

Licence application assessment visit report on compliance with HTA licensing standards

University of Birmingham

HTA reference number 22672

Establishment to be licensed for the

- **procurement, processing, testing and storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

11 Dec 2018

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 the University of Birmingham (the establishment) had met the majority of the HTA standards, there were four minor shortfalls identified where current practices were non-compliant with the HTA licensing standards. These were found in relation to the Governance and Quality and Premises, Facilities and Equipment standards. The shortfalls relate to the contingency plans for storage of tissue, and the maintenance of records, in the event of termination of activities, reporting of Serious Adverse Events and Reactions, risk assessments, and the validation of transport containers.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of the licence 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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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.

Proposed licensable activities to be 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	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Ovarian Tissue	TPA	E	TPA	E			

Background to the establishment and description of inspection activities undertaken

This report describes the licence application assessment visit of the University of Birmingham (the establishment) Advanced Therapies Facility. The establishment applied for a licence for the procurement, processing, testing and storage of ovarian tissue under the Human Tissue

(Quality and Safety for Human Application) Regulations 2007 (as amended) (the Q&S Regulations) for human application and for the storage of relevant material which has come from a human body for use for a scheduled purpose under the Human Tissue Act 2004. Procurement and testing of the ovarian tissues and cells will be undertaken by another establishment under a third party agreement (TPA).

While the establishment has performed some initial process validation using animal and human research material they propose to perform a formal validation of the tissue preservation process which will be transferred from a collaborating scientist in Europe. The aim of this site visit was to provide an assurance that the current facilities were suitable for the procurement, processing, testing and storage of tissue, to allow further validation of the transferred process to proceed utilising a clinical patient cohort.

Patient eligibility will be confirmed, and consent taken, by another establishment, under a TPA. The other establishment will also procure the ovarian tissue. Once transferred to the University of Birmingham the tissue will be processed and stored in accordance with all applicable HTA standards.

Once licensed the establishment will ensure that all equipment used for the collection, processing and storage of human tissues and cells is maintained and, where appropriate, is temperature-monitored and alarmed using their existing systems. The establishment will ensure that all records pertaining to the quality and safety of the tissues and cells are retained for the required time periods as set out in Directions 002/2018.

Patients will be accepted based on pre-defined clinical criteria and will be consented by the third party establishment in accordance with the requirements defined in the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. After procurement by the third party establishment, the tissue will be transferred to the establishment for processing in their clean room suite. Processed tissues and cells will be accepted for storage based on defined acceptance criteria. Tissue will only be stored for autologous use and, after cryopreservation, tissue will be stored in a quarantine liquid nitrogen dewar prior to transfer to a locked -150°C freezer for long term storage.

Description of inspection activities undertaken

As part of the licence application process, the proposed DI submitted documentation relating to storage policies, contingency arrangements, risk assessments and draft agreements prior to the site visit. The documentation was reviewed and it was deemed necessary to undertake a site visit to better understand the establishment's practices to support the activities that will take place under the licence.

The site assessment visit included discussions with senior establishment staff, staff who will be working under the licence, a review of documentation relevant to the establishment's proposed licensable activities, and a visual inspection of the facility. The visual inspection included a tour of the clean room suite, where processing of tissue will be undertaken, areas for the storage of reagents and consumables, and the area where processed tissue will be cryopreserved and stored. The establishment currently undertakes research activities under the remit of a HTA Research licence, and propose to process clinical tissue in a clean room which is currently used to manufacture GMP-grade products for MHRA approved clinical trials. The proposed DI was unavailable during the site visit but a telephone discussion was

undertaken subsequent to the site visit.

