

**Site visit inspection report on performance against HTA quality standards  
St George's Healthcare NHS Trust  
HTA licensing number 12462**

**Licensed for the**

- **procurement, testing, storage, and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, and the**
- **storage of relevant material which has come from a human body for use for a scheduled purpose other than transplantation under the Human Tissue Act 2004**

**2 November 2011**

**Executive Summary**

A site visit inspection of St George's Healthcare NHS Trust (the establishment) was carried out by the HTA on 2 November 2011.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Some shortfalls were found, particularly in relation to consent and governance and quality systems. Particular examples of strengths or good practice are included in the concluding comments section of the report.

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.

All reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

## **Background to the establishment and description of inspection activities undertaken**

St George's Healthcare Trust carries out the procurement and distribution of peripheral blood stem cells obtained either through apheresis or bone marrow harvest. The establishment also purchases and stores frozen femoral heads, strut grafts, tendons and ligaments for use in orthopaedic surgery as and when required, and stores skin samples in a refrigerator for potential use in surgery. In the majority of cases these are stored for less than 48 hours and then disposed of, however occasionally the samples are stored for longer under the authority of their licence.

This was the third routine inspection of the establishment; the previous ones having been undertaken in 2009 and 2007.

The inspection comprised a visual inspection of the outpatient wards where apheresis is undertaken and the areas within the theatres where the tissues are kept in frozen and refrigerated storage; interviews with members of staff and review of relevant documentation.

Audit trails were conducted on the frozen bone samples using records of what had been ordered, received and logged into the freezer storage book and if subsequently used, the details contained in the patient's notes. The samples currently stored within the freezer were compared with the freezer storage records. Only small anomalies were found in the expected delivery date versus the date the tissue was actually received. Since it was only the expected delivery date that was erroneous in a couple of cases this is not considered a shortfall, but advice has been given against GQ6b below.

An audit of records of the cells collected at apheresis was also undertaken. This included the records of collection, the transfer of the cells to another licensed establishment for processing, testing and storage, subsequent transfer back to the establishment and reinfusion in the patient. No anomalies were found.

No skin samples were being stored on site at the time of the inspection, which was reflected in the storage records. However, where records indicated that skin had been stored for more than 48 hours shortfalls were identified (see C1a and GQ5b).

## **Meeting the HTA's licensing standards**

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

**Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed.** A template for this purpose is provided as a separate Word document.

Please see Appendix 2: Human Application standards, to view all human application standards. Standards which do not apply to this licence are highlighted in Appendix 2.

## HTA standards not met

### Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code 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, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice.	<p>There is no formal record of consent to the mandatory blood tests (except HIV) for PBSC and skin procurement.</p> <p>Consent to mandatory blood tests for PBSC patients is routinely taken verbally, but is not recorded on the consent form, other than HIV consent which the establishment document, but was not viewed during the inspection. Recording the consent to blood tests ensures there is an unequivocal account that testing has been discussed with the donor so that they are fully informed about infections that could be detected, otherwise consent would not be valid.</p> <p>The establishment do not intend to store skin for more than 48 hours, however on the occasions when skin has been stored for more than 48 hours there is no record of consent to the mandatory serology tests.</p>	<b>Major</b>
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.	The patient information sheet for procurement and use of PBSCs does not mention that tests for syphilis will be carried out as part of the serology testing.	<b>Minor</b>

## 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.		
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.	<p>There is a procedure that indicates if skin is stored for more than 48 hours then serology tests should be completed, however this procedure has been deviated from on a small number of occasions.</p> <p><b>Minor shortfall</b></p>	<b>Major</b>
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
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.	<p>Serology tests have not been carried out on the small number of skin samples that have been stored for autologous use for more than 48 hours and subsequently disposed of.</p> <p><b>Minor shortfall</b></p> <p>Serology testing as set out in Annex B of Directive 2006/17/EC is a legal requirement to ensure the safety of the tissues and cells and puts the patient receiving the tissue at risk if these have not been undertaken. The findings under GQ1h and GQ5b have accumulated to a major shortfall.</p>	

## Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	C1d	The same consent form is used for infusion of PBSCs as the one labelled for bone marrow transplant. The DI is advised to ensure that the form used to record consent is correctly titled to avoid confusing the patients completing the form and also members of staff who may review the records in the future.
2.	GQ1h	The establishment uses the lower shelf of the fridge for skin storage as a quarantine area. However, the DI is advised to label this shelf as quarantine to ensure it is clear to all members of staff that use the fridge. In addition, the DI is advised to develop a documented procedure on how the quarantine area should be used if there is more than one skin sample stored in the fridge at the same time, either without the results of serological tests, or infected with different infectious diseases.
3.	GQ6b	The DI is advised to accurately record the expected delivery date when samples are ordered, so that if the samples do not arrive when expected this can be followed up straight away.
4.	PFEc/i	The DI is advised to display on the fridge the normal working temperature parameters, the action to be taken and details of the person to contact should it be discovered to be outside this range. This will allow any member of staff working in this area to report the temperature deviation.
5.	D1a	The DI is advised to amend procedures so that the date and time skin samples are disposed of is recorded to make it clear exactly how long the tissue has been stored for. If serology tests have not been undertaken, disposal must occur within 48hours of collection.
6.	D2a	The DI is advised to record the reason for disposal of skin samples, so it is clear if the sample was unsuitable for use for any reason or simply not required.

## Concluding comments

During the inspection of St Georges Healthcare NHS Trust, two major and one minor shortfall were identified by the inspection team. Advice has also been provided to the DI in several areas.

A number of strengths and areas of good practice were also noted and examples are given below.

Having treated several patients that were positive for Hepatitis E, the establishment has decided to include Hepatitis E testing in addition to the mandatory serology tests for all PBSC donors in order to monitor the prevalence of this disease.

To ensure the records of transport of PBSCs are both clearly documented and enable the receiving establishment to confirm delivery has occurred within a suitable timeframe, a system has been developed whereby the time the cells leave the establishment is recorded on the outer label along with the time of receipt at the processing establishment and vice versa for when the cells are returned. These labels are then attached to relevant pages in the patient's records once the cells have been reinfused.

All staff have received training on use of the new apheresis machines purchased a year ago. Furthermore, before decommissioning the old apheresis machines, the establishment is undertaking a process of validation of the new machines to ensure the yield of PBSCs they attain (along with the other blood components they use the machines for) are the same or greater than previously achieved to prevent an adverse impact on patient treatment.

In general, the establishment has good governance systems, written procedures are document controlled, with regular audits of processes and records undertaken. The fridges and freezers used for tissue storage are well monitored and maintained.

**Report sent to DI for factual accuracy: 23/11/11**

**Report returned from DI: 24/11/11**

**Final report issued: 20/12/11**

#### **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: 11 July 2012**

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## Appendix 1: HTA inspection process

The Human Tissue Authority (HTA) regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

The HTA is also the designated Competent Authority for the purposes of the European Union Tissue and Cells Directives (the Directives) so far as they relate to tissues and cells for use in human application (using tissues and cells for patient treatment). On 5 July 2007 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations) came into force. The Regulations formally transposed the Directives into UK law. Under the Regulations the HTA regulates and licences the procurement, testing, processing, storage, distribution, import or export of tissues or cells intended for human application. The HTA has produced detailed Directions to complement the implementation of the Directives.

As part of the regulatory framework, the HTA licenses establishments and undertakes inspections to assess compliance with expected standards.

### Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity;
- the conditions of the licence are met;
- the conditions of third party agreements are met; and
- the information and confidentiality requirements set down in the Regulations are complied with.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

## Appendix 2: HTA Standards

Standards which are not applicable to this establishment have been highlighted.

### 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.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased 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.
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

<b>Standard</b>
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.

d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
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 3: Classification of the level of shortfall

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, which individually do not pose a direct risk of harm to a recipient or living donor, 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 or 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/or cells.

### **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 at the time of the next inspection.

## **Follow up actions**

A template corrective and preventative action plan is available as a separate Word document. 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.