Site visit inspection report on compliance with HTA minimum standards

Royal Stoke University Hospital

HTA licensing number 22593

Licensed for the

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

04 October 2017

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 Royal Stoke University Hospital (the establishment) had met the majority of the HTA standards, seven minor shortfalls were found in relation to the Governance and Quality System standards and the Premises, Facilities and Equipment standards. The minor shortfalls relate to the internal and independent audits, the retention of raw data for 10 years, the reporting of serious adverse events and reactions, the risk assessments, the storage of reagents and the cleaning of critical equipment.

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.

SLA" = Service level agreement; another licensed establishment carries out the activity on behalf of the establishment.

'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
Progenitor Cell, Hematopoietic, PBSC; **PBSC**	**E**	**SLA**	**SLA**	**SLA**	**TPA**		

Background to the establishment and description of inspection activities undertaken

Royal Stoke University Hospital has been licensed by the HTA since 2009. The HTA licence includes the procurement and distribution of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The licensable activities undertaken at this establishment relate to peripheral blood stem cell (PBSC) collections procured for autologous patient treatment. The licensable activities of testing, processing and storage are undertaken by another HTA licensed establishment under the terms of a service level agreement (SLA).

In addition to the HTA licence, the establishment holds JACIE (Joint Accreditation Committee-International Society for Cellular Therapy (Europe) and European Group for Blood and Marrow Transplantation) accreditation for stem cell procurement and transplantation. The last JACIE inspection was in 2017.

The establishment undertakes approximately 50 PBSC procurements and performs approximately 35 transplants per year. Consultants undertake donor assessment and seek consent for the procurement of PBSCs from autologous donors within the haematology and oncology departments of the establishment. Consent discussions also include the provision of appropriate patient information.

Donor blood samples are taken no longer than 30 days prior to the day of harvest. On the day of the procurement, donors are monitored to ensure that the target CD34 counts are reached. PBSC procurement is undertaken by apheresis nurses who confirm the identity of the patient against their medical records. Each collection is assigned a unique code, which ensures traceability from procurement through to processing, storage, distribution and end-use or disposal. The labels with the unique code are provided by the licensed establishment undertaking the processing of the PBSCs.

Procured cells, once harvested, are transported via a pre-arranged courier to the other licensed establishment for processing and storage. Cryopreserved cells for transplantation are returned to the establishment upon request, the transport of which is the responsibility of the other licensed establishment.

The establishment has recently acquired a second apheresis machine and there is also a third one available within the Renal department, as a back-up. The establishment has also other contingency arrangements for the provision of services with another HTA-licensed establishment, if required. The apheresis machines are cleaned between procedures, but this is not recorded in a cleaning log (*minor shortfall PFE5f*).

Apheresis kits are stored in a secure, designated area and the anticoagulant Acid-Citrate-Dextrose Formula A (ACD-A) is stored in a temperature-monitored cabinet. The thermometer used to record the temperatures, within the cabinet, has a minimum and maximum temperature function, but it only stores the temperatures for a 24-hour period. The apheresis nurses undertake daily temperature monitoring and record these details Monday to Friday (*minor shortfall, PFE3a*).

This report describes the establishment's fifth routine inspection, which took place on 4 October 2017. Discussions were held with key members of staff involved in the licensable activities. A review of documentation relevant to the establishment's activities and a visual inspection of the premises, where tissue procurement takes place, the apheresis room and storage areas containing the ACD-A, were also included as part of the inspection.

An audit was performed on three sets of patient records. The audit covered the referral form, signed consent for donation form and the consent for testing, storage and discard of stem cells, the stem cell collection checklist, batch number and expiry of consumables used during apheresis, the serology results, the final report of donation and processing, receipt of delivery and request for issue. The following information, where applicable, was cross-referenced

against each of these documents: donor name, date of birth, unique harvest number and hospital number. Traceability was maintained throughout, but there were a few discrepancies identified in the accompanying documentation (*advice item 5*).

