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**

22 and 23 April 2015

Summary of inspection findings

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

The Haemopoietic Stem Cell Laboratory at Gartnavel General Hospital (the establishment) was found to have met all of the HTA standards. Some advice has been provided in relation to review and format of agreements with third parties, audit and document amendment.

Since the last inspection, the previous DI has retired and the establishment has entered into an agreement to process bone marrow procurements on behalf of the Scottish National Blood Transfusion Service.

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.

'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 of inspection activities undertaken

The establishment procures peripheral blood stem cells (PBSCs) and Donor Lymphocytes for Infusion (DLI) by apheresis at two sites, its satellite establishment at the Schiehallion Unit at the Royal Hospital for Sick Children and the Beatson West of Scotland Cancer Centre, on the Gartnavel site. Apheresis is carried out under the terms of a Third Party Agreement (TPA) with the Scottish National Blood Transfusion Service (SNBTS), which provides apheresis equipment and staff. Staff at the satellite site also procure bone marrow from children. An SNBTS consultant haematologist procures bone marrow from adults, acting under a TPA. Two paediatric haematologists from the satellite site also procure directed cord blood donations at three maternity hospitals within Glasgow. This activity is carried out under TPAs with those staff as the procurement site is not a fixed one. The establishment also processes

bone marrow collections on behalf of SNBTS under the terms of a Service Level Agreement (SLA) entered into between the two HTA licensed organisations.

Processing and storage activities are undertaken at the stem cell laboratory and the cryostore is within the same building. Mandatory testing is carried out by SNBTS acting under a TPA, and microbiology testing is carried out by Greater Glasgow and Clyde Health Board, who provide results on sterility testing of product at various stages of processing, as well as providing the results from environmental monitoring in the clean room following incubation of the settle and contact plates.

Trained medical staff take consent for donation of stem cells, bone marrow and cord blood. Procured cells are transported by SNBTS couriers or courier companies acting under the terms of a TPA, using validated cool boxes to the hub site where processing takes place in a dedicated laboratory.

Blood samples for mandatory virology testing are taken during the 30 days prior to donation, or at donation depending on whether procured cells are to be used immediately or processed for longer term storage. In addition to the mandatory virology testing, which is NAT testing, the establishment does a blanket serology test for HTLV I and II. This is not re-tested at 180 days, but the only allogeneic material stored by the establishment for longer than 180 days is cord blood and DLI. However, staff consenting patients for cord blood donation discuss risk factors for HTLV in their consent discussions with patients, and donation does not proceed if the patient presents an HTLV risk. The DLI forms part of a directed donation where the recipient has already received a transfusion from the donor, the DLI being used in the event the recipient requires further treatment to support engraftment. Any DLI not used for the original recipient is disposed of. Accordingly there is no requirement for repeat testing in relation to HTLV.

Cryoprotectant is added to the cells in a Class II 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 control rate freezing followed by storage in the vapour phase of liquid nitrogen within one of 15 monitored and alarmed storage vessels.

Processing of bone marrow also takes place within the laboratory, and processed cells are either returned for use or placed into storage as appropriate.

Each donation is assigned a unique ISBT (International society for blood transfusion) barcoded label provided in advance by SNBTS. Microbiology in-process 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 used during critical processing steps.

All products are tested for bacterial contamination at various stages and on the final product prior to freezing. Results from environmental monitoring and microbiology testing are evaluated, and non-conformances are discussed during regular governance meetings.

Cells are released for transplantation at two units within hospitals in Glasgow, as well as to registries where required. A defined procedure is followed and there are procedures for concessionary release, for example where environmental monitoring shows results outside defined limits.

The inspection was the fourth HTA inspection of the establishment. The previous inspection was carried out in April 2013 and no shortfalls were identified. The HTA noted that there were on-going difficulties in freeing staff time for audit duties, though some progress has been made in this regard.

This was a routine, scheduled, inspection. A visual inspection of the hub and satellite sites was carried out, including the processing laboratory and cell storage facility at the hub, the out-patients department, ward, and laboratory at the satellite, and the nearby SNBTS apheresis suite used for procurement of PBSCs from adults. During this inspection of the satellite, the lead inspector concentrated on activities relating to directed cord blood, as this element of activity had not been reviewed to any extent during previous inspections.

A review of quality documentation was carried out, including the quality manual, governance policy, policy and procedural documents, record forms and process documentation retained in full patient files and also in shadow files containing documentation only relating to the transplant activity. Round table discussions were held with staff involved in procurement of PBSCs, cord blood and bone marrow, receipt, processing and storage of cells, quality management and environmental monitoring. The DI, who came into post after the last inspection, was interviewed.

An audit of traceability was carried out:

The recorded storage locations of two bags of cells were identified within patient files and the cells located within the storage tank. Traceability details were compared against those held in paper and electronic files.

