Site visit inspection report on compliance with HTA minimum standards

Wessex Blood and Marrow Transplant Unit

HTA licensing number 22526

Licensed for the

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

27-28 February 2018

Summary of inspection findings

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

Although the HTA found that Wessex Blood and Marrow Transplant Unit (the establishment) had met the majority of the HTA's standards, two minor shortfalls were found in relation to: (i) an absence of a documented plan for the contingency storage of records and (ii) incorrect timing of blood sampling for serology testing in clinical trials.

Advice has been given relating to the Consent, Governance and Quality Systems and Premises, Facilities and Equipment standards.

Particular examples of strength 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 DI 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 licenses against four groups of standards:

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

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

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

Licensable activities carried out by the establishment

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

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

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

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

Progenitor Cell, Hematopoietic, PBSC; PBSC	**E**	**SLA**	**TPA**	**SLA**	**SLA**
Progenitor Cell, Hematopoietic, Unspecified; Peripheral Blood Mononuclear Cells (PBMC)	**E**		**TPA**		**SLA**

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by the Wessex Blood and Marrow Transplant Unit (WBMTU; the establishment), which was issued an HTA licence in October 2008. This was the fifth HTA site visit inspection of the establishment (the last inspection was in May 2016). The current inspection was a routine one to assess whether WBMTU is continuing to meet the HTA's standards.

WBMTU is based within the Oncology Unit at Southampton General Hospital, part of University Hospital Southampton NHS Foundation Trust. The Oncology Unit is one of 12 regional cancer centres in the UK, serving a population of around 1.7 million people. It treats a wide range of malignancies, including solid tumours, lymphoma, leukaemia and myeloma.

The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) for the procurement and testing of tissues and cells for human application. Although licensed for testing, this activity is currently carried out under the terms of a third party agreement (TPA) with an unlicensed organisation based within the Trust ('testing centre'; see below).

The establishment undertakes the collection of bone marrow (BM), peripheral blood stem cells (PBSC) and donor lymphocytes (for donor lymphocyte infusion, DLI). Collections are for adult autologous transplantation or are from directed, related adult donors for transplantation at the establishment.

Tissue-typed ('matched') unrelated BM, PBSC, donor lymphocyte and umbilical cord blood donations for transplantation at WBMTU are managed by the 'Anthony Nolan and NHS Stem Cell Registry' under the terms of service level agreements (SLAs) and such collections take place at other centres.

The establishment is also taking part in two separate clinical trials involving advanced therapy medicinal products (ATMPs; see below).

The establishment is accredited by the Joint Accreditation Committee - European Society for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT) (JACIE) and was last inspected by this organisation in June 2015.

The DI is a consultant haematologist, the Corporate Licence Holder (CLH) is University Hospital Southampton NHS Foundation Trust and the CLH Contact (CLHC) is the Trust Medical Director. There are five Persons Designated (PDs) working under the licence: the Associate Specialist for bone marrow transplantation (BMT); the Quality Manager; the Lead Apheresis nurse; the Lead BMT nurse; and the WBMT Service Director.

Procurement

Donor selection (medical assessment) and consent for BM, PBSC and donor lymphocyte collections, as well as for mandatory serology tests, take place in the WBMTU consultation rooms. Patients are consented by trained consultant haematologists working to well-defined procedures. In the case of directed, related donations, medical assessments are conducted by an independent qualified medical practitioner (the Associate Specialist for BMT). The establishment uses a WBMTU consent form for cell mobilisation, the Trust consent form A for collection and NHS Blood and Transplant (NHSBT) consent form 2B, which records consent for cell storage, testing, research and discard (which is routinely performed after the cells have been stored for five years). Human leukocyte antigen tissue typing is carried out at a separate organisation.

Samples for mandatory serology testing are taken up to 30 days prior to cell collection and are transported by WBMTU staff or hospital porters to the testing centre.

