Site visit inspection report on compliance with HTA minimum standards

NHSBT Liverpool

HTA licensing number 11018

Licensed for the

- **procurement, processing, testing, storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, and the**
- **storage of relevant material which has come from a human body for use for Scheduled Purposes other than transplantation under the Human Tissue Act 2004**

21 and 22 June 2012

Summary of inspection findings

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

Although the HTA found that NHSBT Liverpool (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to Governance and Quality Systems. Both minor shortfalls are in relation to the review and oversight of the process of gamma irradiation for the terminal sterilisation of some of the establishment's products.

The establishment continues to operate in compliance with a comprehensive Quality Management System which is well aligned with HTA requirements. The establishment has undergone a change to Designated Individual (DI) since the last inspection. This inspection provided an opportunity to verify their suitability.

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 Paragraph 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 under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

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

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

'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
Peripheral blood stem cells	**TPA**	**E**	**SLA**	**E**	**E**		
Umbilical cord blood	**TPA**	**E**	**SLA**	**E**	**E**		
Bone Marrow	**TPA**	**E**	**SLA**	**E**	**E**		
Donor lymphocyte	**TPA**	**E**	**SLA**	**E**	**E**		

infusion							
Bone	**E**	**E**	**SLA**	**E**	**E**		
Demineralised bone	**E**	**E**	**SLA**	**E**	**E**		
Whole skin	**E**	**E**	**SLA**	**E**	**E**		
Heart valves and vessels	**TPA**	**E**	**SLA**	**E**	**E**		
Amniotic membrane	**TPA**		**SLA**	**E**	**E**		
Cornea and Sclera	**TPA**		**SLA**		**E**		
Tendons / ligaments	**E**	**E**	**SLA**	**E**	**E**		

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by NHSBT Liverpool (the establishment). The establishment carries out procurement, processing, testing, storage and distribution of human tissue and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.The establishment also undertakes research and development projects and, as it may store relevant material for the purpose of research, it maintains a licence under the requirements of the Human Tissue Act (2004).

The licensed establishment comprises a processing suite of 14 clean rooms, a tissue donation facility, cryopreservation and ultra low temperature storage facilities, a tissue release area, research and development laboratories, the National Referral Centre and associated office and administration areas.

The establishment is the UK's major supplier of tissue for human application (patient treatment) and is involved in the entire tissue supply chain from the taking of consent and the medical selection of donors through to tissue retrieval, processing, storage and distribution for end use in hospitals and treatment centres around the UK. The establishment also offers a Stem Cell Immunotherapies (SCI) service, processing, testing, storing and distributing haematopoetic stem cells in the form of peripheral blood stem cells, umbilical cord blood, donor lymphocyte infusion or bone marrow.

Members of staff are, principally, organised within teams that support either the tissue donation processes or the tissue production processes. Through the National Referral Centre (NRC) the establishment obtains consent for deceased and live donations. Members of the Tissue Services Donation Team are responsible for the procurement of tissues from deceased donors. The procurement can take place within the dedicated tissue retrieval facility at the establishment or Tissue Donation Practitioners may travel to the relevant hospital to perform deceased donor retrievals. Tissue Donation Practitioners are based at three regional centres around the UK, one of which is NHSBT Liverpool. Members of the Tissue Services Donation Team are also responsible for the management of a number of nationwide satellite sites which procure surplus bone during, for example, hip replacement surgery. Retrieved tissue is transported back to the establishment for subsequent processing and storage. Members of the Tissue Services Production team are responsible for the processing, cryopreservation, storage, stock control and issue of tissue for end use. The

mandatory donor serological testing and bacteriology testing of products is carried out, in accordance with service level agreements, at separate NHSBT establishments, which hold their own HTA licences.

The establishment has a local Quality Assurance (QA) team which provides review and authorisation of processing records for tissue products prior to distribution of tissue for end use. The QA team is also involved in the maintenance of a programme of quality management in accordance with the local and national requirements of NHSBT quality systems.

In addition to HTA licensable activities the establishment also holds Medicines and Healthcare products Regulatory Agency (MHRA) authorisation as a blood establishment and as a manufacturing site for autologous tears. It also maintains a MHRA wholesale distributor's licence. The NHSBT Liverpool site is also the base for blood collection in the region and issues blood to local hospitals. Outside of the HTA's remit, these aspects of operation were not included within the scope of this inspection.

This was the third site visit inspection of the establishment. The previous inspection was in June 2010 and included a detailed review of the numerous satellite sites across England that are involved in surgical bone collection under this establishment's licence. The timetable for this inspection focused on the processing of the various tissue types at the establishment and was developed with due consideration of the establishment's licensing history, the outcome of previous inspections and pre inspection communication with the DI and the Quality Manager. The inspection comprised visual inspection of the donor retrieval facility, processing, storage and distribution areas; document review and a review of data from the proprietary environmental monitoring system. Over the course of the inspection the inspection team observed processing of different tissue types, specifically cardiovascular tissue, skin and bone, within representative cleanrooms. Interviews were held with members of staff undertaking licensable activities and there was an opportunity to observe a telephone consent procedure conducted by a member of staff in the NRC.

