Site visit inspection report on compliance with HTA minimum standards

Welsh Blood Service

HTA licensing number 22497

Licensed for the

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

9-10 May 2017

Summary of inspection findings

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

Although the HTA found that the Welsh Blood Service (the establishment) had met the majority of the HTA standards, three shortfalls were found related to the absence of procedures to ensure the integrity and safety of products for end use, critical transport conditions for products and oversight of activities at the third party premise.

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**
BM	**TPA**		**E**		**E**	**TPA**	**E**
Cells for DLI	**TPA**		**E**		**E**	**TPA**	**E**

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the Welsh Blood Service (WBS). The establishment is licensed for procurement, testing, distribution and import/export of tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulation 2007. This was a routine site visit to assess whether the establishment is continuing to meet the required HTA standards.

The establishment is a division of the Velindre NHS Trust and is the main volunteer blood collection centre for South, Mid and West Wales. WBS is responsible for providing donor serological testing for all stem cell products whilst the Welsh Transplantation and Immunotherapies Laboratory (WTAIL), which is a part of the establishment, performs histocompatibility testing. The Welsh Bone Marrow Donor Registry (WBMDR) is a section of WTAIL and along with three other national registries forms the NHS Aligned Stem Cell Registry which operates worldwide. Only volunteer blood donors registered on WBS are recruited onto WBMDR. The head of WTAIL is the Designated Individual (DI) on the HTA licence and WBMDR operate under the same governance and management systems as the establishment.

WBMDR oversees the recruitment, selection, medical assessment, mandatory serological testing and confirmatory blood typing of potential stem cell donors. Upon matching with a recipient, the donor undergoes a 'work-up' process where the donor is re-assessed for consent and fitness to donate. Blood samples are taken for mandatory serological marker

testing within 30 days prior to harvest. Blood and bone marrow harvests are performed at a collection centre at a nearby hospital under a TPA. All equipment and reagents used for the procurement process are provided and maintained by WBMDR. Following procurement, trained staff from WBMDR will transport the stem cell product from the collection centre to the establishment and perform a final two-person release check, ensuring that the integrity of packaging, donor identifiers, donor consent, quality tests and serological results are in order prior to distribution to the transplant centres. Transport of the fresh stem cell products to transplant centres within the UK is carried out by a national courier company under an agreement with the establishment. Transport of stem cell products to transplant centres located internationally is arranged by the individual transplant centre receiving the stem cell product, who takes responsibility for ensuring the quality and safety of the cells during transport under appropriate agreement terms with the WBS.

All initial donor screening for mandatory serological markers is performed at the establishment. In the 'work-up' process, the donor is re-tested for mandatory serological markers and further NAT tested for HIV, HCV and HBV. Additional requested tests, including serological testing for HTLV I/II, and confirmatory testing is performed by another HTA-licensed establishment.

The inspection included interviews with the Designated Individual (DI) who is also the Head of the WTAIL, discussions with the head of WBMDR and key members of staff involved in procurement, testing and quality management. The inspection also comprised visual inspections of two sites – the first, the collection centre where the stem cells are procured, sampled and packed; and the main establishment site, where donor testing is performed and where the products are cleared for release. Audits included a review of four donor clinical notes – two for peripheral blood stem cell collection and two for bone marrow harvest. Minor discrepancies were noted relating to the consistency of records filed and record-keeping in transport forms used for courier collection.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	During the inspection it was found that the labels for the bone marrow stem cell product incorrectly stated storage temperatures between 2-25°C, which is not in line with the establishment's validated temperature range of between 2-10°C.	**Minor**
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	There is insufficient oversight of licensable activities at the third party. While the establishment performs audits of activities at the collection centre, the audit failed to reveal several deficiencies relating to documented protocols, training records, risk assessments of processes and premises, procedures for reporting serious adverse events and reactions (SAEARs) and schedules for decontamination of critical equipment. (See advice items 1, 6, 8, 12 and 13)	**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.		
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.	Although the establishment has performed validations on the transport box looking at time and temperatures in transit, there is no defined criteria for transport conditions of stem cell products.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1b	The DI is advised to review all standard operating procedures (SOPs), including SOPs at the third party collection site, to ensure they include sufficient information to carry out procedures to assure the integrity of tissues and cells. This includes, for example: • the SOP for 'Packing of HPC product' which should include the practice of acclimatising the bag for 30 minutes with the lid open prior to packing of the stem cell product to prevent a sudden change in temperature; and • the SOP for 'Collection of HPC Product' which should include details of which laboratory checks to assess prior to placing the donor on the machine and the range of acceptable results. This SOP should also be reviewed by staff performing the procedures to ensure the documented steps are up-to-date with current practices. The amended SOPs should be disseminated to all staff working under the licence, and be included in the staff training programmes.
2.	GQ1b	Stem cell blood products are labelled for storage at 2-6°C. However this is inconsistent with the establishment's validated conditons of between 2-10°C. The DI is advised to review all labels and forms in use to ensure they are accurate and consistent.
3.	GQ2b	The DI is advised to consider adding a checklist in the front of each donor folder which contains donor documentation. During an audit of donor files, the HTA team found that not all files were complete as some forms were missing and transport collection forms were incomplete. The checklist would also represent a mini audit looking at donor consent, testing, procurement, quality tests and transport of each collection individually.
4.	GQ2b	Following internal audits, major non-conformances are logged as an incident. These are followed up by the quality assurance team and suitable action plans are carried out by relevant staff. However, there are no actions and closures for minor discrepancies found during audits. The DI is advised to ensure all non-conformances are investigated and resolved appropriately.
5.	GQ2d	Following collection of stem cells, the collection centre adds a fixed volume of autologous plasma to all products using a closed system. This is performed without prior knowledge of cell counts and is added to collections which may not require dilution, as they may not be stored for long periods prior to transplant. In addition, the extra step may introduce a risk of contamination. The DI is advised to risk assess the addition of plasma as a standard procedure to all stem cell blood products without prior knowledge of cell count or whether storage prior to transport is required. The risk assessment should consider any risks associated with the additional step in sample handling.

