Site visit inspection report on compliance with HTA minimum standards

Gartnavel General Hospital

HTA licensing number 11065

Licensed for the

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

23 and 24 April 2013

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.

Gartnavel General Hospital (the establishment) was found to have met all HTA standards. Some advice has been provided in relation to review of agreements with third parties, audits, environmental monitoring and quality documentation.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

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 type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
PBSC	**TPA/E**	**E**	**TPA**	**E**	**E**		
DLI	**TPA**	**E**	**TPA**	**E**	**E**		
Cord Blood	**E**	**E**	**TPA**	**E**	**E**		
Bone Marrow	**E**	**E**	**TPA**	**E**	**E**		

Background to the establishment and description of inspection activities undertaken

Peripheral blood stem cells (PBSCs) and donor lymphocytes for infusion (DLI) are procured by apheresis at two sites: the establishment's satellite site at the Schiehallion Unit of the Royal Hospital for Sick Children, and at the Beatson West of Scotland Cancer Centre, on the Gartnavel site, under the terms of a Third Party Agreement (TPA) with the Scottish National Blood Transfusion Service (SNBTS). Staff at the satellite site procure bone marrow from children and also procure directed cord blood donations at three maternity hospitals under TPAs with those hospitals.

Processing and storage activities are undertaken at the stem cell laboratory and cryostore at the hub site. Mandatory testing is carried out under a Third Party Agreement (TPA) with SNBTS and microbiology testing is carried out by Greater Glasgow and Clyde Health Board.

The establishment has entered into SLAs with bone marrow registries, governing the provision of bone marrow and PBSC harvests from matching unrelated donors for patient treatment.

Trained medical or nursing staff at the procurement sites take consent for donation of stem cells, bone marrow and cord blood. Procured cells are transported by SNBTS couriers using validated cool boxes to the hub site where processing takes place in a dedicated laboratory clean room.

Blood samples for mandatory virology testing are taken during the 30 days prior to donation or at donation, in accordance with regulatory requirements, depending on whether procured cells are to be used immediately or processed for longer term storage.

Processing of stem cells takes place in a Class II microbiological safety cabinet (MSC), where cryoprotectant is added. If cells are to be stored, the bags containing processed cells are sealed and transferred to the storage area located in the hospital, where they undergo controlled rate freezing followed by storage in the vapour phase of liquid nitrogen within monitored and alarmed storage vessels.

Processing of bone marrow also takes place within the laboratory, and processed cells are either returned for use or placed into storage as appropriate.

Each donation is assigned a unique ISBT (International society for blood transfusion) barcoded number with label sets being provided by SNBTS. Microbiology in-process monitoring takes place using settle plates which are kept in the MSC and on the work surfaces in the laboratory where processing takes place. Glove prints are taken at the end of each processing session. In-process particle monitors are used during critical processing steps.

All products are tested for bacterial contamination prior to freezing. Results from environmental monitoring and microbiology testing are evaluated, and non-conformances are discussed during regular governance meetings.

The inspection was the third HTA inspection of the establishment. The previous inspection was carried out in April 2011 and the shortfalls identified, relating to process validation, risk assessment and environmental monitoring, were addressed in advance of publication of the finalised inspection report.

This was a routine, scheduled, inspection. A visual inspection of the hub and satellite sites was carried out, including the processing laboratory and cell storage facility at the hub, the nearby SNBTS apheresis suite used for procurement of PBSCs from adults, and the out-patients department, ward, theatre and laboratory at the satellite.

A review of quality documentation was carried out, including the quality manual, governance policy, policy and procedural documents, record forms and process documentation retained both in full patient files and in local shadow files containing documentation only related to the transplant activity.

Eight sets of patient records were reviewed to confirm the presence of signed consent forms, traceability records, virology results and processing records. In addition, environmental monitoring records were reviewed as were incident reports, staff training records, equipment validation and maintenance records, records of concessionary release of cells, risk assessments and audit records.

The HTA chose not to audit cells held in storage in the liquid nitrogen vessels in light of the potential risk of thermal shock damage to bags containing cells, and also having noted that the establishment had recorded a discovered error in storage location as a reported incident. Advice has been provided in relation to how storage may be audited as part of the process of storage and removal of processed cells.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ1p	As Third Part Agreements (TPAs) must meet specific requirements in relation to the way licensable activities are carried out and, in particular, to how serious adverse events or reactions are reported, the DI is advised to consider, when reviewing existing agreements entered into with other individuals or establishments, whether these should take the form of Service Level Agreements or Third Party Agreements. In particular, the DI should consider how the agreement with SNBTS in Edinburgh, relating to bone marrow procurement, is structured when it is up for review. By doing so each party will be aware of the licence under which activity is being carried out, which will assist in the accurate reporting and investigation of any serious adverse event or reaction.
2.	GQ2b	The HTA noted that staffing shortages have impacted compliance with the establishment's quality procedures (see GQ3k below), in particular that no audits of laboratory processes were carried out in 2012. The HTA also noted that there is a schedule of audits for 2013, and various audits have been carried out already this year. However, there is some concern that on-going staff pressures may continue to affect the carrying out of audits. The DI is advised to incorporate on-going audit of the cryostore storage tanks into the procedures used by staff when placing bags of cells into storage or retrieving cells for use. By doing so, any systemic failures in traceability or storage procedures may be identified at an early stage.
3.	GQ3k	The HTA noted that various elements of the establishment's quality procedure, including the carrying out of scheduled audits, risk assessment review and disposal of cells stored for long periods, have been delayed or are at risk of not being carried out as a result of staff being fully occupied in carrying out processing work. The DI is advised to consider whether the current staffing levels allow staff sufficient time to carry out transplant-related processing as well as governance-related work required to meet regulatory requirements, and to keep staffing levels under review. By reviewing staffing levels and ensuring that sufficient trained staff are available to carry out all aspects of licensed activity, including those related to compliance with HTA and other regulatory standards, he will minimise the risk of non-compliance with regulatory requirements potentially affecting the ability of the establishment to carry out licensed activities.