As part of the inspection a traceability audit was conducted relating to six different tissue types that had been procured, processed and stored by the establishment. Two of the six had also been distributed. Records relating to consent, procurement, testing, processing, storage and distribution were reviewed for completeness, consistency and compliance with procedural requirements. No anomalies or discrepancies were noted.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	SOP 955/2 on the packaging of tissue for terminal sterilisation by a third party contractor does not include a schematic of each of the approved, validated, load configurations to provide additional assurance that each load is consistently and correctly packed prior to terminal sterilisation by the contractor organisation.	**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 establishment was unable to provide verification that the 2009 performance qualification of terminal sterilisation by gamma irradiation had been reviewed and approved by the establishment's Quality Assurance team.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1 (a)	The DI is advised to revise section 1 of Stem Cell and Immunotherapy Services' form: '2B' entitled: "Consent for the Testing, Storage and Discard of Stem Cells or Lymphocytes". The current form 2B does not reflect that testing for HTLV-1 is routinely conducted as part of the virology screening. It is noted that other forms in use by the establishment include reference to HTLV-1 testing.
2.	GQ2 (a)	The DI is advised to revise the draft Quality Manual to ensure that section 1 reflects the establishment's licensable activities of procurement, processing, testing, storage and distribution in accordance with the Quality and Safety Regulations 2007.
3.	GQ2 (d)	The DI is advised to conduct a formal review of the data and report(s) supporting the 2005 publication entitled: "Validation of radiation dose received by frozen unprocessed and processed bone during terminal sterilisation" to ensure that it

		meets the establishment's current validation requirements.
4.	GQ2 (d)	In view of the fact that the last full validation of the gamma irradiation sterilisation process was conducted in 2005, the DI is advised to conduct a formal review of the establishment's arrangements for periodic performance qualification of the delivery of required radiation doses to ensure that it addresses all of the establishment's product load configurations and meets the establishment's validation requirements.
5.	GQ7 (f)	The DI is advised that it would be timely to conduct another recall simulation exercise in order to provide assurance that the current systems and procedures remain effective.
6.	GQ8 & PFE1 (a)	The DI is advised to develop a policy document detailing new and / or investigational product categories that would be considered either acceptable or unacceptable for introduction to the establishment's suite of clean rooms.
7.	PFE2 (b)	The DI is advised to review the occasional incidents of over-pressure in the clean rooms (for example over-pressure in room F145 on 7 April 2012) to determine the root cause of these sporadic incidents and the potential impact on the overall pressure regime of the suite of clean rooms.
8.	Licensing	As the, on-site, dedicated tissue retrieval facility has its own HTA licence (reference: HTA post mortem licence 12499) which covers storage as well as the removal of relevant material under the Human Tissue Act (2004), the DI is advised to consider whether the licensable activity of storage under the Human Tissue Act (2004) is also required under this HTA licence (11018).

Concluding comments

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 establishment has a robust and comprehensive Quality Management System which is well supported at both local and national levels. Members of staff who are involved in licensable activities demonstrate a strong commitment to meeting regulatory requirements. The DI has established an effective governance structure. There is good use of the role of 'Persons Designated' to maintain appropriate oversight of licensable activities.

The inspection identified many procedural controls which demonstrate the establishment's commitment to quality and ongoing quality improvement initiatives. For example, the development of a 'Hospital Database' for regional mortuary's quality documents so that Tissue Donation Practitioners work in accordance with ratified procedures during the procurement of tissue from deceased donors; the National Referral Centre process for obtaining fully informed consent; and the 'Quality Assurance Champion' initiative that is being operated within tissue production services.

The facilities are well designed and benefit from a rolling maintenance programme to maintain high standards of environmental control, fabric and finish. Equipment such as ultra low temperature freezers are the subject of a rolling programme of renewal or upgrade. The members of staff observed working within the cleanroom suite during the inspection demonstrated good standards of aseptic practice. There is a comprehensive environmental monitoring programme which is well supported by a proprietary environmental monitoring system. The dedicated tissue retrieval centre provides a well designed and managed local environment in which tissue can be procured under the total control of the establishment.

There is one area of operation that requires improvement. This is reflected in the two minor shortfalls relating to review and oversight of the process of gamma irradiation for the terminal sterilisation of some of the establishment's products. 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 two minor shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 19 July 2012

Report returned from DI: 6 August 2012

Final report issued: 7 August 2012

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: 28 September 2012

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
b) If there is a third party procuring tissues and / or cells on behalf of the establishment the third party agreement ensures that consent is obtained in accordance with the requirements of the HT Act 2004, the Q&S Regulations and the HTA's Codes of Practice.
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
b) If third parties act as procurers of tissues and / or cells, the third party agreement details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

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

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

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

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

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.

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

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

Disposal

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

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.