Site visit inspection report on compliance with HTA minimum standards

Royal Devon and Exeter NHS Foundation Trust

HTA licensing number 11132

Licensed for the

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

9 March 2016

Summary of inspection findings

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

Although the HTA found that Royal Devon and Exeter NHS Foundation Trust (the establishment) had met the majority of the HTA standards, shortfalls were found in relation to the governance and quality system and premises facilities and equipment standards.

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.

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
PBSC	**E**	**E**	**E**	**E**			

Background to the establishment and description of inspection activities undertaken

The establishment is licensed for the procurement, processing, testing and storage of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

The establishment has been licensed by the HTA since January 2007 and this is the fifth routine site visit inspection. The timetable was developed in consideration of the establishment's annual activity data, previous inspection report and pre-inspection discussions with the DI. During the inspection all areas where licensable activities take place were visited including areas where procurement, donor testing, processing and storage take

place. Reviews of the establishment's documentation were undertaken and interviews were held with key members of staff.

The establishment procures peripheral blood stem cells (PBSCs) from donors for autologous use. Consent for procurement, donor testing and storage of cells is sought by the donor's treating clinician with consent for the apheresis sought by the apheresis nurse prior to starting the procedure. The apheresis nurse records the patient's consent to the procedure in the patient's clinical records however this part of the consent process is not described in the establishment's standard operating procedure (SOP) on seeking consent; advice has been given to the DI below regarding including this process in the SOP (see advice item 1).

The procured PBSCs are processed for cryopreservation using a closed system. Processing takes place in a dedicated area of a general laboratory. The processing area is separate to much of the laboratory's routine activity which helps to minimise interruptions of the staff performing the processing.

Once frozen, using a controlled rate freezer, the cells are stored in one of two liquid nitrogen storage tanks. The establishment has two controlled rate freezers meaning a back up is available if needed. The liquid nitrogen storage tanks are monitored using a remote alarm system which, should the temperature deviate from the required setting, triggers an alarm which contacts the laboratory via an autodialer. There is also an escalation procedure, should an alarm not be responded to, whereby the switchboard followed, by security and then finally the on call trauma bleep holder will be contacted.

The establishment undertakes monthly alarm tests to verify that the system is working appropriately and is alerting the appropriate member of staff. Over the course of these tests and on different occasions, the staff that make up the escalation list are contacted to assure the DI that there is an appropriate response to the alarm from each staff member on the escalation list. The establishment does not however record which level of the escalation list is contacted nor does it have a schedule to ensure that over a defined period, all levels of the escalation list are checked. Advice has been given to the DI below regarding creating a schedule for the alarm tests to ensure that all appropriate members of staff are subject to an alarm test (see advice item 4).

The establishment has a third liquid nitrogen tank which can be used to quarantine any cells that are being stored which have been procured from donors with positive serological infectious disease test results. The quarantine tank is filled with liquid nitrogen should it be needed to store cells and is also linked to the establishment's alarm system. Procured cells from donors with Hepatitis A or C positive results can be processed and stored at the establishment. Procured cells from donors with positive test results for Hepatitis B and HIV can be processed at the establishment but are sent to another HTA licensed facility for storage.

The establishment has contingency arrangements in place with another HTA licensed establishment covering both the processing and storage of cells should the establishment be affected by an adverse event which prevented them from operating as usual.

The establishment monitors the performance of the cell processing and cryopreservation by reviewing engraftment data for all PBSC transplants that are undertaken. Should there be a failure or delay in engraftment, pilot sample tubes of cells from the affected donor are sent to another HTA licensed establishment for colony forming unit (CFU) analysis to assess the functionality of the preserved cells. Monitoring of engraftment data for all transplants takes place in one of the establishment's multidisciplinary governance meetings. It was reported during the inspection that a slight downward trend in engraftment efficiency has been found. The establishment is currently investigating the best way to research this further in order to identify any issues with the establishment's processes that may be responsible for the trend.

Advice has been given below to the DI regarding validation and monitoring of the establishment's procedures (see advice item 4).

As part of the inspection process, a traceability audit was carried out. Firstly, three sets of patient clinical notes were reviewed. The review included a check to verify that all mandatory markers had been tested and that these tests occurred at procurement or within 30 days prior to procurement. Signed donor consent forms were also reviewed to ensure that they had been signed and witnessed in accordance with the establishment's consent procedure. In all three cases, appropriate consent forms and testing results were seen and no anomalies were found.

In addition to the clinical notes the processing records were also reviewed in all three cases. The cells from one donor had been sent off site to another HTA licensed establishment for processing in accordance with the establishment's contingency procedure. In this case the original unique identifier was cross checked against the new identifier added during processing. Both identifiers were then traced from procurement to sending the cells, processing, return of cells into storage at the establishment and finally, transplant. Traceability was maintained throughout and no anomalies were found in any of the three sets of records reviewed.

An audit of cells stored in the establishment's liquid nitrogen tanks was also undertaken. Details of two sets of stored cells were taken and their location details were cross checked between the paper tank map, the processing records and the electronically held record of location. No anomalies were found. The cells were not retrieved from the liquid nitrogen storage tanks to prevent any impact to the cells caused by being exposed to higher temperatures. However, as all traceability records cross checked correctly it was felt that location traceability was being maintained.

