



## **Site visit inspection report on compliance with HTA minimum 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**

**20 August 2015**

### **Summary of inspection findings**

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

Although the HTA found that St George's Healthcare NHS Trust ("the establishment") had met the majority of the HTA's licensing standards, two minor shortfalls were identified in relation to completion of consent forms and temperature monitoring. The HTA has also given advice to the Designated Individual on consent, audits, sample traceability, document control, temperature control and staff training.

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.

'E\*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'SLA' = Service level agreement; another licenced 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 type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
PBSC	E	SLA	E	SLA	TPA		
Bone Marrow	E*	SLA*	E*	SLA*	TPA*		

<b>Bone and tendons</b>				<b>E</b>			
<b>Skin</b>	<b>E</b>		<b>E*</b>	<b>E*</b>			
<b>Arteries / Veins</b>	<b>E</b>		<b>E*</b>	<b>E*</b>			

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

St George's Healthcare Trust carries out the procurement, testing and distribution of peripheral blood stem cells obtained through apheresis. Donor consent and testing is carried out at the establishment, while processing and storage takes place at a different HTA licensed establishment under a Service Level Agreement (SLA). The establishment also purchases and stores frozen femoral heads, strut grafts, tendons and ligaments for use in orthopaedic surgery, as and when required. In the past, the establishment procured and stored skin and vessel/artery samples for longer than 48 hours, in a refrigerator, for potential use in surgery. Storage of cellular material for longer than 48 hours is a licensable activity that falls within the remit of the HTA. This material is not however currently stored for longer than 48 hours and the establishment is in the process of evaluating whether this activity may be required in the future.

This was the fifth routine inspection of the establishment, the last one having been undertaken in October 2013.

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; as well as interviews with members of staff and a review of relevant documentation.

Audit trails were conducted on the frozen bone and tendon samples using records of what had been ordered, received and logged into the freezer storage book. The samples currently stored within the freezer were compared with the freezer storage records. No anomalies were found.

An audit of records of the cells collected at apheresis was also undertaken. This included the records of donor consent, cell collection, the transfer of the cells to another licensed establishment for processing and storage, subsequent transfer back to the establishment and reinfusion into the patient. One anomaly was found, where the original consent form included ticks to indicate that the patient had given their informed consent and signed the form, while the carbon copy only included the donor's signature but not the ticks. In addition, the signature of the apheresis nurse seeking consent and confirming that information had been explained to the patient was present on the original, but not on the carbon copy of the consent form (see shortfall under C1e).

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 one shortfall was identified, as the patient consent form had not been filled in indicating that consent might not have been taken (see shortfall under C1e). No vessel/artery samples were being stored on site at the time of the inspection. Records for two patients

receiving vessel material in the past were audited during the inspection. No anomalies were found.

### 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

#### 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.		
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.	Several anomalies were identified during the audit of consent forms as part of the inspection. One anomaly was found where the original consent form included ticks to indicate that the patient had given their informed consent and signed the form, while the carbon copy only included the donor's signature but not the ticks. In addition, the signature of the apheresis nurse seeking consent and confirming that information had been explained to the patient was present on the original, but not on the carbon copy of the consent form. Another anomaly was identified where records indicated that skin had been stored for more than 48 hours but the patient consent form had not been filled in. The establishment was therefore not able to formally demonstrate that consent for storage was obtained.	<b>Minor</b>

### Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	Although temperature is monitored at two points during the day in the room where ACD-A is stored, minimum and maximum temperatures of the room are not recorded. The DI needs to implement a system to monitor the upper and lower temperatures in this area to ensure that the room temperature does not exceed the upper and lower limits set by the manufacturer of the product. If the temperature is found to exceed these limits, the establishment should seek guidance from the manufacturer on the stability of the product and to carry out a risk assessment of the storage conditions. In addition, the establishment has stopped recording minimum and maximum temperatures in the freezer used to store bone and tendon material since May 2015. The DI should reinstate these recordings, to ensure that material is kept at optimal temperature at all times.	<b>Minor</b>

### Advice

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

No.	Standard	Advice
1.	C1d/GQ1d	There are currently two versions of the consent form for HPC transplant, which are both in circulation. One version of the form has had the question about mandatory serology testing removed. The establishment is advised to select the version of the form they plan to use and remove the other version from circulation, in order to maintain record consistency.
2.	C3a	In light of the findings of the internal audits and the audit carried out during the inspection, the DI is advised to further develop the training provided to members of staff seeking consent, to ensure that information is accurately captured and consent forms are filled in appropriately.
3.	GQ1b	The DI is advised to finalise the decision on whether skin and artery/vessel samples will be stored beyond 48 hours, and update the documentation accordingly and as soon as possible. The current documentation does not contain adequate information on licensing requirements when material is stored for longer than 48 hours.
4.	GQ1c	Governance meetings covering information relevant to the licence have recently been reinstated. The establishment is encouraged to continue holding these meetings on a regular basis and ensure that minutes are taken and are made

		available to all relevant members of staff.
5.	GQ2b/ GQ4b	During the last three annual audits, the establishment has found that the ability to identify the healthcare professional responsible for consent needs to be improved. As progress has not been made in this area over three consecutive years, the establishment should prioritise this matter, identifying and implementing the actions that need to be taken to address the issue.
6.	GQ4a	Although the establishment's log sheets for bone and tendon material include hand-written comments about samples being returned to the freezer if unused, there are no clear procedures in place and the forms do not include fields to ensure that this information is captured in a consistent manner. The DI is advised to develop the appropriate documentation to ensure that all information is recorded appropriately and a process is implemented for the management of material that is returned to the freezer when not used.
7.	GQ4b	The establishment is advised to review and update HTA-related information available on the intranet, as several links have been found to be incorrect and some of the information was out of date. This will ensure that relevant information is readily available to members of staff.
8.	GQ4c	The current form used to record traceability information on skin samples is not fully updated at times, with information on the person responsible for procurement missing on several occasions. The DI should ensure that all staff are recording information appropriately, particularly as it is not currently easy to assess that staff involved in the procurement of skin samples have received appropriate training.
9.	GQ8d	The establishment has recently undertaken a number of self-assessment compliance exercises which have identified several areas of improvement required. The establishment is advised to update current SOPs and risk assessments to reflect the findings of these exercises and ensure that all documentation reflects current practices. Any agreed action identified should be assigned and time bound in order to formalise the process and ensure that changes are implemented in a timely manner.
10.	N/A	The DI and CLHc are advised to consider appointing Persons Designated to assist the DI in her role and ensure that any serious adverse events or reactions can be reported and investigated in her absence.

### Concluding comments

During the inspection of St George's Healthcare NHS Trust, two minor shortfalls were identified by the inspection team in relation to completion of consent forms and temperature monitoring. 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.

Online tests are used to assess whether staff have obtained the necessary knowledge required for activities they undertake as part of their posts. Staff are dedicated to patient care and use up-to-date equipment to increase comfort for the patients. Throughout the organisation there was a clear commitment to further continuous improvement. This was evidenced, in part, by the use of ultrasound equipment for siting of apheresis lines. The

establishment has also achieved JACIE accreditation, which further verifies the establishment's strength in patient care.

The HTA requires that the DI 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 shortfall identified during the inspection.

**Report sent to DI for factual accuracy: 14 September 2015**

**Report returned from DI: 29 September 2015**

**Final report issued: 7 October 2015**

**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: 29 January 2016**

## Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not currently applicable to this establishment are shown in grey text.

### 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.
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.
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.
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.
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

<b>Standard</b>
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.

## 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.