4.	GQ4a	The DI is advised to remind staff of the need to initial and date deletions, amendments or other handwritten changes made to documents in order that the person making the change can be identified and an audit trail is maintained.
5.	GQ4b	The HTA noted that no audit schedule was in place for 2012 and only limited audits were carried out because of staffing pressures. The establishment has an audit schedule for 2013 and some audits have been carried out already, but the HTA notes the concerns of establishment staff that transplant-related work pressures may impact negatively on their ability to carry out planned audits, which may then lead to non-compliance with regulatory requirements. The HTA advises the DI to review progress on audit and related governance work periodically, in order to identify whether the existing staffing level is allowing work to be completed as scheduled. The DI is also advised to ensure that the potential risk of regulatory non-compliance resulting from staffing pressures is recorded on the establishment's risk register to ensure that factors influencing this are subject to on-going review.
6.	GQ7a	The DI is advised to consider, when next reviewing the "Circular of Information for Administration of Haemopoietic Stem Cells" document (BMT 300 002 02), whether the HTA definitions of Serious Adverse Event and Serious Adverse Reactions should be incorporated. This may assist clinical staff involved in procurement or use of cells in deciding what incidents need to be reported to the DI, for onward reporting to the HTA.
7.	PFE2b	The DI is advised to review the scope of monitoring that is currently carried out in the MSC and in the background environment, with particular reference to the variety of settle plates used in each location, to ensure optimal environmental monitoring. The DI is also advised to consider what corrective actions should be put in place when an environmental monitoring alert limit is reached, and how that action is documented.
8.	PFE2d	The DI is advised to monitor the wearing of mob caps by staff involved in processing of cells to ensure that these are being worn consistently, as required by Eudralex Annex 1. The DI is further advised to amend the processing SOP to detail the requirement to wear a mob cap, in order that staff are reminded of this requirement and so that failure to do so is recorded as a non-conformance in the relevant processing records.
9.	PFE5b	The DI is advised to ensure that the service contract for the Planar controlled rate freezers is included in any overall equipment maintenance contract when it is next reviewed.
10.	N/A	The DI is advised to inform the HTA whether the licensed activity of Import/Export is required by the establishment as the HTA noted that no import or export activity has taken place.

Concluding comments

The HTA saw various examples of good practice during the inspection. At the hub and satellite, activities are carried out by experienced staff and there are quality managers in place with specific responsibilities for the quality systems used at each site.

There appears to be good communication between staff at the processing laboratory with those involved in the clinical areas of procurement and transplant, and the HTA noted that staff involved in all aspects of the licensed activity take part in planning and multi-disciplinary team meetings, which helps to ensure a linked approach to patient treatment and related cellular processing.

Consent for donation is dealt with by trained medical or nursing staff, and patients and families are provided with detailed information on the risks and benefits of proposed treatments, also being given ample opportunity to ask questions and consider information before signing consent forms.

Risk assessments have been carried out and, in particular, the risks associated with collection of directed cord blood donations at maternity hospitals have been well considered and documented. In particular, a decision has been taken that this activity is carried out only by two paediatric specialist doctors and agreements have been entered into with named maternity units.

The establishment uses local processing files containing copies of relevant forms, records and documents related solely to the processing activity, with copies held in the principal patient record, therefore allowing staff easy access to relevant information, even when the principal medical record for the patient is elsewhere in the hospital.

The HTA noted the concerns of the DI and staff involved in the licensed activity that recent changes to staffing levels have resulted in planned activities relating to quality management (in particular audit) and the licensed activity (specifically on-going disposal of cells which have been stored for longer periods and which may no longer be required) being delayed or not carried out.

The HTA has given advice to the Designated Individual with respect to this and in relation to agreements, audits, some elements of governance documentation, and clean room clothing procedures.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 15 May 2013

Report returned from DI: 22 May 2013

Final report issued: 22 May 2013

Appendix 1: HTA standards

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

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

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.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
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 003/2010 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 003/2010 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 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.
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.
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.