6.	GQ7a	The TPA with the collection centre stipulates the requirement for local SAEARs to be reported to the DI, and on to the HTA within 24 hours. However there are no documented procedures at the collection centre for reporting and escalating an incident. The DI is advised to ensure a SOP is available for staff at the third party premise to follow, which clearly defines the roles and responsibilities of personnel investigating and reporting such events, so the HTA can be informed within the 24 hours from the point of dicsovery.
7.	GQ8a	The DI is advised to ensure that risk assessments are reviewed annually to ensure their continued suitability.
8.	PFE1a	While there are procedures in place at the third party premises to mitigate the risks related to security, overnight storage of collections and contamination during sampling have not been assessed. The DI should ensure all premises risk assessments relating to the third party are formally documented and that these are disseminated to staff to support training.
9.	PFE4e	The DI is advised to consider the value of the temperature request box on the prescription form in the context of the service being offered.
10.	PFE4e/g	The DI is advised to either record the time the stem cell product is placed into the transport box or train staff to set the temperature logger to start recording when they place the stem cell product in the box. This will enable the establishment to determine the temperature within the box during transport and help determine if the product was transported under suitable conditions. The HTA understands that data loggers used to record temperatures during transport are programmed to start recording temperatures at 9am on the day of procurement. Temperature loggers are placed in the box along with the stem cell product, once procurement and release checks are completed, which can occur at any time in the day. Since the establishment does not currently record when the transport box is packed and the temperature loggers start continuously recording temperature after 9am, it is difficult to determine the temperature of the stem cell unit during transport. The inspection team noted that transplant centres do, however, record the time when they receive the product.
11.	PFE5f	The DI should ensure the equipment used for docking and sealing at the third party premised is regularly cleaned and decontaminated as part of the maintenance schedule.
12.	GQ4k/PFE3a	Reagents used for harvests are stored at a separate pharmacy department and temperatures are monitored by pharmacy staff. The DI should ensure that the agreement with the collection centre stipulates that staff at the third party have oversight over reagent storage conditions as any deviations in in temperatures may have an impact on licensable activities. The DI should also ensure that the agreement includes retention of temperature data relating to reagent storage for 10 years in line with Directions 003/2010.
13.	-	The DI is advised to update the establishment's quality manual to refer to the HTA's new Codes of Practice.

Concluding comments

There are three areas of practice that require improvement, resulting in minor shortfalls. These relate to the absence of procedures to identify incorrect temperature noted on labels attached to bone marrow harvests, oversight of activities at the third party and absence of defined transport conditions. The HTA has given advice to the Designated Individual with respect to reviewing documented protocols, audits, premises risk assessments, transport conditions, temperature criteria for products in transit and records for maintenance of critical equipment and reagents.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 7 June 2017

Report returned from DI: 21 June 2017

Final report issued: 22 June 2017

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: 30 November 2017

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.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.

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

f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.

GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
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.

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.