Site visit inspection report on compliance with HTA minimum standards

Lindare Medical Ltd

HTA licensing number 22577

Licensed for the

- **storage, distribution and import of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

22 May 2018

Summary of inspection findings

Although the HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation, advice has been given to seek expert guidance to assess whether imported tissues meet the equivalent Quality and Safety standards as products produced in Europe.

Although the HTA found that Lindare Medical Ltd (the establishment) had met some of the HTA standards, one major and thirteen minor shortfalls were found in relation to Governance and Quality systems (GQ) and Premises, Facilities and Equipment (PFE) standards. The major shortfall relates to the requirement for the establishment to ensure that imports from non-EEA states meet the standards of quality and safety set out in Directions 002/2018. The minor shortfalls relate to the format of the SEC and the absence of any SEC records for two types of product; the limited scope of internal audits and risk assessments; the absence of: independent audits, contingency agreements in the event of cessation of activities and recall procedures; the requirement to ensure staff are aware of regulatory requirements; the requirement to ensure end users retain product traceability for 30 years; temperature monitors have not been calibrated and the requirement to report SAEARS within 24 hours of discovery.

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
Musculoskeletal, Bone; Cancellous Bone Particles				**E**	**E**	**E**	
Musculoskeletal, Bone; Bone Strut				**E**	**E**	**E**	
Musculoskeletal, Bone; DBM* putty				**E**	**E**	**E**	

*DBM –demineralised bone material

Background to the establishment and description of inspection activities undertaken

The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ('the Quality and Safety Regulations 2007') to store, distribute and import tissues and cells for human application. The establishment imports acellular bone

products (chips and putty) from a single third country supplier (3CS) based in the United States of America (USA). Acellular material is also distributed to the establishment from a tissue bank in the Netherlands.

All of the acellular material received is in a sealed, packaged form. Donor selection, consent, procurement, testing and processing take place within the USA or the Netherlands. Material which is found to be damaged on receipt by the establishment, or which exceeds storage dates is sent to a disposal company for incineration. Products that are distributed from the Netherlands have the Single European Code (SEC) applied to each product. For tissue imported from the United States, the supplier provides details of the SEC and the establishment, on receipt of the product, prints and applies this to the outer packaging. There is a two-person check in place to prevent any transcription errors and to also ensure the correct SEC is applied to the appropriate tissue product.

The establishment is principally an administrative office with secure temperature-monitored storage for packaged acellular products. The ordering, receipt, storage and disposal of bone products is recorded on paper-based records and electronic databases under the supervision of the current Designated Individual (DI). Orders are received from end users, who are NHS and private sector hospitals within the UK, and products are shipped to them using tracked postal services.

The establishment also acts as a broker, via a third party agreement, for a second licensed establishment which provides frozen musculoskeletal tissue to end users on behalf of the establishment. This second establishment is responsible for the import and transport of the tissue. In the event of a serious adverse event or serious adverse reaction (SAEAR), end users of the frozen tissue will inform Lindare Medical Ltd who, in turn, will notify the second establishment.

This was the fourth routine inspection since the establishment was licensed and the first since the amended Quality and Safety Regulations came into force on 1 April 2018. The member of staff who is responsible for the ordering, receipt, storage and disposal of bone products has recently been appointed as DI. The inspection involved a visual inspection of the premises, review of documents including the processing records of four imported products selected prior to the inspection and discussions with the establishment staff and the US supplier. The four products audited were a femoral shaft, cortical strut and two types of crushed cancellous bone particles. There were no discrepancies identified except with the format of the SEC. During the visual inspection there were a number of products that did not have a SEC and a further three tissue types identified that were not listed on the establishment’s Importing Tissue Establishment Licence Certificate (ITELC).

Inspection findings

Although the HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation, there were no systems in place to assess whether the imported tissues meet the equivalent Quality and Safety standards as products produced in Europe. In addition, the establishment had not included three tissue types in their import licence application. Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the DI has a statutory duty to ensure that the conditions of the licence are complied with. Advice has been given to seek suitable expertise to assist in assessing the tissue procurement and processing activities of the 3CS to ensure they meet the Quality and Safety standards as products produced in Europe.

