Site visit inspection report on compliance with HTA minimum standards

Edge Medical (Biologics) Ltd

HTA licensing number 22646

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**

29 January 2014

Summary of inspection findings

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

Although the HTA found that Edge Medical (Biologics) Ltd (the establishment) had met the majority of the HTA standards, nine shortfalls were found in relation to Governance and Quality Systems, Premises, Facilities and Equipment, and Disposal. The two major shortfalls relate to the need for robust systems to be in place to ensure that the standards of quality and safety of imported tissues are equivalent to those outlined in Directions 003/2010, and to the need for relevant material to be stored in appropriately monitored conditions that maintain tissue integrity. The remaining minor shortfalls relate to aspects of the establishment's document control system, the content of key standard operating procedures and agreements, and the systems in place for the management of products delivered to end users 'by hand' by staff at the establishment.

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.

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

'SLA' = Service level agreement; another licensed establishment carries out this activity.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
DBM				**E**	**E**	**E**	
Bone chips				**E**	**E**	**E**	
Tendons				**SLA**	**SLA**	**E**	
Meniscus				**SLA**	**SLA**	**E**	
Skin				**SLA**	**SLA**	**E**	

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by Edge Medical (Biologics) Ltd. The establishment is licensed for the storage, distribution and import of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and has been licensed by the HTA since August 2013.

At the time of the inspection, the establishment had entered into agreements with four tissue banks in the USA, each of which were registered with the US Food and Drug Administration (FDA) to process, package, store, label and distribute Human Cells, Tissues, and Cellular

and Tissue-based Products (HCT/P's). All four tissue suppliers were also accredited by the American Association of Tissue Banks (AATB). Under the terms of these agreements, the establishment imports a range of demineralised bone matrix (DBM) products and acellular bone chips. These products are stored securely at ambient temperature in the establishment's premises in Cheadle prior to being distributed to hospitals across the UK for end use. The establishment also imports frozen tendons and femoral heads from its US suppliers. These products are sent directly to another HTA-licensed establishment for cryo-storage prior to being distributed for end use. A service level agreement (SLA) is in place for this activity.

Serology testing of donors is carried out by the US tissue banks in accordance with the requirements of Annex II of Directive 2006/17/EC. This includes the requirement for all donors living in, or originating from, high incidence areas, or with sexual partners originating from those areas, to be tested for HTLV-1.

This report describes the establishment's first site visit inspection which took place on 29th January 2014. The inspection included a review of documentation relevant to the establishment's activities and a visual inspection of the areas of the establishment where licensable activities take place. Due to the limited number of staff currently working under the authority of this licence, formal interviews with key personnel were not performed. However, the Designated Individual was on hand throughout the inspection to answer questions from the inspection team.

An audit of the DBM products and bone chips held in storage at the time of the inspection was performed. Stocks were cross-checked with appropriate records to ensure that the latter contained all relevant documentation and that the information contained therein, such as unique product identification numbers and expiry dates, was accurate. Although the goods received notes, which also capture information on issued stock, had not been updated for three products sent to end users, these discrepancies were resolved using ancillary records. No further discrepancies were found.

At the time of the inspection, the establishment were additionally storing the records and samples from another HTA-licensed premises that had recently ceased carrying out licensable activities. An audit of these samples was also performed. Although the establishment could account for 16 of the 17 transferred samples, one sample that should have been in stock was not present (see below).

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.		
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.	Although many of the establishment's standard operating procedures (SOPs) were subject to document control, certain key documents, such as the document entitled 'Terms and Conditions of Supply', had not been incorporated into the system.	**Minor**
n) The establishment ensures imports from non-EEA states meet the standards of quality and safety set out in Directions 003/2010.	At the time of the inspection, the establishment had not taken sufficient steps to ensure that imports from non-EEA states meet the standards of quality and safety set out in Directions 003/2010. Although the establishment has written agreements in place with each of its US suppliers, these state that it is the responsibility of Edge Medical (Biologics) Ltd to ensure that imported material meets the requirements of EU and UK legislation. Under the terms of the agreements, the supplier is only responsible for providing documentation to enable such an assessment to be made. Despite this, the establishment was unable to provide any evidence that demonstrated that an appropriate due diligence exercise had been undertaken.	**Major**

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.	At the time of the inspection, the DI was unable to produce any temperature monitoring records for the rooms where tissue products are currently being, and had previously been, stored. It was indicated to the inspection team that all the monitoring records had been lost during an office relocation that took place in September 2013. These records contain raw data that evidences the fact that the tissue products are being stored in a way that maintains their quality and safety. As a result, they must be kept for 10 years after the use, expiry date or disposal of the tissues and / or cells.	**Minor**
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
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.	The document entitled 'Terms and Conditions of Supply', which is provided to end users of tissue products distributed by the establishment, does not include the requirement to report SAEARs to the HTA within 24 hours as set out in the "Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment" which forms the Annex to Directions 003/2010.	**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.	Although the establishment has put in place a risk assessment that covers the storage of human tissue products, both in terms of the risks to the samples themselves and to staff involved in the carrying out of licensable activities, the current version of the document does not include consideration of the risks associated with the import/export or distribution of relevant material (see also Advice item 7. below).	**Minor**