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
GQ2 There is a documented system of quality management and audit.		
b) There is an internal audit system for all licensable activities.	Internal audits are carried out that include the consent forms and record keeping, the stem cell donor screening policy and collection data. However, the scope of the audits was limited and did not cover the full range of activities carried out under the licence.	**Minor**
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.	The establishment has not conducted an independent audit to verify compliance with all applicable HTA standards since the last site visit.	**Minor**
GQ4 There is a systematic and planned approach to the management of records.		
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.	The establishment has a policy for the retention of records. However, staff were not able to provide the assurance that raw data, such as temperature records were being retained for 10 years after the use, expiry date or disposal of cells.	**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.	A review of the incident records revealed three occasions when the incident should have been reported as a Serious Adverse Events and Serious Reactions (SAEARs) to the HTA within 24 hours of discovery.	**Minor**
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.	Although the establishment has carried out a number of risk assessments, they were limited in scope and did not adequately capture all of the risks associated with the activities being carried out under the licence or the full range of control measures that are in place.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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.	The anticoagulant ACD-A is stored in a cabinet with a minimum and maximum temperature range of 15-30˚C. The manufacturer recommends a storage temperature of 15-25˚C. A review of the temperature records indicated an occasion, where temperatures over 25˚C were recorded. This deviation was not identified nor appropriate action was taken to establish what impact, if any, this excursion had on the quality and safety of the product. Furthermore, the thermometer used by the establishment stores the temperature data for a period of 24 hours only. Establishment staff monitor and document the temperature during working hours on Monday to Friday only. There is no provision for reviewing and recording temperatures over the weekend and bank holidays and as a result, there is a risk that any deviations that take place over the weekend may go unnoticed. **Prior to the end of the inspection, the DI proposed to move the ACD-A to a temperature controlled room, which is monitored, with immediate effect.**	**Minor** **The HTA has assessed this information as satisfactory and considers this standard to be met.**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	Although the establishment staff regularly clean the apheresis equipment before and after use, this is not recorded.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1d	The DI is advised to review the establishments' standard operating procedures (SOPs) to ensure they include up-to-date references to the new HTA Codes of Practice and Standards. The DI is advised to update the SOPs to reflect that the establishment currently has two apheresis machines and how they plan to rotate their use.
2.	GQ1s	The DI is advised to review the new agreement with the transport provider to ensure it includes the requirement for third parties to report SAEARs to the establishment within 24 hours of discovery.
3.	GQ2b,c	With reference to the above shortfalls, the DI is advised to formalise and record the processes involved in internal and independent audits in an SOP. This will ensure that new and existing members of staff are consistent in their approach to audits. The establishment periodically carries out audits of consent forms and records. The audit report produced gives a summary for the completion of the consent forms, but does not clarify or provide context for the results. Clarity on how this audit is performed will assure the DI of its rigour, and enable other staff to perform such audits in the future. The results of all audit findings, and actions taken, should be formally recorded and discussed at governance meetings, to ensure continuing improvement of processes and practices. The DI is also advised to schedule the independent audit to occur in the intervening year between HTA inspections.
4.	GQ2d	The establishment annually re-validates the transportation boxes to ensure they continue to achieve the intended results. The DI is advised to put identifiers on the boxes. This will enable the establishment to identify the boxes used to transport PBSCs and to track their performance over the years.
5.	GQ3e	The establishment provides training of new staff and refresher training to existing members of staff. The DI is advised to ensure all staff rotate on the apheresis and re-infusion procedures to maintain their skills and competency and that this is reflected in the establishment's records.
6.	GQ4b	A number of discrepancies were noted during the audit of the establishment's patient forms. Examples include: • the Apheresis procedural checklist was not always included in the patient records. • the date when the Apheresis procedural checklist was completed was not always circled in. The DI is advised to to ensure that all records are completed accurately.

7.	GQ7c	Current practice is that SAEARs can only be reported by the DI. The DI is advised to appoint at least one other member of staff as persons designate (PD) who could report SAEARs to the HTA in the DI's absence and to ensure that they have access to the HTA's Portal for this purpose.
8.	PFE3d	Current practice is for the establishment to store the PBMCs indefinitely, unless the donor is deceased in which case the establishment storing the unit will be notified and asked to dispose of the relevant units. The DI is advised to document this procedure in an SOP.

Concluding comments

The HTA observed a number of good practices during the course of the inspection. All staff involved in the licensable activities function well together as a team under the DI to provide a well-organised and coordinated service for patients. The team constantly strives to improve their practices as exemplified by the prompt action to address the shortfall related to the storage of ACD-A.

Seven areas of practice were identified during the inspection that require improvement, each resulting in minor shortfalls. The HTA has also given advice to the DI with respect to updating the SOPs, reviewing the agreements, the audits of the establishments' patient records, the internal and independent audits, SAEARs reporting and staff training.

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: 2017/10/23

Report returned from DI: 2017/11/06

Final report issued: 2017/11/28

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: 2019/03/06

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
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.
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.
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.
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.
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
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.