

**Site visit inspection report on performance against HTA quality standards  
Salisbury NHS Foundation Trust  
HTA licensing number 11102**

**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**

**26 July 2011**

**Executive Summary**

A site-visit inspection of Salisbury NHS Foundation Trust (the establishment) was carried out by the HTA on 26 July 2011.

The establishment was found to meet many of the HTA standards across the four areas of: consent (C); governance and quality systems (GQS); premises, facilities and equipment (PFE); and disposal (D). Minor shortfalls were found in relation to some of the C, GQS and PFE standards; pages 3 - 5 give further details. Examples of strengths and good practice are included in the concluding comments section of the report.

The HTA found the Designated Individual, the Licence Holder (Salisbury NHS Foundation Trust), the premises and the practices to be suitable in accordance with the requirements of the legislation.

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

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

This report refers to the activities carried out by Salisbury NHS Foundation Trust (the establishment). This was the third routine site-visit inspection of the establishment by the HTA since it was issued an HTA licence in 2006.

The establishment runs a haematopoietic stem cell transplant programme, which includes procurement of peripheral blood stem cells (PBSCs) for autologous transplant at the establishment. In 2010, the establishment procured two PBSC units. The establishment carried out three autologous PBSC transplants during that time.

Procured cells are transported by courier to NHS Blood and Transplant – Stem Cell and Immunotherapies Unit (NHSBT – SCI) Southampton for processing and storage. There is a Service Level Agreement (SLA) in place with NHSBT – SCI Southampton (HTA licensing number 11053) and a third party agreement in place with the courier service.

Serological and microbiological sample testing is carried out by an external organisation, which is not licensed by the HTA. There is no formal third party agreement (TPA) with this organisation.

An agreement is in place with Royal Bournemouth and Christchurch NHS Foundation Trust (HTA licensing number 11129) both for the re-provision of service in an emergency and as a contingency for equipment failure.

The site-visit inspection included the visual inspection of the clinical areas, the consenting rooms and the re-furnished apheresis suite. The suite contains one apheresis machine. This will be replaced with a new machine in October. Interviews were conducted with the Designated Individual (DI), the Deputy Director of Nursing (who is the Corporate Licence Holder contact) and the two Persons Designated.

A vertical traceability audit was carried out from consent in patient notes through to distribution, return and transplantation for three patients. All samples were fully traceable.

### **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 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.		
d) Consent forms comply with the HTA Codes of Practice.	There are some inconsistencies in documentation for the consenting process. For example, the Trust 'Patient agreement form for autologous stem cell transplantation' is beyond its review date and there is a duplication error on the final page of some of the forms.	Minor

### Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and/or cells and minimise the risk of contamination.	There are some inconsistencies in the quality management documentation.  Inconsistencies in internal references within documents were observed. For example, one Standard Operating Procedure (SOP) had an annex of NHSBT – SCI Southampton attached, rather than the listed Trust document.	Minor
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.	Non-conforming consignments (e.g. broken bags upon arrival, samples with low CD34 counts) are returned to NHSBT – SCI Southampton for disposal. This is not documented in an SOP on the management of non-conforming consignments, however.	Minor
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.	There is no formalised TPA with the organisation which performs serological testing for the establishment.	Minor
t) There are procedures for the re-	An informal agreement is in place with Royal Bournemouth and Christchurch NHS	Minor

provision of service in an emergency.	Foundation Trust (HTA licensing number 11129) for the re-provision of service in an emergency. However, this has not been formalised into an SLA.	
GQ4 There is a systematic and planned approach to the management of records.	This standard is assessed under the sub-standards below.	
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.	The Trust policy 'Access to Health Records' and the Departmental SOP on record retention do not include the specific transplant record retention requirements as specified by Directions 003/2010.	<b>Minor</b>
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.	There is no formalised contingency plan in place with a licensed establishment.	<b>Minor</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.	There is no formalised TPA with the organisation which performs serological testing for the establishment.	<b>Minor</b>
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.	Events that would fulfill the HTA definitions of serious adverse events and reactions are not included in the Trust policy as being reportable to the HTA.	<b>Minor</b>
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.	There is a mismatch between the Trust policy and the Departmental SOP in the reporting time of serious adverse events or reactions to the HTA.	<b>Minor</b>
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.	The adverse incident SOP does not explicitly include procedures to identify and decide the fate of cells affected by an adverse event, reaction or deviation.	<b>Minor</b>
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		