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.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	Although tissue samples were being stored in an air-conditioned facility, at the time of the inspection the establishment was neither monitoring nor recording the temperature of the room in which the tissue products were being stored. As a result, they were unable to demonstrate that the tissues were being stored in conditions that maintained their quality and safety. Furthermore, the DI was unable to provide evidence that any such monitoring had taken place since the licence was first issued (see shortfall GQ4h). At the time of the inspection, all of the tissue products being held by the establishment had a stated storage temperature range of 15-30^{o}C. Despite this, the establishment's risk assessment stated that only if the storage conditions for tissue products were to go outside of the temperature range of 5-40^{o}C would a decision be made as to whether samples should be disposed of. The DI was unable to provide evidence that supported the use of these limits for the specific products being stored.	**Major**
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.		
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport. 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. g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.	Despite a significant number of products being delivered directly to end users by staff at the establishment, SOPs on the transport of human tissue did not set out the procedures to follow on such occasions. The risks associated with this method of transportation had not been adequately identified and documented, nor had the critical transport conditions required to maintain the properties of the tissue.	**Minor**

d) Records are kept of transportation and delivery.	At the time of the inspection, a significant number of DBM products were being delivered directly to end users by staff at the establishment. On such occasions, the associated delivery records frequently lacked a signature from a member of staff at the receiving establishment acknowledging receipt of the product(s).	**Minor**

Disposal

Standard	**Inspection findings**	**Level of shortfall**
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.	At the time of the inspection, the establishment was unable to satisfactorily account for one of the products that had been transferred to Edge Medical (Biologics) Ltd from another HTA-licensed organisation that had ceased activities. The inspection team were advised that it had most likely been disposed of by a sales representative who had been using the product for demonstration purposes. However, the establishment was unable to provide any evidence that demonstrated that the product in question had been disposed of in line with the establishment's SOP or in another appropriate manner.	**Minor**

Advice

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

No.	**Standard**	**Advice**
1.	GQ1c	The DI is advised to review the frequency of management review meetings to ensure that it is appropriate for the size of the organisation and the level of licensable activity being performed, both now and in the future. The relevant SOP should be updated accordingly and the revised schedule of meetings adhered to.
2.	GQ1d	The DI is advised to include a 'review by' date on controlled documents to ensure that they are reviewed on a regular basis.
3.	GQ1p	The DI is advised to review the content of the agreement between the establishment and the HTA-licensed premises storing frozen products on its behalf to ensure that it clearly sets out the roles and responsibilities of the two parties in relation to the distribution of such material. As a minimum, the agreement should include sufficient detail to ensure that the transport requirements set out in the 'Guide to Quality and Safety Assurance for Human

		Tissues and Cells for Patient Treatment' are met.
4.	GQ2b and GQ4b	The DI is advised to review the establishment's existing internal audit schedule to ensure that its scope is sufficiently broad to encompass all licensable activities. The audits performed by staff at the establishment should not be restricted to a review of SOPs and policies, but should also include regular reviews of records (for example goods received notes, temperature monitoring logs) and stocks.
5.	GQ4c	The DI is advised to implement a consistent, accepted procedure for correcting errors in written records. Such an approach, which could include striking through errors with a single line and initialling and dating corrections, would facilitate audit. The use of correction fluid within written records should be avoided.
6.	GQ4m	The DI is advised to review the wording of the cessation of business agreement to ensure that records and stocks are transferred to another HTA-licensed premises in the event of the termination of the establishment's activities. References to other requirements as a pre-requisite for the transfer of these items should be removed as they are not consistent with the requirements of the legislation.
7.	GQ8a	The DI is advised to review the format of the establishment's existing risk assessment and to consider whether the use of an appropriate risk matrix would better enable the establishment to identify those areas of working practice that require the implementation of additional control measures. The DI should also consider including a section in the risk assessment template for capturing the need for, and nature of, any further control measures to be actioned.
8.	PFE2a	The DI is advised to review the practice of storing demonstration products alongside products intended for clinical use. Although such products are clearly labelled as 'Not for clinical use', physical segregation of such products would further mitigate the risk of them being issued by mistake.
9.	PFE4i	At the time of the inspection, there was an inconsistent approach to the labelling of imported products, with only approximately half of the products in storage having had stickers detailing the UK distributor added to the packaging. The DI is therefore advised to review the establishment's tissue receipt procedure to ensure that contains clear guidance on when this information should be added to products. This will help reduce the risk of products being issued without the information required by Directions 003/2010.

Concluding comments

Nine areas of practice were identified during the inspection that require improvement, including two major and seven minor shortfalls. These relate to the approach taken by the establishment to ensure that imported products, and those products delivered directly to end users by staff at the establishment, meet the quality and safety standards set out in Directions 003/2010. Systems should also be in place to ensure that the conditions in which tissue products are stored are monitored and that associated records are retained securely for an appropriate period of time. Additional shortfalls were noted in relation to aspects of the establishment's document control system, the scope of their risk assessments, and the need for end user documentation to capture the required timelines for SAEARs reporting.

The HTA has given advice to the Designated Individual with respect to a number of practices and procedures. It is the HTA's expectation that the DI will give due consideration to this

guidance and implement the recommendations wherever practicable. This will not only help the establishment further develop its working practices and governance systems, but also contribute towards ensuring regulatory compliance in the future when evidence of more established governance and quality systems, such as audits and meetings, will be expected.

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: 25 February 2014

Report returned from DI: 11 March 2014

Final report issued: 10 April 2014

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: 11 December 2014

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.
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 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.
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.
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.

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.