Site visit inspection report on compliance with HTA minimum standards

Globus Medical UK Ltd

HTA licensing number 22597

Licensed for the

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

01 February 2013

Summary of inspection findings

Globus Medical UK Ltd (the establishment) was subject to a themed inspection. The themes selected for 2012/13 include quality management, contingency planning and risk management. A change to the acellular product being distributed by the establishment made it necessary to review additional standards around testing, transport and storage conditions during the inspection.

Although the HTA found that the establishment had met the majority of the HTA standards, one major and nine minor shortfalls were found, particularly in relation to quality management, donor serology testing, temperature monitoring and audit. Two of the minor shortfalls related to standards GQ4k and GQ7g, which require agreements with end users to ensure that they maintain traceability records and report any SAEARs. One major shortfall was identified against these standards following the previous inspection in 2011. This was addressed by the establishment, to the satisfaction of the HTA within the timescale agreed, by documenting the process for SAEARs reporting and the requirements for end users to record and store traceability data. However, during the recent inspection the HTA found that end user agreements were still not in place, establishment staff had very little knowledge of the documentation previously produced and there was a lack of evidence to confirm that end users have been made aware of the reporting and record keeping requirements.

The HTA found the newly appointed Designated Individual to be suitable in accordance with the requirements of the legislation; however protected time is required to ensure that this individual is able to undertake the role effectively. Whilst the Corporate Licence Holder remains suitable, the corporate licence holder contact unexpectedly left the organisation two weeks prior to the inspection and a replacement had not been found by the time of the inspection.

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.

However, a themed inspection may be carried out at establishments which have been found previously to represent a lower risk. Themes target standards against which the HTA identified common shortfalls across the human application sector in 2011. The themes selected for 2012/13 are outlined in the table below.

Themes	**HTA Standards**
Quality management	
Standard operating procedures for licensed activity	GQ1(b)
Document control system	GQ1(d)
Quality Management System – continuous and systematic improvement	GQ2(a)-(c)
Internal audit system for licensable activities	
Contingency Planning	
Plan to ensure records of traceability are maintained for 10 or 30 years as required.	GQ4(m)
Risk Management	
Procedures for the identification, reporting, investigation and recording of adverse events and reactions	GQ7
Risk assessments	GQ8
Traceability	GQ6

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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 type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
DBM				**E**	**E**	**E**	**E**

Background to the establishment and description of inspection activities undertaken

The establishment is a branch of the American parent company Globus Medical Inc. Globus Medical UK Ltd carries out the import and distribution of demineralised bone matrix (DBM) putty, which is supplied by an American non-profit tissue bank, AlloSource. DBM is supplied to end users in three volumes; 1, 5 and 10cc, for use in orthopaedic surgery. The establishment operates a sale or return policy with a small number of its end users, which means that DBM samples supplied to one organisation may be returned and then redistributed to another end user, providing checks on expiry date and packaging integrity are passed. Samples which have expired or are nearing their expiry date are exported to the parent company for disposal.

This was the second routine inspection of the establishment, the first one having been undertaken in 2011. The previous inspection identified areas of non-compliance with HTA standards, which were reflected in one major and four minor shortfalls. These were addressed by the establishment to the satisfaction of the HTA and subsequently closed. Advice and guidance was provided in two areas, but was found not to have been acted upon.

A themed inspection was carried out this time, comprising a visual inspection of the stock room, interviews with members of staff and review of relevant documentation.

In addition to the standards specified as part of the themed inspection, the HTA focused on standards relating to donor testing requirements, agreements with end users, staff training, records management and agreements with couriers regarding transport conditions. Several of these standards warranted inclusion in the inspection due to the establishment changing their supplier of DBM since the last inspection. The HTA found some shortfalls against meeting these HTA standards and advice has also been provided in a number of areas to assist further improvement.

An audit trail was conducted in relation to the number of 1, 5 and 10cc boxes of DBM putty stored in the stock room compared with the number recorded on the electronic database, a review of the expiry dates of these samples and the records of samples delivered and dispatched to end users. Anomalies were found in the number of products stored, which are

described in more detail under GQ4e. Advice has also been provided regarding products nearing their expiry dates under PFE3d.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. At the time of inspection the named corporate licence holder contact had left the company and a replacement was being sought, see advice provided below.

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 003/2010.	The establishment imports DBM putty from a company based in America. The patient information sheet which accompanies each sample confirms that donors undergo serological tests. However, routine testing for HTLV1/2 is not included and there is no indication of the circumstances under which this testing would be performed, such as if the donor was from an area of high incidence, as required by the Directions 003/2010.	**Major**
GQ1p) 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. GQ7g) 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.	The establishment does not have a written agreement with the end user organisations it distributes to, or provide an information leaflet, that sets out the requirements to store the DBM between 15-30 degrees Celsius prior to use or return to the licensed establishment for re-distribution and the requirement to notify the establishment of any SAEAR within 24 hours.	**Minor**

GQ2 There is a documented system of quality management and audit.		
GQ2a) There is a quality management system which ensures continuous and systematic improvement. GQ8b) 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.	There are a number of organisation-wide SOPs in place, but these have not been reviewed since 2010, which is beyond the yearly review period specified in SOP GQP3; similarly, risk assessments have not been reviewed yearly as specified in GQP24.	**Minor**
b) There is an internal audit system for all licensable activities.	An internal audit has recently been carried out, however no report has been written to record the findings of the audit or any corrective actions that need to be, or have been, carried out. The summary information about what was reviewed during the audit was very brief and it was not clear that all applicable licensable areas had been included.	**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.	No independent audit has been conducted.	**Minor**
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.	Staff attend formal product training and complete on-line training which is recorded, however there is no record of competency-based training against SOPs, particularly in relation to SAEARs reporting, and staff were not familiar with the content of these documents.	**Minor**

