Site visit inspection report on compliance with HTA minimum standards

Gartnavel General Hospital

HTA licensing number 11065

Licensed for the

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

19-20 April 2017

Summary of inspection findings

Although the HTA found that Gartnavel General Hospital (the establishment) had met the majority of the HTA standards, one major shortfall was found in relation to Premises, Facilities and Equipment. This was related to ensuring that environmental controls are in place to avoid potential contamination.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

Licensable activities carried out by the establishment

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

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

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
PBSC	**TPA**	**E**	**TPA**	**E**	**E/TPA**	**E***	**E***
DLI	**TPA**	**E**	**TPA**	**E**	**E/TPA**		
Cord blood	**TPA**	**E**	**TPA**	**E**	**E/TPA**		
Bone marrow	**E/TPA**	**E**	**TPA**	**E**	**E/TPA**		

Background to the establishment and description

This report refers to the activities carried out at the Gartnavel General Hospital. The establishment is licensed for the procurement, processing, testing, storage, distribution, import, and export of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The establishment has been licensed by the HTA since August 2006 and has been inspected on four previous occasions. Since the last inspection there has been an interim Designated Individual (DI) followed by the appointment of a permanent DI in 2016. The establishment has a new cryostore and as a consequence has increased the storage capacity of the department. In addition, the satellite, which was formerly the Royal Hospital for Sick Children, has now relocated to the Queen Elizabeth University Hospital (QEUH) site and is now known as the Royal Hospital for Children (RHC). The establishment held Joint Accreditation Committee-ISCT (Europe) & EBMT (JACIE) accreditation. This lapsed with the move of services to the QEUH; the establishment is currently seeking re-accreditation.

The establishment procures peripheral blood stem cells (PBSC) and donor lymphocytes for infusion (DLI) under a third party agreement (TPA) with the Scottish National Blood Transfusion Service (SNBTS). Procurement of PBSC occurs at the Beatson West of Scotland Cancer Centre, on the Gartnavel General Hospital site and at the Schiehallion Haematology/Oncology unit of the RCH. Most of the PBSC procured are for autologous use. In the past year, 208 units were procured under the establishment's licence of which 174 were for autologous use. The establishment also received 58 units via registries.

Bone marrow is procured from children at the RCH. Bone marrow collections involve either autologous back-up bone marrow or collection for a related recipient. Regular meetings are held between the hub and satellite to discuss and plan procurement activities and to ensure bone marrow kits, supplied by SNBTS, are available on the day of procurement. The harvested units are sent to the hub in validated transport boxes by courier. Adult bone marrow is procured, under a TPA, by SNBTS at the Beatson West of Scotland Cancer Centre.

Cord blood is generally procured at the QEUH and procurement at this site is the 'norm' where possible. Procurement may also occur at Glasgow Royal Infirmary and the Royal Alexandra Hospital Paisley. Procurement of cord blood is undertaken under the terms of a TPA with three paediatric haematologists based at the RCH. Cord blood units are transferred to the hub via a courier. However, on occasions if the cord blood unit is procured late in the day or over the weekend the cord blood unit is stored in a temperature-monitored fridge in the blood laboratory at the QEUH.

Processing and storage occurs in the Stem Cell Laboratory based at the hub. The processing room contains a dedicated Class II microbiological safety cabinet which should maintain a grade A tissue processing environment in a background of grade D. A weekly clean is carried out at the start of the week by the processing staff and the laminar air flow cabinet is then left switched on for the rest of the working week. Settle and contact plates are used to monitor the effectiveness of the cleaning process and a sample of the water in the main laboratory is also taken. In-process microbiological monitoring takes place using settle plates which are kept in the Class II microbiological safety cabinet and on the work surfaces in the laboratory where processing takes place. Glove prints are taken at the end of each processing session. In-process particle monitoring is performed during critical processing steps. All samples for environmental monitoring are sent to the Department of Microbiology at NHS Greater Glasgow and Clyde. The floor is cleaned on a weekly basis by domestic staff. Within the processing room is a store room used to store items required for processing but also consumables such as gloves and vials required by the processing laboratory in general.

The cryoprotectant is prepared in the Class II microbiological safety cabinet in the processing room, then transferred to temperature-monitored fridge for cooling. Cryoprotectant is added to the cells in the microbiological safety cabinet. The bags containing processed stem cells are sealed, double wrapped and transferred to the storage area located in the hospital, where they undergo controlled-rate freezing followed by storage in the vapour phase of liquid nitrogen within monitored and alarmed storage vessels. As a precaution, the cryopreserved units are split and stored in separate storage vessels. Three pilot tubes are also stored for each sample and these are stored in a separate vessel to the cryopreserved units.

A number of quality control checks are carried out on each tissue type. These are carried out on incoming materials, during processing, and on finished products. The tests include total nucleated, mononuclear and CD34+ cell counts in starting and finished products prior to cryopreservation, and anaerobic and aerobic bacteriology cultures from the finished products prior to cryopreservation to ensure sterility. In addition, every year, cell potency assays

(colony formation units) are undertaken on a number of samples which have been cryopreserved.

