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 export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

14th – 15th May 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 Gartnavel General Hospital (the establishment) had met the majority of the HTA standards, four minor shortfalls were found in relation to the governance and quality systems. The shortfalls are related to the responsibilities of a third party, a validated processing time, the internal audit and the donor selection criteria.

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 (DI), Licence Holder (LH), 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.

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

'SLA' = Service level agreement; the establishment is licensed for this activity but another establishment (licensed) carries out the activity on their behalf.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Hematopoietic, PBSC; PBSC	**TPA**	**E**	**SLA**	**E**	**E/TPA**		**E**
Progenitor Cell, Hematopoietic, Bone Marrow; Bone Marrow	**E/TPA**	**E**	**SLA**	**E**	**E/TPA**		
Progenitor Cell, Hematopoietic, Cord Blood; Cord Blood	**TPA**	**E**	**SLA**	**E**	**E/TPA**		
Mature Cell, T Cell (DLI); DLI	**TPA**	**E**	**SLA**	**E**	**E/TPA**		

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at the Gartnavel General Hospital where the hub is located. The establishment is licensed for the procurement, processing, testing, storage, distribution and export of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). The establishment has been

licensed by the HTA since August 2006 and this was the sixth inspection. The current inspection was a routine one to assess whether the establishment is continuing to meet the HTA's standards. The establishment holds Joint Accreditation Committee-ISCT (Europe) & EBMT (JACIE) accreditation. For four months in 2018/2019 an interim DI oversaw the licensable activities.

The Royal Hospital for Children (RHC) is the satellite located at the Queen Elizabeth University Hospital (QEUH) site. Currently there are building works at the RHC, which means the paediatric haematology out-patient and in-patient wards have been temporarily moved from the Schiehallion Unit at the RHC to a ward in the QEUH.

The establishment procures peripheral blood stem cells (PBSC) and donor lymphocytes for infusion (DLI) under a third party agreement (TPA) with the Clinical Apheresis Unit. Procurement of PBSC occurs at the Beatson West of Scotland Cancer Centre on the Gartnavel General Hospital site, and during normal operation at the Schiehallion haematology unit of the RHC. Most of the PBSC procured are for autologous use. The establishment also receives units for processing via registries.

Bone marrow is procured from children at the RHC for either autologous use or the use of a related recipient. The harvested units are sent to the hub in validated transport boxes by a courier under a third party agreement. Adult bone marrow is procured, under a service level agreement, by SNBTS at the Beatson West of Scotland Cancer Centre. Regular meetings are held between the teams at the hub and the satellite to discuss and plan procurement activities.

Cord blood is generally procured at the QEUH maternity unit. Procurement of cord blood is undertaken under the terms of third party agreements with three paediatric haematologists based at the RCH. Cord blood procurement and processing is currently carried out very infrequently.

Serology testing of donors is carried out by SNBTS under a service level agreement.

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 (see advice item 6). A weekly clean is carried out by the processing staff, and a schedule for the alternation of disinfectants used is in place. The floor is cleaned on a weekly basis by trained domestic staff. Settle and contact plates are used to monitor the effectiveness of the cleaning process, and a sample of water from the taps 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. Glove prints are taken at the end of each processing session. In-process non-viable particle monitoring is performed during critical processing steps. All samples for environmental monitoring are sent to the Department of Microbiology based at the Glasgow Royal Infirmary. The establishment tracks trends in the counts of bacterial colonies on settle and glove plates to monitor microbiological safety (see advice item 5).

The cryoprotectant is prepared in the Class II microbiological safety cabinet in the processing room, then transferred to a temperature-monitored fridge for cooling. Cryoprotectant is added to the cells in the microbiological safety cabinet (see shortfall against standard GQ2d). The bags containing processed stem cells are heat-sealed, double wrapped and transferred to the cryo-storage area located on the ground floor of the same building, where they undergo controlled-rate freezing followed by storage in the vapour phase of liquid nitrogen. The liquid nitrogen storage vessels are locked, temperature-monitored and fitted with alarms. As a precaution, the cryopreserved units are split and stored in separate storage vessels. Three cryotubes 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. In addition, every year, cell viability assays 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 and the cryostore. Roundtable discussions were held with processing and quality staff to review both donor and recipient notes, processing records, and governance documents. At the satellite site a visual inspection of the temporary procurement and reinfusion wards took place. A roundtable discussion was held with staff, and covered consent, staff training, incidents and audit activities.

