Site visit inspection report on compliance with HTA minimum standards

JnJ Medical

HTA licensing number 22647

Licensed for the

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

13-14 February 2019

Summary of inspection findings

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

Although the HTA found that JnJ Medical (the establishment) had met many of the HTA's standards, seven minor shortfalls were found in relation to: the absence of a current third party agreement with the courier service; the absence of an internal audit covering all licensable activities; the absence of regular independent audit; the absence of documented requirements for the retention of raw data; the absence of documented requirements for the retention of traceability records; the absence of a documented plan for contingency storage of records and; a lack of availability of risk assessments, for staff, for HTA-licensed activities.

Advice has been given relating to the Governance and Quality, and Premises, Facilities and Equipment standards.

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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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 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.

Tissue Category; Tissue Type	Storage	Distribution
Musculoskeletal, Bone; Acellular Bone	**E**	**TPA**
Musculoskeletal, Bone; Cancellous and Cortical Bone Particles	**E**	**TPA**
Musculoskeletal, Bone; DBM	**E**	**TPA**
Musculoskeletal, Bone; DBM Putty	**E**	**TPA**

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by JnJ Medical (the establishment), which was issued an HTA licence in October 2013. This was the third HTA site visit inspection of the establishment (the last inspection was in January 2017) and the first since the amended Human Tissue (Quality and Safety for Human Application) Regulations 2007 came into force on 1 April 2018 [Q&S Regulations (as amended)]. The current inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards.

The establishment is the UK subsidiary of the DePuy Synthes Companies, part of the Johnson & Johnson organisation. It supplies a range of products to orthopaedic departments within hospitals in the UK.

JnJ Medical is licensed under the Q&S Regulations (as amended) for the storage and distribution of tissues and cells for human application and has a quality management system that is compliant with International Organization for Standardization (ISO) standard 13485: 2016.

The DI is the establishment's Customer and Logistics Services (CLS) UK Quality and Compliance Manager, the Corporate Licence Holder (CLH) is the DePuy Companies and the CLH Contact (CLHC) is a CLS MD Operations Senior Manager. There are two Persons Designated (PDs) working under the licence, a Regulatory Affairs Specialist and the Distribution Quality Assurance Business Unit Leader.

The establishment receives tissue from the Dutch arm of the organisation. The Dutch company imports products from a supplier in the United States of America (USA) and is regulated by the Dutch competent authority. The donor can be identified by the 'material number', used by the US supplier, on each product label. Upon receipt, the Dutch company applies the Single European Code (SEC) to each product. Distribution of products within Europe, including the UK, is by international courier under the terms of an agreement with the Dutch company. Tissues distributed to the UK include demineralised bone matrix (DBM), DBM putty, bone particles (separately cortical and cancellous) and anterior cervical fusion (ACF) spacers.

Product Receipt

Upon receipt, the establishment carries out a quality control (integrity) check of each shipment to confirm receipt of the correct consignment and that packaging is undamaged. Products failing to meet acceptance criteria are quarantined in a dedicated inventory cage and returned to the Dutch company using the contracted courier. The quarantine area also includes products which have exceeded their expiry date.

Products are tracked using the material number and a unique individual 'batch number' provided by the US supplier, which ensure full traceability back to the original donor. All products received are logged onto the establishment's electronic database.

Storage

The site is a secure facility that houses the establishment's offices and product storage area. There is electronic access control.

Products are stored under controlled ambient temperature conditions. Temperatures are continuously monitored and recorded on a daily basis using maximum/minimum thermometers.

Distribution

Products are distributed to end users using a separate courier working under the terms of a third party agreement [TPA; see shortfall against standard GQ1(p)]. Distribution is carried out using the terms and conditions on the invoice as the end user agreement. The products are accompanied by documentation which includes information on the reporting of serious adverse events and adverse reactions (SAEARs) to the establishment and on the requirement to store traceability data (see *Advice*, item 5). Delivery is tracked by the courier, with all delivery and dispatch notes retained on file at the establishment.

Products not required by the end user are returned to the establishment (see *Advice*, item 2).

Disposal

The establishment does not dispose of any products but returns them to the Dutch company for disposal.

Contingency

There is a documented plan for the management of products in the event of termination of activities but no plan for the contingency storage of records [see shortfall against standard GQ4(m)].

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection report, communications with the HTA since the last inspection and annual activity data. The inspection included a visual inspection of the product storage area and the area for product receipt and distribution, the packing area and the quarantine area. Discussions and interviews were held with key staff and documentation was reviewed. Interviews were held with the DI, CLHC, both PDs and the establishment's external Senior Quality Assurance/Risk Assessment consultant in the Netherlands.

