Site visit inspection report on compliance with HTA minimum standards

Salisbury NHS Foundation Trust

HTA licensing number 11102

Licensed for the

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

15-16 July 2019

Summary of inspection findings

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

Although the HTA found that Salisbury NHS Foundation Trust (the establishment) had met the majority of the HTA standards, 12 minor shortfalls were found in relation to governance and quality systems (GQS) and premises, facilities and equipment (PFE) standards. The shortfalls were related to document control, agreements, documentation of training, data retention, audit of records for completeness, systems for handling of serology testing samples, the Single European Code (SEC), incident reporting, risk assessments, the lack of a documented maximum storage period of cells, the validation of transport containers, and the servicing and monitoring of equipment.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

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

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

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

'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (unlicensed) carries out the activity on their behalf.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Haematopoietic, PBSC; PBSC	**E**	**SLA**	**TPA**	**SLA**	**TPA**		

Background to the establishment and description of inspection activities undertaken

Salisbury NHS Foundation Trust is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) for procurement, donor testing and distribution of autologous adult peripheral blood stem cells (PBSCs). Processing and storage activities are performed by a neighbouring HTA-licensed establishment under the terms of a service level agreement (SLA). The establishment is a Joint Accreditation Committee ISCT-Europe (JACIE) satellite of the JACIE hub at University Hospital Southampton NHS Foundation Trust (UHS).

The establishment provides an autologous donor transplant service to patients. Consultant Haematologists identify patients as potential candidates for a stem cell transplant procedure. Trained Apheresis Clinical Nurse Specialists (CNSs) lead the consent discussions and provide the patient with the appropriate information leaflets. The Apheresis CNSs follow the patients throughout their treatment and will also provide a personalised care plan. Patients are given the opportunity during the consent discussions to meet the transplant team at UHS.

Blood samples for mandatory serological testing are taken not more than 30 days before the date of procurement of stem cells. Donor serological testing takes place at a laboratory that is accredited by United Kingdom Accreditation Service (UKAS), under the terms of a third party agreement (TPA). The serology test results are communicated directly to the processing and

storage establishment and to UHS, where infusion of the PBSCs takes place. Serological testing is additionally performed by an on-site microbiology laboratory, for internal quality assurance purposes. The on-site laboratory is not UKAS-accredited; therefore the results obtained are not used to inform clinical decisions.

The establishment has one apheresis machine; however, further contingency arrangements are in place with UHS. Apheresis kits and reagents are stored in a secure, temperature-monitored store room. The store room is temperature monitored using calibrated maximum and minimum temperature probes, and staff manually record the temperatures onto the appropriate form each weekday. The temperature probes retain the data for the weekend period and this is recorded on the Monday.

On the day of the procurement the sample taken for CD34 testing is sent to the processing laboratory. Procurement commences once the results have been received by telephone confirming that the required CD34 counts have been achieved. The Apheresis CNS reconfirms consent prior to apheresis. Each collection is assigned a unique code, which ensures traceability from procurement through to processing, storage, distribution and end-use or disposal. The labels with the unique identifier code are provided by the processing establishment.

Procured cells are packaged in a transport box and a temperature logger is placed into the box before securing. The secured box is collected from the apheresis ward by pre-arranged couriers and transported to the processing establishment where the cells are processed and cryopreserved. Samples are taken for bacteriology testing after cell processing at the neighbouring HTA-licensed establishment. Transplantation takes place at UHS, where the cryopreserved cells are sent upon request.

This was the sixth routine inspection of the establishment to assess whether the establishment is continuing to meet the required HTA standards. Discussions were held with the deputy for the Designated Individual (DI) who is also the Clinical Lead for Cancer Transformation, Chemotherapy and Oncology, the Stem Cell Collection Programme Director, who is also a Consultant Haematologist and the Education Lead, both the Apheresis CNSs, the Senior Ward nurse, the Quality Coordinator and the Microbiology staff.

A visual inspection was conducted of the ward where the apheresis takes place, the on-site microbiology laboratory where samples for testing are booked-in and temporarily stored, and the storage areas where the reagents, consumables, ice-packs and transport boxes are kept. Documentation relevant to the establishment's licensable activities was also reviewed which included policies and procedures, temperature records of the store room and microbiology laboratory fridge, servicing and calibration records for equipment, training records, governance meeting minutes, audits, risk assessments, agreements and disposal records.

