Site visit inspection report on compliance with HTA minimum standards

Edge Medical (Biologics) Ltd

HTA licensing number 22646

Licensed for the

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

13 January 2016

Summary of inspection findings

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

The HTA found that Edge Medical (Biologics) Ltd (the establishment) had met the majority of the HTA standards. Minor shortfalls were found in relation to: document control; some documented procedures (the receipt of tissues; the storage of temperature records; SAEARs reporting to the HTA and; the disposal of tissue) and; independent audit against protocols and HTA standards.

While the report was being drafted, the HTA received further information and some revised SOPs from the establishment which demonstrated its proactive approach to addressing the inspection findings. Further information to address the shortfalls will be sought through the CAPA process.

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 (DI) are set out in Section 18 of the Human Tissue Act 2004 ('the HT Act'). 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 licenses 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 HTA-licensed establishment carries out this activity on behalf of this establishment.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Demineralised bone matrix (DBM)	-	-	-	E	E	E	-
Acellular bone chips	-	-	-	E	E	E	-
Femoral heads	-	-	-	SLA	SLA	E	-
Tendons	-	-	-	SLA	SLA	E	-
Meniscus	-	-	-	SLA	SLA	E	-

Background to the establishment and description of inspection activities undertaken

Edge Medical (Biologics) Ltd (the establishment) is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Quality and Safety Regulations 2007) for storage, distribution, import and export of tissues for human application.

The establishment imports cellular and acellular tissues for use in orthopaedic surgical procedures from tissue banks in the United States of America (USA). These tissue banks are licensed by the USA Food and Drug Administration and are accredited by the American Association of Tissue Banks. The tissue banks perform donor selection and serology testing, and the procurement and processing of tissues. The establishment's written agreements with

the tissue banks provide assurance those activities are carried out in accordance with requirements of the European Union Tissues and Cells Directives (EUTCDs).

Edge Medical stores demineralised bone matrix (DBM) and acellular bone chips at ambient temperature. The temperature of the storage cupboard is monitored using an electronic data-logger. Consignments failing checks made on receipt are quarantined and returned to the supplier (refer to shortfall against GQ1g). The establishment has a service level agreement (SLA) with another licensed establishment to store frozen tissues on its behalf prior to distribution to end users. Those tissues are sent from Edge Medical directly to that other licensed establishment. Edge Medical can also arrange for shipment of frozen tissues from a tissue bank directly to an end user.

End users consist mainly of NHS and private hospitals in the UK. Documentation sent with the tissues informs end users they must maintain traceability records for 30 years, and report a suspected serious adverse event or adverse reaction (SAEAR) to the establishment within 24 hours of discovery.

Edge Medical has been licensed by the HTA since August 2013. The HTA inspects establishments licensed under the Quality and Safety Regulations 2007 every two years. A routine site visit inspection took place in January 2014. In 2015, the establishment re-located to new premises near Manchester Airport. This report describes the second, routine, site visit inspection, and the first on the new premises. The inspectors met with staff, reviewed documentation and visually inspected the premises. Audits of records were carried out in relation to:

- two units of frozen tissue that had been disposed of;
- storage of all DBM products at the establishment;
- storage of one size of bone chips at the establishment;
- processing of two orders for frozen tissue;
- tissue bank documentation for two donors.

Two anomalies were found. The number of boxes listed on the inventory for one size of DBM syringe did not match the number of units stored. Staff were aware of this discrepancy and explained the inventory was to be updated following recent changes to an order. Also, the expiry date for another size of DBM syringe had not been transcribed to the inventory (refer to advice item 10).

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.	The 'Documentation Control' standard operating procedure (SOP reference EMB009) does not define a review period for key quality documents such as SOPs or risk assessments. Also, review dates are not printed on any documents, presenting a risk that staff might refer to an out of date version. *(While the report was being drafted the DI submitted an updated version of SOP EMB009 stating quality documents will be replaced from 30 April 2016 and subsequently be reviewed every two years. Further evidence to demonstrate the shortfall has been addressed will be requested through the CAPA process)*	**Minor**