GQ4 There is a systematic and planned approach to the management of 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.	The establishment maintains a computer database, which records the total number of each type of product held in stock based on the number received and the number distributed. The HTA carried out a sample audit during the inspection and found that the number of samples in stock for each of the 1cc, 5cc and 10cc volumes of DBM was either one higher or one lower than the number recorded on the database. Since the individual sample batch number is not recorded on the database it was not easy to identify where these discrepancies had occurred and in some cases whether this meant that product had been distributed to the end user and not logged.	**Minor**
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. k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.	Records of the batch number of the DBM and the hospital it was sent to are routinely recorded. Each box of product contains a recipient details sheet, which has to be completed by the hospital staff and sent directly back to Globus Medical in America where it will be kept for 30 years. However, there is no agreement with the hospitals regarding the requirement to complete these sheets, nor is written information provided that the product details must be recorded in the patient file and kept for 30 years. Globus Medical UK Ltd currently has no oversight of how many recipient detail forms are sent to the parent company in America, so any missing records are not being followed up.	**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 risk assessments that have been carried out relate solely to health and safety concerns and do not assess the risks to the quality and safety of the bone product, in particular during transportation and storage both at the licensed establishment and at the end users establishment (if products are distributed on a sale or return basis).	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
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.	The establishment uses a courier to transport the samples to the end user. The samples are usually collected late afternoon and held at the depot overnight before delivery the next day. The establishment does not hold a third party agreement with the courier to ensure transport conditions are appropriate, and information has not been provided to the courier to ensure the samples are always maintained within the 15-30 degrees Celsius storage parameters. During severe weather conditions, it is possible that the samples will be stored outside the temperature parameters for short periods of time. No evidence was available to support the possibility that brief periods of storage outside the required parameters would not adversely affect the product and subsequently the recipient patient.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1c	A meeting is held between the DI and other senior staff involved in the stock management and handling complaints/ incidents on a six monthly basis. The DI is advised to ensure the minutes of this meeting include greater detail of the matters discussed, so that there is a complete record and that staff unable to attend can easily update themselves.
2.	GQ1d	The 'Guidance manual for HTA compliance' contains the issue date but does not include other forms of document control such as review dates and version number, which the DI is advised to add. This document also needs updating as it refers to the 'Fresh check indicator', a label attached to the previous DBM product the establishment distributed which is no longer applicable.
3.	GQ1h / PFE2a	A high level shelf in the stock room is used for the quarantine of non-conforming products but the sign indicating that this was the quarantine shelf was not present at time of inspection. The DI is advised to ensure that this shelf is appropriately labelled so that all staff are aware that these products are not available for onward distribution.

4.	GQ4b	The DI is advised to ensure a regular stock check is carried out against the computer database to ensure all samples are appropriately accounted for and all records are complete and accurate.
5.	PFE3c	The temperature of the area in the stock room where the DBM is stored is recorded every working day. The DI is advised to record the max and min temperatures as well as the current temperature, so that any deviations in temperature, which may occur over the weekend or overnight when the heating in the building is not on, will also be recorded. The DI is further advised to include on the temperature recording form the required temperature range and the action to take if the parameters are exceeded.
6.	PFE3d	During audit of DBM held in stock, one of the samples was found to be within five weeks of its expiry date and some others only had two months shelf life remaining. The DI is advised to keep a systematic record of the expiry date against each individual sample batch number to make stock control more efficient and reduce the risk of a sample being distributed beyond its expiry date.
7.	Licence	The DI is advised to ensure that a replacement is identified for the CLHC role as soon as possible. This individual will be responsible for ensuring the HTA licence fee is paid and should be able to replace the DI if they are not able to fulfil their role; they therefore must have a suitable level of authority to be able to meet these requirements.

Concluding comments

During the inspection of Globus Medical UK Ltd a number of strengths and areas of good practice were noted and examples are given below.

The establishment has a good system of checking the acellular products for packaging integrity and that what has been received matches what was expected. When samples are dispatched with a variety of expiry dates a ‘use this one first’ sticker is placed on the sample with the shortest time to expiry.

Although evidence was provided following the previous inspection to demonstrate that the shortfalls identified had been addressed, there was little evidence of continuous improvement of quality systems since then. Significant changes in licensing personnel as well as the acellular product itself have had an adverse impact on the establishment’s ability to continue to meet HTA standards. The new Designated Individual took up the role shortly before the inspection, and whilst every effort was made on their part to identify and fulfill gaps in compliance, the HTA acknowledges that there was insufficient time to do this in full.

There are a number of areas of practice that require improvement, including (one) major shortfalls and (nine) minor shortfalls. The HTA has given advice to the Designated Individual with respect to replacement of the corporate licence holder contact, meeting minutes, quarantine arrangements, temperature monitoring and regular audit of stock.

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: 27 February 2013

Report returned from DI: No factual accuracy comments received from the DI

Final report issued: 20 March 2013

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

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.
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.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
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.

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

f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.

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

Premises, Facilities and Equipment

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

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

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.