Inspection findings

The HTA found the proposed Designated Individual and the proposed 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.		
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.	The establishment currently have no contingency plan in place for the transfer of stored tissue and cells to another HTA licensed establishment, or for the continued maintenance of records of traceability, in the event of termination of activities. The proposed DI should ensure that these contingency plans are developed and in place, with immediate effect once the HTA licence has been granted.	Minor
GQ7 There are systems to ensure that all adverse events are investigated promptly.		
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	The establishment has a defined policy for reporting and investigating non-conformances and deviations. However, this policy does not specifically include a process to ensure that Serious Adverse Events and Reactions are reported to the HTA within the required 24 hour time frame.	Minor

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
<p>a) There are documented risk assessments for all practices and processes.</p> <p>And</p> <p>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.</p>	<p>The establishment risk assessments do not cover all proposed practices and processes or address the risks specifically related to the tissue and cells (e.g. loss of tissue if a storage freezer fails) rather than risks to the individuals associated with the process.</p> <p>The current process is for the establishment to review risk assessments every two years.</p>	Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination.		
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.	The process for transporting procured material from the third party establishment to the establishment for processing has been partially validated. The proposed DI must ensure that the transport process and container are adequately validated.	Minor

Advice

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

No.	Standard	Advice
1.	GQ1p	The establishment has provided a draft Third Party Agreement for the procurement and testing of tissue. The proposed DI should ensure this agreement is finalised and signed once the HTA licence has been granted and prior to any tissue being procured for processing under the licence.
2.	GQ1r	<p>The establishment has plans to offer services to a third party establishment. A draft agreement was provided and the proposed DI should ensure that this agreement clearly describes the responsibilities for each party as set out in Directions 002/2018, pertaining, for example, to the:</p> <ul style="list-style-type: none"> reporting of serious adverse event and reactions (SAEAR)

		<ul style="list-style-type: none"> • retention of traceability records and raw data, • acceptance and rejection of tissues and cells, • auditing of third parties; and • licensing arrangements for the release of the tissue and any associated future distribution.
3.	GQ2b and GQ2c	The establishment undertake regular audits of their facility and governance systems. The proposed DI should ensure that once the licence is granted the internal audit schedule is amended to include audits of all licensable activities, and to ensure that there is a an independent audit against the HTA licensing standards.
4.	PFE3a	The establishment stores ambient consumables within two temperature-monitored store rooms. The two store rooms have different acceptable temperature ranges. The proposed DI is advised to review this storage arrangement and ensure the temperature ranges are appropriate for the ambient consumables stored within each room, and consider if it would be possible to standardise the temperature range in the two rooms.
5.	PFE5k	<p>The establishment plan to cryopreserve tissue using a controlled-rate freezer (CRF). The proposed DI is advised to develop a contingency plan for accessing an alternative CRF, or develop an alternative freezing protocol, that may be used in the event the CRF breaks down.</p> <p>In addition, the DI is advised to develop a process to follow should the CRF fail during a cryopreservation run.</p>
6.	N/A	The proposed DI is advised to review all documents to ensure that they refer to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and Directions 002/2018 which have superseded Directions 003/2010.

Concluding comments

The establishment holds a MHRA Manufacturer's Licence and maintains a GMP compliant clean room suite which will be used for processing tissue. The room is well organised with strict access control and good oversight of environmental, pressure, and temperature monitoring. With regular maintenance and servicing of the suite, including a printed daily record of all monitoring systems, maintained in real time, there is an assurance that the suite is fit for purpose on the day it is used.

There are a number of areas of practice that require improvement, to become compliant with the HTA licensing standards, and these have resulted in four minor shortfalls related to contingency plans for continued storage of tissues, and maintenance of records, in the event the establishment ceased licensable activities, processes for reporting Serious Adverse Events and Reactions to the HTA, risk assessments and the validation of the process for transport of material from the third part procurement establishment to the processing facility. There were several other areas of practice that may benefit from further improvement and the HTA has provided advice to the proposed Designated Individual with respect to these.

The HTA has assessed the establishment as suitable to be licensed for the activities specified; procurement, processing, testing and storage Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the storage of relevant material which has

come from a human body for use for a scheduled purpose, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the site visit.

Report sent to DI for factual accuracy: 11 January 2019

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 18 January 2019

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 is included.
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.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

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.
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.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.

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

f) There are procedures to ensure that donor documentation, as specified by Directions 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 002/2018.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 002/2018.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
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.
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.
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.