g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	SOPs for receipt of tissue shipments and accompanying documentation contain insufficient detail on the checks that must be undertaken: • the 'Direct shipments' SOP (reference EMB019) does not specify the product information which must be verified by the client or end user upon receipt of frozen tissue, for example: that the tissue type and identification number are correct; donor serology testing results are negative, and; that the tissue is within its expiry date; • receipt checks of tissues delivered to the establishment include the product reference number, lot number and expiry date. However, these are not specified in the 'Standard Operating Procedure' SOP (reference EMB024) for receipting procedures. *(Refer to advice item 3)* *(While the report was being drafted, the DI submitted a revised version of SOP EMB019 that clarifies the checks to be undertaken of tissues and documentation. Further evidence to demonstrate the shortfall has been addressed will be requested through the CAPA process)*	**Minor**
GQ2 There is a documented system of quality management and audit.		
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.	An independent audit to verify compliance with protocols and HTA standards has not taken place since the establishment was granted an HTA licence in August 2013. *(While the report was being drafted, the DI outlined proposals for an independent audit to take place in March 2016. Further evidence to demonstrate the shortfall has been addressed will be requested through the CAPA process)*	**Minor**
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.	It is an EUTCD requirement that raw data critical to the quality and safety of tissues are kept for ten years after their use, expiry date or disposal. However, the 'Handling, storage and packaging' SOP (reference EMB022) states written temperature records for the storage cupboard will be retained 'for future reference'. This SOP needs to state the ten-year timeframe.	**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 'Serious adverse event or serious adverse reaction' SOP (reference EMB026) contains inaccuracies: • the hyperlink to the HTA's website does not work; • the page on the HTA's website from which a SAEAR notification can be made has changed, but the SOP refers to the previous webpage; • the SOP refers to the first version of the HTA 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment', published in November 2010. The HTA published a second version of this document in June 2015. *(Refer to advice item 11)* *(While the report was being drafted, the DI submitted a revised version of SOP EMB026 in which the hyperlink to the HTA's website had been removed, and the second version of the 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment' was cited. Further evidence to demonstrate the shortfall has been addressed will be requested through the CAPA process)*	**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.	The 'Disposal and destruction' SOP (reference EMB027) does not state that the date, method and reason for disposal of tissues must be recorded. This SOP also does not refer to use of the 'Product destruction form' to record the disposal of tissue.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1b	The 'Handling, storage and packaging' SOP (reference EMB022) quotes the optimal product storage temperature range as stated on the product insert (15-30 ^{o}C). The 'Rejected goods' SOP (reference EMB023) quotes a wider temperature range that has been validated by the manufacturer (0-40 ^{o}C). The DI is advised to state the temperature range from the product insert in the 'Rejected goods' SOP. *(While the report was being drafted, the DI submitted a revised version of SOP EMB023 stating the 15-30 ^{o}C optimal storage temperature range.)*
2.	GQ1d	The date of issue of the 'Standard operating procedure' SOP (reference EMB024) pre-dates granting of the licence in August 2013. This appears to be a typographical error. The DI is advised to put the correct issue date on this SOP.
3.	GQ1g	The DI is advised to liaise with the establishment which stores frozen tissue on its behalf under an SLA to ensure that its SOP for tissue receipt provides detailed instruction on the information to be verified for every shipment.
4.	GQ1h	The DI is advised to give examples of what would be a non-conforming product in the 'Control of non-conforming product' SOP (reference EMB021), for example: • if a product's outer packaging is compromised; • an incorrect unit of tissue is received, or; • tissue is received that is beyond its expiry date.
5.	GQ2a	The DI is advised to ensure the establishment's licensing number appears correctly in the 'Quality Manual', 'Definitions' and 'Standard operating procedure' documents (reference numbers EMB001, EMB004 and EMB024).
6.	GQ2b	The DI regularly audits SOPs to ensure these adequately describe current practice. However, an audit in September 2015 failed to identify numerous instances where SOPs are incorrect or insufficiently detailed, as set out elsewhere in this HTA inspection report. The DI is advised that a more objective review would be achieved if SOPs were audited by persons who do not routinely carry out those activities.
7.	GQ3e	The DI is advised to keep attendance records of training sessions for sales representatives. The DI is also advised to keep records to verify sales representatives have read key documents such as SOPs relevant to their role.
8.	GQ4a	The DI is advised to review storage arrangements for traceability records. A recent incident involving these records has highlighted the need to strengthen local arrangements for their storage.
9.	GQ4m	The DI is advised that the agreement in place with another establishment in the event of termination of licensable activities should state the establishment's new address, and clarify that only tissue traceability records and raw data critical to the quality and safety of tissues and cells need to be transferred.
10.	GQ6b	The DI is advised to correct stock inventory records as soon as an error or anomaly is identified.

11.	GQ7 a	The DI is advised that the second version of the 'Guide to quality and safety assurance for human tissues and cells for patient treatment', published in June 2015, is available at: https://www.hta.gov.uk/sites/default/files/Guide%20to%20Quality%20and%20Safety%20Assurance%20for%20Tissues%20and%20Cells%20for%20Patient%20Treatment.pdf SAEARs reporting is described on pages 39 and 40.
12.	D2	Some units of tissue received from another licensed establishment remain in quarantine storage pending disposal, as these are beyond their expiry date. The DI is advised to ensure these tissues are disposed of promptly to avoid the inadvertent risk of them being distributed to end users.

Concluding comments

A number of areas of practice require improvement, including six minor shortfalls. The HTA has given advice to the DI with respect to governance and quality systems, and disposal of tissue. While the report was being drafted, the establishment provided additional information and some revised SOPs to HTA, which partially address some of the inspection's findings. This demonstrates a proactive approach to meeting HTA licensing standards. Further information to fully address all of the shortfalls will be sought through the CAPA process.

The HTA requires that the DI 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: 08 February 2016

Report returned from DI: 29 February 2016

Final report issued: 1 March 2016

Completion of corrective and preventative actions (CAPA) plan

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

Date: 15/07/2016

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.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
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.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
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.
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.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken

and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
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.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
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.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.

c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.