing is undertaken at another HTA-licensed establishment under a service level agreement.

On the day of the surgery, the theatre nurse will prepare up to 15 syringes labelled with the patient's ID, name and expiry date. A fixed volume of adipose tissue is harvested from either the abdomen or flank, washed with 20% albumin and filtered into labelled syringes by the surgeon within the theatre. The syringes are then double-bagged and stored in a quarantine

freezer located in theatre set between -10ºC to -30ºC. The theatre nurse is responsible for updating the tissue register, which provides information on the number of syringes available for for top-up treatments and alerts staff to tissue expiry dates. Upon receipt of serological results from the testing laboratory, the tissue is transferred from the quarantine freezer to one of three -10ºC to -30ºC freezers for up to a period of two years. If any serological results are positive, tissue will be stored in separate compartments in the quarantine freezer. Albumin is stored in a refrigerator set between 2-8ºC in a room adjacent to the operating theatre.

The inspection included discussions with the Designated Individual, Practice Manager and theatre nurse, a visual inspection of the storage facilities and a document review of all licensable activities. An audit of three patient records was also carried out looking at consent, timing of serological results and batch numbers of material used in procurement. Discrepancies were found relating to the consistency of record keeping for reagent batch numbers and the use of correct consent forms.

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.	The establishment does not perform sterility checks on the tissue prior to long-term storage.	**Major**
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	The establishment does not currently have in place regular governance meetings which cover issues relating to HTA licensable activities.	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Although the establishment has an audit schedule covering the range of activities under the licence, the audits were not completed. For example an audit of patient records and consent which were due in 2016 was not carried out.	**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 does not retain raw data for 10 years.	**Minor**
j) Records are kept of products and material coming into contact with the tissues and / or cells.	The establishment does not keep records of the batch numbers of all consumables and materials that come into contact with the tissue during procurement.	**Minor**
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.	The establishment does not have a procedure for ensuring records are transferred to a HTA-licensed establishment, as set out in the Guide to Quality and Safety of Tissues and Cells for Human Application.	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
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.	The current procedures for ensuring tissue viability do not set out a criteria for identifying tissue which has deviated from quality and safety standards. At present the establishment only performs visual and odour checks on tissue which do not provide the required assurance that the tissue is sterile and fit for use. In addition, in the event of freezer failures, there are no defined and documented procedures setting out the acceptable time frames and temperatures required to maintain tissue integrity before discard is necessary.	**Major**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
b) There are systems to deal with emergencies on a 24 hour basis.	The establishment has no system in place to be alerted to, or deal with, the breakdown of a freezer in a timely manner. The establishment relies on external temperature probes to alarm if the temperature deviates out of the set range. The probes do not provide information on when temperature deviations occur and the alarm is not audible outside the theatre.	**Major**
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	The establishment relies on a single staff member to record temperatures of storage freezers. There is no review and recording of temperature charts in the staff member's absence. During the inspection it was noted there was no records for three weeks during the staff member's annual leave. There is no recording of temperatures of storage facilities during weekends and holiday periods.	
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.	The establishment relies on external temperature probes for monitoring and recording temperatures of the storage freezers. While a single point check is performed as part of freezer maintenance, the temperature probes are not calibrated according to the manufacturer's instructions. During the inspection, the inspection team found the alarm for the temperature probe of the quarantine freezer was turned off as it had malfunctioned. Although this was identified prior to inspection, no actions were taken.	**Major**
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.		

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
k) There are contingency plans for equipment failure.	Although the establishment has in place a contingency plan in the event of a power failure, this does not include sufficient steps to ensure the safety and integrity of the tissue during transfer and storage of tissue in cool boxes. Critical time frames and temperatures under which tissues would be deemed unsuitable for end use are not clearly set out. The establishment has no procedures in place for all other possible contingencies, including for example, failure of a single or multiple freezer or storage facility failures during work days and weekends.	**Major**

Advice

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

No.	Standard	Advice
1.	C1d	The DI is advised to amend the Blood Test Consent Forms to refer to the correct HTA Regulations for blood samples taken on the day of tissue harvest and remove references to the HTA in consent forms for blood samples taken prior to the tissue harvest.
2.	GQ1b	The DI should ensure the standard operational procedure (SOP) for Fat Freezing is aligned with practices, for example: • storage of human albumin should be at a temperatures between 2ºC to 8ºC, not 2ºC to 25ºC; and • traceability data should be kept for 30 years, not 10.
3.	GQ4d	Serological test results are provided by the testing laboratory to the establishment in two forms – emails, and hard copies, which are stored in the patient records. While all other traceability information is backed up to an external server daily, serological tests results remain separate. The establishment is advised to back up emails containing patients' test results for full traceability.
4.	GQ4j	The DI is advised to include a dedicated box in the patient information sheet to capture reagents and consumables which come to contact with tissues to ensure this is always recorded.
5.	GQ4j	Tissue is stored in medical grade syringes intended for general purpose aspiration and injection at room temperatures. The DI is advised to contact the manufacturer to obtain confirmation that long-term storage of the syringes at

		temperatures between -10ºC to -30ºC do not adversely affect the integrity of the plastic and sterility.
6.	PFE3c	Review of temperature charts reveal two of the freezers regularly reach temperatures of -11ºC during periods of low activity. The DI is advised to ensure the all the freezers are sufficiently robust to maintain storage of tissue stably at required temperatures and temperature probes provide accurate readings to ensure tissue is stored within the required -10ºC to -30ºC range.
7.	PFE5d	The DI should ensure maintenance contractors verify temperatures of each shelf within the freezers as the temperature probe is only located on one shelf.
8.	PFE5k	Over the course of the inspection, staff members described inconsistent contingency procedures in the event of a power failure. The protocols were not in line with the SOP in place. The DI should ensure all new contingency procedures are included as part of staff training.
9.	-	The DI is advised to review the temperature at which tissue is frozen and stored in light of recent guidance, for example as recommended in the European Pharmacopeia for tissue freezing.

Concluding comments

There are several areas of practice that require improvement, which resulted in five major and five minor shortfalls. The major shortfalls relate to absence of procedures to ensure the sterility of the tissue used in patients, monitor and record storage facility temperatures, systems to deal with emergencies in a timely manner, clear contingency plans for storage of tissue and the criteria to identify critical time frames and temperature conditions under which the tissue integrity and safety would be affected. The minor shortfalls relate to the absence of internal audits against all licensable activities, transfer of records in the event of termination of activities, procedures to store raw data for 10 years, documentation of material which come in contact with tissues and cells and regular quality and governance meetings.

The HTA has given advice to the Designated Individual with respect to consent forms, reviewing SOPs, back up of serological results, recording of reagent batch numbers, maintenance contracts, storage facilities and validation of plastics used for tissue storage.

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: 4 September 2017

Report returned from DI: 19 September 2017

Final report issued: 19 September 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 14 October 2019

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement 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.

r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.

c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
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.
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.

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.
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.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
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.