A traceability audit was performed with three sets of autologous patient records. The review comprised of confirmation checks that the records contained all relevant documentation, which included consent forms, apheresis procedure worksheets, stem cell harvest logs, serology and bacteriology test results, request to collect and process forms, delivery records, summary of products issued for transplant records and a final report from the processing facility. Several examples were noted of records not having been fully completed.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
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.	Since the last inspection, the old document control system was made obsolete. The establishment is working as a JACIE satellite under the hub which controls the electronic document control system for all JACIE sites. Currently the establishment has limited access to the system, therefore monthly checks were implemented to ensure the hard copies held on site are up-to-date. During the document review, it was noted that the monthly checks had not been carried out for several months within the past two years. In addition to this, some of the active documents currently in use at the establishment did not have document control or version numbers.	**Minor**
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2018. s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	The establishment has written agreements with third parties. The current TPA with the testing laboratory does not set out the serious adverse event and reactions (SAEARs) reporting responsibilities of each party. This issue was also identified at the last HTA inspection. Whilst the establishment took corrective actions to update the TPA at the time, there was a reorganisation of the management at the testing laboratory. This led to subsequent changes to the TPA which does not currently meet the standards.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	Staff are trained to record the temperatures of the store room where the reagents and consumables are kept. However, the training is not formally documented.	**Minor**

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.	Although the establishment retains raw data for 10 years after the use, expiry or disposal of cells, there is no documented procedure in place. This issue was also identified at the last HTA inspection. Whilst the establishment had updated their procedures following the last inspection; the relevant document has been made obsolete since the merge of document control systems with the JACIE hub.	**Minor**
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.	During an audit of the temperature records for the reagent and consumables store room and the 'white cell procedure sheet' for apheresis. It was noted that several forms were incomplete; with missing information such as temperatures, target CD34 dose, and the dates and times of documented checks. The establishment does not have a system in place for the regular audit of records that would enable such omissions to be identified and resolved.	**Minor**
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 002/2018.	During an audit of serology testing records, it was noted that the blood samples from one donor were not received into the testing laboratory until two days after collection. The establishment was unable to account for the storage of the blood samples during this period, or demonstrate what storage conditions are acceptable for the blood samples, as specified by the manufacturer of the serology test kits. The establishment was also unable to demonstrate that sufficient control measures were in place, to ensure that the testing activities are carried out in accordance with HTA standards.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment does not currently have procedures in place to ensure that the SEC-DI is applied after procurement as set out in Directions 002/2018.	**Minor**
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.	During an audit of the temperature records, several excursions were noted above the required set limit which were not recorded as a local incidents. The establishment could not demonstrate what action had been taken to assess the impact of the excursions on the quality and safety of the reagents in storage at that time.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
a) There are documented risk assessments for all practices and processes. c) Staff can access risk assessments and are made aware of local hazards at training.	The establishment's risk assessments do not cover the risks associated with all licensable activities. For example, the following activities have not been adequately risk assessed: • the consent, procurement and release for circulation of cells; • donor testing; • the handling and storage of samples for serology testing; • the storage of the testing kits and reagents, including the conditions of storage and associated security arrangements; and • the storage of apheresis equipment in a publicly accessible space. In addition to this, the establishment's risk assessments are not accessible to the staff working under the licence.	**Minor**
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.		

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
d) There is a documented, specified maximum storage period for tissues and / or cells.	There is no documented, specified maximum storage period for tissues and/or cells.	**Minor**
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.		
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.	The establishment has four transport boxes which have been evaluated to determine their ability to maintain the required temperature of 2-8ºC for the time needed to transport samples. The validated times range from approximately three hours to seven hours for the individual boxes. The current validation of the transport boxes was based on the use of a bag of saline which had been previously chilled at 4ºC for 24 hours, in the place of the cells. This was not representative of the temperature of the cells; at the point at which they are placed into the transport boxes. As a result, the validation does not provide assurance that the transport boxes can adequately maintain a temperature of 2-8ºC for the upper limit of four hours, as specified in SOP 'C-P-31'.	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
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. f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	An on-site microbiology sample fridge is used to temporarily store serology samples prior to sending to the testing laboratory. The fridge is not regularly cleaned or serviced. During an audit of the fridge temperature records, it was noted that the temperatures frequently deviated outside of the establishment's required range. It was also noted that there were several days in the month during which the temperatures had not been recorded. The current systems in place do not provide	**Minor**

	assurance that the fridge is adequately maintained, appropriately temperature-monitored, or that action is taken to report incidents when temperature excursions are identified.	