Audits of traceability were carried out on:

- the patient records of five PBSC donations (one allogeneic donation obtained via a registry; two allogeneic donations; two autologous donations);
- the patient record of one allogeneic cord blood donation obtained via a registry; and
- the patient records of two allogeneic bone marrow donations.

Where relevant, processing records were also reviewed. No discrepancies were found.

Inspection findings

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

Compliance with HTA standard.

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.		
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	The third party agreement with the courier company does not specify their responsibilities for reporting serious adverse events and reactions to the establishment.	**Minor**
GQ2 There is a documented system of quality management and audit.		

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.	The maximum exposure time between cells and cryoprotectant before controlled-rate freezing is not defined. Although there is no evidence that current procedures are compromising the cell viability in processed products, a maximum exposure time should be validated and documented.	**Minor**
GQ4 There is a systematic and planned approach to the management 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.	The records relating to licensable activities undertaken at the satellite site were not audited by staff in 2018 despite the site undergoing considerable change in this period. In addition to this, an internal audit of records, which was performed in 2017, identified various discrepancies and recommended that a further audit be conducted in 2018; this audit was not carried out.	**Minor**
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.	The donor selection forms for adult and paediatric donors do not include questions about xenograft transplantation nor about ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ2c	The DI is advised to schedule the independent audit for the intervening year when no HTA inspection takes place.
2.	GQ3e	Currently staff at the satellite site acknowledge that they have read SOPs and risk assessments by signing a paper document. The DI is advised to make use of their electronic quality management software to prompt staff to read new versions of documents and acknowledge they have done so.
3.	GQ4j	The processing laboratory uses partially pre-printed batch record forms. The DI is advised to put frequent and stringent version controls in place to ensure batch records of all products coming into contact with cells are accurate.

4.	GQ7b	Various SOPs for the satellite site require staff to report serious incidents to the DI in 24 hours. The DI is advised to reword such paragraphs to ensure staff report such incidents to the DI immediately, allowing onward reporting to the HTA within 24 hours of discovery.
5.	PFE2b	Upon review of the microbial environmental monitoring for the Grade A environment it was found that bacterial colonies were detected on plates in four percent of processing events. Currently processing staff reach into the Grade A area with disinfected but ungloved hands before putting on sterile gloves. The DI is advised to risk-assess this process and to consider changes to the gowning procedure in order to further control the processing environment. In addition, the DI is advised to set acceptable limits for microbial excursions and to investigate each excursion.
6.	PFE2d	In order to further reduce bacterial burden in the Grade D environment of the processing laboratory, the DI is advised to consider that staff entering the room wear hair covers and overshoes that have not been worn in the corridor. The DI is further advised to ensure that staff do not wear the same white laboratory coats inside the processing laboratory and outside of the building on the way to the cryostore. The DI is also advised to request bacterial speciation of any colonies detected on settle plates inside the Grade A processing area. This would help to identify potential sources of contamination.
7.	PFE5b	The processing laboratory holds a large number of pieces of equipment. The DI is advised to maintain a schedule for the service and maintenance of relevant equipment, to ensure this is conducted at the required frequency.

Concluding comments

Many areas of strength and good practice were observed during the inspection: the processing laboratory is operated by a dedicated and experienced team with good communication links to the procuring teams. The quality management system is comprehensive and of a very high standard.

There are a number of areas of practice that require improvement, including four minor shortfalls. The HTA has also given advice to the Designated Individual with respect to improving the governance and quality system, the gowning procedure for work in the Grade A environment, the protective clothing for entering the processing laboratory, and ensuring the timely maintenance of equipment.

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: 3rd June 2019

Report returned from DI: 14th June 2019

Final report issued: 18th June 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
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 002/2018 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 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.
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.
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.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2018.
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 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.
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.
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.
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 002/2018.
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 002/2018.
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.