The apheresis unit contains three apheresis machines. Following collection, cells are packaged and transported by staff from the 'processing centre' (see below) to the processing centre using validated procedures. The processing centre provides Information Standard for Blood and Transplant (ISBT) 128 labels used to label PBSC, DLI and BM collections. Transplant products are returned to the transplant unit by processing centre staff using similar validated procedures. Reagents and consumables for apheresis are stored in a secure, temperature-monitored WBMTU storage area.

The establishment is taking part in two clinical trials involving the collection of peripheral blood mononuclear cells (PBMCs). One is for the production of a T-cell depleted CD4 lymphocyte-enriched ATMP for use in the autologous treatment of haematological malignancy and the other is for the production of a gamma-delta lymphocyte ATMP for use in the autologous treatment of solid tumours. Patients for one of the clinical trials are consented by consultant haematologists but, for the other, consultant medical oncologists seek consent (see *Advice*, item 1). In both cases, blood samples for donor testing are taken up to 30 days prior to cell collection [see shortfall against standard GQ5(b)].

There are twenty-five operating theatres and any one of these can be used for BM procurement. Following collection, cells are packaged and transported by processing centre staff to the processing centre. Transplant products are returned to the transplant unit by processing centre staff using validated procedures similar to those used for the collections detailed above. Reagents and consumables for BM procurement are stored in the WBMTU storage facility.

Processing, cryopreservation and storage

Processing, cryopreservation and storage are carried out at the processing centre, a separate HTA-licensed establishment within the hospital grounds, under the terms of an SLA. Products that are not required clinically are released for research and are stored under the processing centre's HTA research licence. Products with minimal cell counts are disposed of by the processing centre.

Sterility analysis (for both bacteria and fungi) is performed in the Trust's Microbiology-Virology Department. Haematocrit levels, blood group and chimerism analyses are performed in the Trust's Haematology-Blood Transfusion Department.

Testing

The testing centre is an on-site specialist laboratory, which is part of the Public Health England Public Health Laboratory (PHE-PHL) network. It is accredited by the United Kingdom Accreditation Service (UKAS) to International Organization for Standardization (ISO) standard 15189 (2012). Testing is carried out under the terms of a TPA. Antibody tests for a range of

viruses and bacteria are carried out, including HTLV-1, HIV-1 and 2, HBsAg, HBc, HCV and *T. pallidum*, as well as confirmatory serology and Nucleic Acid Amplification Technique (NAT) testing (including HEV NAT testing).

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection reports, communications with the HTA since the last inspection and annual activity data. The inspection included a visual inspection of the consultation rooms, apheresis unit and operating theatre complex. Discussions and interviews were held with key staff and documentation was reviewed. Interviews were held with the DI, CLHC and four PDs.

Audits of traceability were carried out:

- The electronic and paper records of seven donations were reviewed (two autologous BM/two autologous PBSC/one directed, related BM/two directed, related PBSC) along with the corresponding transplants. The following information was cross-referenced: donor selection and donor/recipient consent forms, apheresis care plans and worksheets, product labels, results of serological and microbiological analysis, and processing worksheets. The establishment uses name, date of birth, hospital number and ISBT number as identifiers for each donation. There were three minor discrepancies noted - two consent forms for the insertion of lines had not been fully completed for autologous PBSC donations and one product label for an autologous BM donation had been incorrectly transcribed.

Inspection findings

The HTA found the DI and the CLH to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records.		
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.	There is no documented plan for the contingency storage of records of traceability and raw data in the event of termination of activities.	**Minor**
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.	In the two clinical trials taking place at the establishment, the PBMCs are not being taken at the same time as PBSCs but are being taken separately. In this case, donors of PBMCs used as the starting material for ATMPs must have a blood sample taken at the time of donation or, if not possible, within seven days post donation in order to meet the requirements set out in Annex II of 2006/17/EC. The wider testing window that is permitted for donors of PBSCs and BM (i.e. up to 30 days prior to donation) does not apply in these circumstances.	**Minor**

Advice

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

No.	Standard	Advice
1.	C3(a), (b)	There are inconsistencies in the consent-training requirements for those seeking consent. Consultant haematologists undertake a specific consent training (and refresher training) programme. This consists of attendance at a presentation given by the Quality Manager. On the other hand, consultant medical oncologists receive Good Clinical Practice consent training but not training provided by the Quality Manager. The DI is advised to ensure that training is consistent for all those seeking consent. The DI is also advised to consider expanding on the consent-training programme by: (i) recording familiarity with the HTA Code of Practice on 'Guiding principles and the fundamental principle of consent' (Code A) and (ii) recording individuals being observed when seeking consent.