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.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	At the time of the inspection the establishment did not have a current SOP describing the apheresis procurement procedure. The procedure available to staff referred to the use of a previously used apheresis machine and not the machine currently being used at the establishment. Although an SOP was found during the document review which related to the correct machine, this SOP had been archived and was not available to establishment staff. Staff are appropriately trained on the use of the apheresis machine by the supplying company however the SOP is important as it should contain the establishment's specific procedures including, but not limited to, labelling the bags of cells.	**Major (cumulative)**
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.	During the review of the establishment's documentation a number of the procedural documents were found to be past their review date. Examples of out of date procedures included, but was not limited to, the SOPs referring to the thawing and reinfusion of cryogenically stored PBSCs, data collection to ensure patient safety. In addition, although the establishment's consent seeking SOP had been reviewed and was in date, an old version of the form used to record donor consent was appended to the document which poses a risk that establishment staff may use an incorrect form. The old version of the form informed donors that cells would be stored for five years when in fact the current version states that cells will be stored for ten years meaning the use of the incorrect form may misinform donors.	

GQ2 There is a documented system of quality management and audit.		
a) There is a quality management system which ensures continuous and systematic improvement.	An example of an incorrect procedural document relating to procurement was in place at the establishment, a number of documents had become out of date without appropriate review and an example of an out of date form being appended to the consent procedure which was in date and had been reviewed all suggest that the quality management system is not operating as it should. Without appropriate documentation and a schedule of regular review of procedural documents to ensure they remain fit for purpose there is an increased risk that procedures will not be carried out as the DI expects which may also pose a risk to the quality and safety of the tissues and cells.	
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	A review of the temperature monitoring records relating to the area used to store the fluids used during apheresis showed that the storage temperature limits had been incorrectly defined. The establishment was using 30^{o}C as the maximum permitted storage temperature while the temperature range on the ACD-A was listed as 25^{o}C. A review of the data showed that the temperature had not exceeded 25^{o}C however by using an incorrect upper limit there is a risk that a temperature excursion may not be acted upon appropriately. In addition, the data relating to the temperature of the storage area where the fluids are stored are reviewed at the end of each month. Reviewing the storage temperature data at the end of each month means that any excursion from the required storage conditions would not be detected until this review of the data. If there was a temperature excursion during the month prior to the review of the data, some fluids may have already been used without staff being aware of the deviation from the required storage conditions.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The DI is advised to include the process where the apheresis nurse seeks consent for the apheresis procedure prior to it commencing and records this in the donor's clinical notes in the establishment's SOP relating to donor consent.
2.	GQ2(d)	It was reported during the inspection that a slight downward trend in engraftment efficiency has been found and the establishment are currently investigating the best way to research this further in order to identify any issues with the establishment's processes that may be responsible for the trend. The DI is advised to continue with her plans to develop suitable processes to evaluate the licensable activity to ensure that they continue to achieve the intended results.
3.	GQ5b	Although the establishment routinely carries out HTLV1/2 testing for all donors, this is not captured in the consent form or in the form used by members of staff for the request to process cells from peripheral blood. The DI is advised to update all the relevant documentation to accurately reflect the arrangements currently in place at the establishment in relation to HTLV1/2 testing.
4.	PFE3(c)	The establishment undertakes monthly alarm tests to verify that the system is working appropriately and contacting the appropriate member of staff. Over the course of these tests and on different occasions, the various staff that make up the escalation list are contacted to assure the DI that there is an appropriate response to the alarm from each staff member on the escalation list. The DI is advised to put in place a schedule of tests to help assure herself that all members of staff identified to respond to the establishment's liquid nitrogen storage alarm are scheduled to be involved in an alarm test as part of the monthly alarm checks that take place.
5.	PFE3(c)	The liquid nitrogen levels of the storage tanks are manually checked using a dip stick three times a week. Establishment staff sign a check sheet to indicate that a level check has been performed. The DI is advised to amend the liquid nitrogen level check sheet so that the expected liquid nitrogen level is included on the sheet. This will help to remind staff undertaking the checks of the expected level of liquid nitrogen.

Concluding comments

Despite the shortfalls that were identified, some areas of good practice were identified during the inspection and an example of these is included below.

The establishment processes the procured cells in a dedicated area of a general laboratory. The processing area is separate to much of the laboratory's routine activity which helps to minimise interruptions of the staff performing the processing. In addition to the siting of the processing area the establishment has a sign which is displayed during processing events. The sign alerts other laboratory staff that processing is taking place and reminds them not to interrupt the operator undertaking the processing. This helps to reduce the risk of an interruption to the operator during processing meaning that their concentration is not effected.

There are a number of areas of practice that require improvement, including one major and one minor shortfall. The HTA has given advice to the Designated Individual with respect to documentation and monitoring of processes.

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: 8 April 2016

Report returned from DI: 20 April 2016

Final report issued: 12 May 2016

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: 10 November 2016

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
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 003/2010.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.

s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.

e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using CE marked diagnostic tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured,

processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.
h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

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.

d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.

i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 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.