A bag of cells was located within one of the storage tanks and the details noted. The storage location was compared with that recorded within the patient paper and electronic records as were the unique identifiers.

No discrepancies were found.

In addition, five shadow patient files, four at the hub and one at the satellite, were reviewed for the presence of copy consent forms, processing worksheets, reagent records and traceability labelling and reconciliation.

No discrepancies were found other than some changes to entries which had not been initialled and a record which had not been amended following a move of stored cells to another location. However, it was noted that the move had taken place on the day of the inspection and staff had not yet had the opportunity to update the paper file, though the electronic record had been amended.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	GQ1p	The DI is advised to consider, when reviewing existing agreements entered into with other individuals or establishments, whether these should take the form of Service Level Agreements or Third Party Agreements, depending on whether the other party to the agreement is carrying out licensable activity or is itself licensed. The DI is also advised that the current TPA governing procurement of cells by apheresis should also be with SNBTS Technical Services with respect to the carrying out of mandatory virology testing.
2.	GQ2b, GQ4b	The HTA noted that staffing shortages have meant that only limited audits of laboratory processes were carried out in 2014, although there is a schedule of audits for 2015, and some audits have been carried out this year. The HTA also noted that audits have been carried out in relation to the procurement carried out by SNBTS and also in relation to activities carried out at the satellite site, including examination audits of processes carried out by laboratory staff involved in bone marrow procurement. The DI is advised to regularly review progress per the planned schedule and to seek to incorporate on-going audit of the cryostore storage tanks into the procedures used by staff when placing bags of cells into storage or retrieving cells for use. The DI is also advised to consider whether non-laboratory staff may usefully carry out internal horizontal audit of accuracy, legibility and completeness of documentation. By doing so, any systemic failures in traceability or storage procedures, or in relation to documentation, may be identified.
3.	GQ2c	The HTA noted that other agencies, including SNBTS and a commercial company, have carried out audits in an independent manner which, combined, would appear to be against all HTA standards. The DI is advised that this standard can also be met by establishment quality staff, or those involved at the satellite or procurement site, carrying out audit functions, provided an independent methodology is used. The DI is further advised to ensure that if a commercial entity is involved in such audits, the audit record makes it clear that compliance with all HTA standards is being audited.
4.	GQ4a	The DI is advised to remind staff of the need to initial deletions, amendments or other handwritten changes made to documents in order that the person making the change can be identified.
5.	PFE2b	The HTA noted that the establishment has experienced difficulties relating to the reliability of the particle monitors used during critical processing, leading to the need for concessionary release of products in some cases, and that the DI is considering a change to these. The HTA advises the DI to keep the performance of the particle monitors under review and to change this equipment if it continues to prove unreliable.

Concluding comments

The HTA saw various examples of good practice during the inspection. At the hub and satellite, activities are carried out by experienced staff and there are quality managers in place with specific responsibilities for the quality systems used at each site. The quality

systems appear to integrate well, largely as a result of the good communication between these staff members.

The various licensed activities are carried out by staff across several locations, but there appears to be good communication between staff at the processing laboratory with those involved in the clinical areas of procurement and transplant. The HTA noted that members of staff involved in different aspects of the licensed activity take part in planning and multi-disciplinary team meetings, which helps provide a linked approach to patient treatment and related cellular processing.

Consent for donation is dealt with by medically qualified staff, at consultant or associate specialist level, or trained nursing staff. Patients and families are provided with detailed information on the risks and benefits of proposed treatments, and are given ample opportunity to ask questions and consider information before signing consent forms. The establishment uses “shadow” files containing duplicates of relevant forms, records and documents for each patient, therefore allowing staff easy access to relevant information, even when the principal medical record for the patient is elsewhere in the hospital.

Where autologous donors have donated cells which are of sufficient volume to be stored in multiple bags, bags are not all stored within the same liquid nitrogen vessel, minimising the risk of total loss in the event of equipment failure.

There are two different quarantine systems in place, one for unknown virology and one where there is positive virology, with robust procedures in place to govern how samples requiring quarantine are managed.

The document control system is managed electronically with robust procedures in place to ensure that only current versions of documents are in use. Training records and requirements are also managed electronically, with procedures in place to ensure that prompts are made if training requirements are not met.

The incident reporting system appears to be extremely robust, ensuring that the DI is kept appraised of all incidents which could possibly require to be reported to the HTA.

Staff within the laboratory at the satellite site, who are involved in bone marrow procurement in theatre, undergo an examination assessment of this activity at least annually. If such an assessment has not been successfully completed, that staff member is “shadowed” on their next involvement in bone marrow procurement.

The HTA has given advice to the Designated Individual with respect to agreements, audits and some elements of governance documentation as well as in relation to particle monitors.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 16 May 2015

Report returned from DI: 22 May 2015

Final report issued: 22 May 2015

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.
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.