2.	GQ1(c)	Joint governance meetings, involving DIs across the different sectors, are a feature in several other organisations that hold multiple HTA licences. The Trust is the CLH on two HTA licences and the University of Southampton is CLH on two additional HTA licences. In addition, the processing centre has its own HTA licence. Although there are frequent local meetings of the WBMT Quality Management Programme, there are currently no meetings between DIs and individuals named on the licences described above. The DI and CLHCs are advised to consider setting up joint governance meetings involving staff on all of these licences as an opportunity for shared learning.
3.	GQ2(b)	There is a well-developed audit schedule. The DI is advised to consider adding the following to the schedule: (i) the completion of consent forms and (ii) procedural audits, to ensure that current practices adequately reflect the content of standard operating procedures (SOPs).
4.	GQ3(e)	There is detailed competence training for apheresis staff, which has currently been completed by 50% of staff. The DI is advised to ensure that this training is completed by all relevant staff members.
5.	GQ5(b)	During the inspection, it was noted that the TPA with the testing centre did not include the activity of donor HEV NAT testing in the Appendix. The DI is advised to ensure that this agreement is updated accordingly.
6.	GQ8(a)	Although there is a wide range of risk assessments for licensed activities, the risk assessment for BM procurement lacks detail. The DI is advised to amend this risk assessment accordingly.
7.	GQ8(c)	Although staff can access risk assessments, the DI is advised to consider introducing a system whereby staff 'sign-off' that they have read and are familiar with risk assessments, similar to the process used for SOPs.
8.	PFE5(e)	The DI is advised to consider keeping local records of service visits and maintenance agreements for critical equipment to ensure that such equipment is maintained on a regular basis.
9.	PFE5(f)	The DI is advised to consider adding a column to the apheresis worksheet recording the cleaning of apheresis lines after each run.

Concluding comments

During the inspection, areas of strength and good practice were noted:

- There is a dedicated team with good lines of communication between staff performing licensed activities. This includes communication and involvement with staff in the processing centre.
- The Trust has a separate HTA licence for paediatric haematology (HTA licensing number 22567). The DI for the paediatric licence retired in September 2016 and the DI on the current licence became DI on both. The DI and her team have worked hard to standardise personnel and practices on both licences. The organisation is currently awaiting joint JACIE accreditation.
- There are extensive bi-monthly local meetings of the WBMT Quality Management

Programme attended by clinicians, nurses and laboratory staff from all the relevant disciplines within the Trust.

- There is an annual haematopoietic transplantation educational forum for clinicians and other professionals based in the Wessex region who refer patients to the establishment.
- The establishment has set up an extensive range of SLAs for the contingency provision of adult apheresis services.
- There is a detailed Quality Management System, which has been extended to include the two other HTA-licensed collection centres in the Wessex region where donors come to establishment for transplantation.
- The establishment has good follow-up procedures for both internal and independent audits, with actions assigned to appropriate staff and findings distributed throughout the team.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the DI with respect to the Consent, Governance and Quality Systems and Premises, Facilities and Equipment standards.

The HTA requires that the DI 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: 27 March 2018

Report returned from DI: 4 April 2018

Final report issued: 2 May 2018

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: 23 January 2019

Appendix 1: HTA standards

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

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

Consent

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

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
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.

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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 or the HTA Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to 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 represents a systemic failure and therefore is 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 straight away.

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 the proposed action plan the establishment will be notified of the follow-up approach the HTA will take.