Advice

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

No.	Standard	Advice
1.	GQ1b	The establishment's labelling policy, 'C-P-26' specifies mandatory two-person checks for a number of steps during apheresis and labelling. During the audit of documentation, it was apparent that only one person signed the documents. The DI is advised to initiate a documented two-person signature check for full traceability to provide assurance that the two-person checks were carried out in accordance with the policy.
2.	GQ1r	The establishment has a SLA with a neighbouring HTA-licensed establishment for the processing and storage of cells. The DI is advised to update these agreements to include details of the responsibilities for the assignment, use, and recording of the Single European Code.
3.	GQ1r	The DI is advised to put systems in place to ensure that third parties carrying out courier services have received adequate training for handling shipments, documentation completion and incident reporting.
4.	GQ2b	The DI is advised to include a review and sign-off process of temperature records in the establishment's documented procedures to ensure that that the storage conditions of the reagents and consumables are satisfactorily met before use.
5.	GQ3e, GQ6d, GQ8a	The processing and storage establishment has plans to apply the SEC-DI onto the new labels, as required, which would be securely e-mailed to the establishment for printing. As part of the change control process, the DI is advised to carry out a documented risk assessment for the new procedures. The DI is also advised to ensure standard operating procedures are in place, and training has been carried out prior to the use of the new labels.
6.	GQ4i	The establishment keeps all records relating to the procurement, receipt, reinfusion or discard of stem cells in a separate document wallet in the patient's medical records. A label is affixed to the wallet, which states "Stem cell donor, notes to be retained for 30 years from date of donation". The DI is advised to update the establishment's standard procedures and labels to make it clearer that the minimum data to ensure traceability from donor to recipient as required by Directions 002/2018 are kept for 30 years after the use, expiry or disposal of tissues and/or cells.
7.	PFE3a	The DI is advised to update the current "Product receipt and acceptance" form to capture the date when consumables and reagents were received. This would enable the establishment to detect which of the stored batches of products could be affected if there was a temperature excursion or other

		adverse events which could impact the quality and safety of products used for patients.
8.	PFE4h	The DI is advised to consider validating the boxes under the extremes of external temperatures; which could be experienced when transporting during the different seasons. The DI is also advised to periodically check that these boxes are fit-for-purpose.
9.	PFE5j	The DI is advised to update the appropriate forms to include the serial number of the temperature probe used to monitor each area and each shipment of cells, so that this can be traced back to the calibration records, if required.

Concluding comments

The HTA observed a number of good practices during the course of the inspection. The establishment's staff regularly attend a range of governance meetings that cover the licensable activities. Some of these meetings incorporate the other neighbouring establishments and the agenda is focussed on regulatory and clinical issues, the audit programme and shared experiences.

Staff were found to be experienced, knowledgeable and actively engaged in providing continuous improvement to the quality systems; this was demonstrated by staff proactively putting corrective measures in place to address some of the areas identified during inspection.

There are a number of areas of practice that require improvement, including 12 minor shortfalls related to document control, agreements, documentation of training, data retention, audit of records for completeness, systems for handling of serology testing samples, the SEC, incident reporting, risk assessments, the lack of a documented maximum storage period of cells, the validation of transport containers, and the servicing and monitoring of equipment.

The HTA has given advice to the Designated Individual with respect to fully documenting two-person checks, updating agreements, courier training, review of records, the SEC, updating standard procedures and labels related to record retention, documenting product receipt dates, transport box validation, and documenting the serial number of the probes used for temperature monitoring within the appropriate records.

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

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

Report sent to DI for factual accuracy: 06 August 2019

Report returned from DI: 09 August 2019

Final report issued: 13 August 2019

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 002/2018 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.
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.
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 002/2018.
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 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
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 002/2018 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.
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 002/2018.
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 002/2018.

d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
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.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.

b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
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

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.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

Or

A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major and, which can be addressed

by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.