Audits of traceability were carried out:

- Three acellular products (two ACF spacers and one DBM putty product) were selected at random from the storage bins. Labelling details, details of order, receipt, release and return (of one product), and product location were checked on the electronic database. There were no discrepancies noted.
- The training records of four representative members of staff who handled the products were also checked. No discrepancies were noted.

Inspection findings

The HTA found the DI and the CLH 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.		
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.	During the inspection, the establishment was unable to provide evidence of an up-to-date TPA with the courier distributing products to end users. See *Advice*, item 1.	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	The establishment performs regular checks to ensure that the inventory of acellular products matches records in the tissue register and on the electronic database. In addition, the establishment performs regular audits against the ISO 13485: 2016 standards. However, neither of these constitutes an assessment of compliance against the full range of applicable standards under the Q&S Regulations (as amended).	**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.	Although a self-assessment compliance report has been completed and reviewed by the external consultant, there has been no independent audit carried out against the full range of applicable standards under the Q&S Regulations (as amended).	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.	There is currently no documented requirement to retain raw data for 10 years.	**Minor**
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.	There is currently no documented requirement to retain traceability data from donor to recipient for 30 years.	**Minor**

m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.	There is no documented plan for the contingency storage of records of traceability and raw data in the event of termination of activities.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
c) Staff can access risk assessments and are made aware of local hazards at training.	Although there are risk assessments, these are not currently available to staff. ***Prior to the final report being issued, the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**Minor** ***The HTA now considers this standard to be fully met.***

Advice

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

No.	Standard	Advice
1.	GQ1(p)	When formulating the new TPA with the courier, the DI is advised to ensure that there is: (i) a formal obligation for the third party to inform the establishment within 24 hours in the event of a serious adverse event or reaction (SAEAR) taking place which could impact on the quality or safety of the product being transported; (ii) an inclusion of references to the Q&S Regulations (as amended).
2.	GQ1(k)	The establishment has a documented checklist to assess products returned from end users and their suitability for re-issue. The DI is advised to consider including a risk assessment for inappropriate storage by the end user as part of the documented checklist.
3.	GQ2(a)	The Quality Manual is currently written against the ISO 13485: 2016 standards. The DI is advised to consider adding references to the HTA standards as an Appendix.
4.	GQ3(f)	The DI is advised to consider incorporating the relevant parts of the 'Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment' as part of the establishment's current regulatory training programme. In addition, the DI is advised to consider including examples of SAEARs and the requirement to report SAEARs to the HTA within 24 hours of discovery.
5.	GQ4(k)	The DI is advised to consider adding the requirement to include the SEC label in the patient's notes as part of the end user agreement, to ensure full traceability from receipt to end use.
6.	GQ6(d)	During the inspection, it was noted that a small number of products had been received by the establishment in January 2018, then issued and returned.

		These products did not contain the SEC label. DI is advised to refer to the 'HTA guidance on coding and import regulations for tissues and cells in the human application sector' (page 9) covering the SEC requirements for products placed into storage before 1 April 2018.
7.	PFE2(c)	The DI is advised to ensure that cleaning staff are working to a documented procedure and schedule and that full records of shelf cleaning are kept.

Concluding comments

During the inspection, areas of strength and good practice were noted:

- There is a good working relationship and a comprehensive and effective system of communication between the establishment and the external consultant. The CLHC visits the Dutch company and the external consultant on a regular basis.
- Staff are formally trained to ISO 13485: 2016 standards on British Standards Institute courses before they are deemed competent to carry out internal audits.

There are a number of areas of practice that require improvement, including seven minor shortfalls. The DI has worked proactively to address one of the shortfalls before submission of the final report and this is reflected in the report. The HTA has given advice to the DI with respect to the Governance and Quality, and Premises, Facilities and Equipment standards.

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: 14 March 2019

Report returned from DI: 20 March 2019

Final report issued: 17 April 2019

Completion of corrective and preventative actions (CAPA) plan

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

Date: 14 May 2020

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
C2 Information about the consent process is provided and in a variety of formats.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
k) There is a procedure for handling returned products.

l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 002/2018.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.

i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.

c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
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 002/2018.
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 002/2018.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.

c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to 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 represents a systemic failure and therefore is 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 straight away.

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 the proposed action plan the establishment will be notified of the follow-up approach the HTA will take.