The inspection included a visual inspection of the apheresis unit at the Beatson West of Scotland Cancer Centre where PBSC are procured, the processing laboratory, the cryostore and a visit to the satellite site. A roundtable discussion was held with the processing staff to review both donor and recipient notes and processing records. A further roundtable discussion was held at the satellite site to understand the patient pathway and review both donor and recipient notes. An audit of patient records for PBSC donations from one sibling and one autologous donor; one bone marrow donation obtained through a registry and one directed cord blood procurement was conducted. The relevant processing records were also reviewed. No discrepancies were found in any of the records.

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

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE2 Environmental controls are in place to avoid potential contamination.		
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	A review of the environmental monitoring data showed that the establishment achieved a grade A over D environment for approximately 95 % of processing events. The results of the trending reports, observed during inspection, showed that colony forming units (cfu) were observed on settle plates or finger dabs in the Grade A laminar airflow cabinet. The trending report also noted that in the first six months following the purchase of a new in-process particle monitor, there were five occasions when staff failed to start the particle counter correctly.	**Major**

	Good Manufacturing Practice (GMP) guidelines (Annex 1) outlines limits for cfu counts on settle plates, contact plates and finger dabs in a Grade A environment – and these should be less than one. Staff do not change their outdoor footwear or wear shoe covers before accessing the processing room. The establishment relies on anti-microbial flooring to remove contamination carried by footwear. This flooring was installed in 2011. The expected life efficiency of the flooring, according to the manufacturer, is one to five years. The flooring has not been serviced by the manufacturer, nor has the establishment undertaken any validation of the flooring to ensuring that it is still effective. Entrance to the processing room is restricted when processing is underway. A sign is placed on the door to alert staff. However, this sign is not removed when processing is not in progress. During the inspection there was considerable traffic of staff entering the processing room to access consumables from the store room. A large sharps bin is stored below the cabinet and is re-used for the disposal of sharps, which have been in contact with processed cells. The sharps bin has a flap-style lid that does not close. The bin is emptied weekly, or when full whichever is the sooner.	

Advice

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

No.	Standard	Advice
1.	GQ1b	The DI is advised to update SOP BMT 301-002-05 for the conduct of process simulation tests to include the actions to be taken if contamination is detected.

2.	GQ1s	The DI is advised to amend the TPA with the courier company for any Serious Adverse Event or Serious Reaction (SAEARS) to be reported to the establishment within 24 hours of discovery instead of immediately as this may be subject to different interpretations.
3.	GQ1s	Training of the couriers in the transport of tissues and cells is carried out by a representative of the courier company. The DI is advised to carry out periodic checks to ensure that the courier staff have been trained according to the standard operating procedure (SOP).
4.	GQ3e	The DI is advised to update training records to reflect training in the use of the new particle monitor.
5.	GQ4b	The DI is advised to check patient records for completeness.
6.	PFE2b	As part of the clean room practices the DI is advised to: • Consider the use of overshoes or use of dedicated shoes for use in the processing room. • Consider the practice of keeping waste in the processing room for longer than is necessary and encouraged to switch to smaller bins that are emptied more frequently. • Re-site the store room, or if that is not possible limit access to it to the period before the weekly clean of the processing room. • Displaying the signage restricting access to the processing room only when required. • Re-train staff or otherwise remind them of the importance of using the particle monitor during processing.
7.	PFE2c	Weekly microbial monitoring of the water in the processing laboratory is undertaken. The results, alongside the environmental monitoring data, are reviewed by the Head of Microbiology who then makes a decision whether a deep clean is required. The DI is advised to establish and record what the alert limits are and what action has been taken for all the environmental monitoring undertaken by the establishment.
8.	PFE5c	The DI is advised to conduct periodic challenges of the temperature monitoring system and to document the outcome.
9.	GQ7a	The SOP for reporting SAEARs states that this is the responsibility of the DI or deputy. The DI is advised to ensure that all the Persons Designated (PD) on the licence have current log-in status to the SAEARS portal to enable SAEARs reporting in the absence of the DI. The SOP should also be amended to reflect this.
10.	D1a	In order to dispose of any cryopreserved units, the staff in the stem cell processing laboratory must first seek permission from the treating consultants. A timely response is not always forthcoming and, as a result, the establishment is reaching capacity for the storage of cells for human application. The DI is advised to consider including a set storage period on the consent form and to consider modifying procedures to indicate steps to be taken when that set period has expired.

11.		Cord blood procured out of hours or at the weekend is stored at the blood laboratory next to the satellite site. The DI should have oversight of the storage facility at the blood laboratory. If cord blood is to be stored for greater than 48 hours the DI should extend the satellite site license to allow for this storage.

Concluding comments

There were a number of strengths observed during this inspection. The new DI works closely with, and is supported by, experienced staff in the processing facility. The DI meets regularly with staff involved in the transplant programme to plan upcoming procurements and review transplant outcomes.

There are areas of practice that require improvement, including one major shortfall. The HTA has given advice to the Designated Individual with respect to updating the SOPs, documenting the environmental alert limits and actions taken, amending the TPA with the courier firm with regards to SAEARS reporting and to audit courier training and the out of hours storage area for cord blood.

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: 19 May 2017

Report returned from DI: 5 June 2017

Final report issued: 7 June 2017

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: 18 May 2018

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.
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.

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.