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.		
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018	Although there is an agreement in place between the establishment and the tissue supplier in the USA, the last time staff from the establishment visited the supplier was in 2011.Since then no checks have been undertaken and documented to ensure that tissue imported from outside the EEA meets the required specifications.	**Major**
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.	The establishment has an agreement to transfer tissue to another company. However, this agreement is out of date and the company no longer exists.	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Internal audits are limited to checking the establishment's inventory of acellular products and are not against all applicable HTA standards.	**Minor**
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	The last independent audit was undertaken just before the previous HTA inspection. There is no audit scheduled or agreement in place with an independent auditor.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
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.	There was no documented evidence that the establishment's sales staff had received any training in the HTA's regulatory requirements, including the more recent changes to the import and coding regulations.	**Minor**

k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.	The end user agreements do not stipulate the requirement to maintain full tissue traceability for the minimum 30 years after clinical use.	**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 has an agreement to transfer records to another company in the event that activities are terminated. However, this agreement is out of date and the company no longer exists.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment applies the SEC provided by the supplier in the USA. However, the format of the SEC is not in line with requirements as this is broken up into eight lines as opposed to a maximum of two successive lines. During the inspection, two products types were identified as not having provisions for the SEC. These products were received by the establishment after October 2016.	**Minor**
GQ7 There are systems to ensure that all adverse events 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.	The establishment has documents that make reference to SAEARs; however, they do not include the requirement to report SAEARs to the HTA within 24 hours of discovery as set out in Directions 002/2018.	**Minor**
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.	The establishment does not have a policy or Standard Operating Procedure (SOP) of the actions to take in the event of product recall.	**Minor**

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.	The establishment has in place risk assessments; however, these were limited in scope and do not fully capture all the risks associated with activities that may affect the quality and safety of tissues and cells.	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	The temperature of the room where the tissues are stored is monitored and documented during the working week. The establishment has an additional device which will raise an alarm if the room exceeds a specified temperature. However, at the time of the inspection, the temperature recorded by this device was not being captured nor had the alarm been tested.	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The temperature measuring devices have not been calibrated or tested to ensure the alarm is working and staff know how to respond in the event of a temperature excursion.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.		
c) There is a documented procedure on disposal which ensures that there is no cross contamination	The SOP for quarantining and disposal did not include details of the circumstances when a tissue product should be quarantined or disposed of.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1b	The DI is advised to review the following documents: • The SOP for the receipt of tissue to include details such as the two-person check of product details, batch number and SEC details. • The incident spreadsheet, in consideration of adding a column to highlight whether an incident is reportable as a SAEAR to the HTA. • The procedure for handling and maintaining traceability of tissue products, to include the SEC requirement. • The storage room SOP, as the temperature limits are stated as between 5˚C and 30˚C. However the temperature limits on all tissue products is stated as 15˚C and 30˚C. This SOP should also include the frequency and documenting of the testing of the temperature alarm, the person/people expected to respond and the actions to take in response to the alarm.
2.	GQ1c	The current DI has not participated in governance meetings, which were chaired by the previous DI, who is also the Corporate Licence Holder contact. The DI is advised to attend such meetings and ensure that the minutes of the meetings are documented.
3.	GQ4l	The DI is advised to amend the Donor and Batch release form to include a check for HTLV-1 test results as some sections of the form state that this is not applicable.
4.	GQ7a	The DI is advised to separate the complaints SOP from the SAEARs SOP as the current single document does not clearly separate the two procedures. The DI is also advised to ensure that the agreement with the postal service provider includes a contact number in the event of an issue with the transportation and delivery of a product to an end user.

5.	N/A	In general, the sales team are present when products supplied by the establishment are used. The DI is advised to consider appointing some of the sales team as Persons Designated (PDs) to assist in the reporting of SAEARs.
6.	N/A	The DI is advised to review all documents to ensure they include references to the correct legislation; for example, *the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)*.

Concluding comments

There are a number of areas of practice that require improvement, which resulted in one major shortfall and thirteen minor shortfalls. The major shortfall relates to the requirement for the establishment to ensure that imports from non-EEA states meet the standards of quality and safety set out in Directions 002/2018. The remaining minor shortfalls are related to governance and quality and premises, facilities and equipment.

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: 21 June 2018

Report returned from DI: 2 July 2018

Final report issued: 5 July 2018

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: 22 July 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.
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the 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.
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 002/2018 is included.

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.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased 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.
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.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018.
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 002/2018.
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 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
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 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
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 002/2018.
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 002/2018.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.

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

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 002/2018.

b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.

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.