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.	Although risk assessments of licensable activities are available there is no evidence that they are reviewed on a regular basis.	<b>Minor</b>
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### Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
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.	A risk assessment of the re-furnished apheresis suite has not yet been completed.	<b>Minor</b>
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
k) There are contingency plans for equipment failure.	An informal agreement is in place with Royal Bournemouth and Christchurch NHS Foundation Trust (HTA licensing number 11129) as a contingency for equipment failure. However, this has not been formalised into an SLA.	<b>Minor</b>

### Advice

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

No	Regulatory reference	Advice
1.	C1a	The DI is advised to modify the Trust policy on consent, which wrongly refers to the HTA code of practice on Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation rather than the HTA code of practice on Consent.
2.	C3a	The DI is advised to update the 'Competency assessment questionnaire' as it does not make any reference to the HTA code of practice on Consent, nor does it request that staff have read this code.
3.	GQ1a	The DI is advised to consider making the organisational chart into a controlled document so that it is reviewed regularly.
4.	GQ1c	The DI is advised to consider setting up quarterly HTA governance meetings, which are recorded by agendas and minutes.
5.	GQ1d	The DI is advised to modify the statement that 'The review period for SOPs is not more than 12 months' and give it a definite timeframe.
6.	GQ2a	The DI is advised to update the Quality Manual to include a description of the new apheresis suite.
7.	GQ2d PFE4b, 4h	The DI is advised to obtain written assurance from NHSBT that the transport boxes and the transport process have been validated.
8.	GQ3k	The DI may wish to consider identifying dedicated time for a quality management system.

9.	GQ4e	Although information on the quantities of cells that are procured, tested, stored and distributed or otherwise disposed of is available, it is not in a single register. Notes, spreadsheets and records are kept in various places. The DI may wish to consider creating a single register, which is also reconciled with the register of cells held by NHSBT – SCI Southampton.
10.	GQ4h	The DI is advised to consider creating an SOP which ensures that raw data, which are critical to the quality and safety of cells, are kept for 10 years after the use, expiry date or disposal of cells.
11.	PFE1a	In the risk assessment of the premises, the DI is advised to include an assessment of any risk to a patient/donor undergoing apheresis whilst nursing staff have left the room, since the donor may not be visible at all times or may not have recourse to a call bell.

### Concluding comments

Overall the HTA is satisfied that the premises are suitable. They are well maintained, are monitored and are fit for purpose.

Overall, the HTA is satisfied that the practices undertaken under the licence are suitable. In addition, the HTA observed several strengths and areas of good practice, including:

- The setting up of a consent training programme, which includes Good Clinical Practice (GCP) compliance training and HTA E-learning.
- The setting up of an agreement for the 'Provision of an independent HTA compliance audit for haematology stem cell transplant establishments'. This audit forms part of a three-way reciprocal audit involving the establishment and two other HTA-licensed PBSC establishments. It examines compliance with the relevant HTA Directions, codes of practice and other requirements.
- The observation that all staff involved in the licensable activities function well together as a team under the DI.

**Report sent to DI for factual accuracy: 11 August 2011**

**Report returned from DI: 25 August 2011**

**Final report issued: 22 September 2011**

Once the establishment has been able to comment on the factual accuracy of the report, it will be published on the HTA website.

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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.
GG2 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.
GG3 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.
GG4 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

<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.
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.