Site visit inspection report on compliance with HTA minimum standards

South East Tissue Services SNBTS

HTA licensing number 11010

Licensed for the

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

19-23 March 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 South East Tissue Services, Scottish National Blood Transfusion Service (SNBTS) (the establishment) had met the majority of the HTA standards, a shortfall was found, in relation to premises, facilities and equipment.

The shortfall related to the requirement for in process particle monitoring, necessary to comply with Annex 1 of Eudra Lex Good Manufacturing Process. This issue had been raised as a matter of advice and guidance by the HTA following the previous inspection in March 2010 and at the time of this inspection was being addressed by the establishment.

Other items of advice and guidance provided by the HTA at the last inspection had been considered by the establishment and, where appropriate, acted upon.

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

'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**	**E/TPA**	**E**	**E/TPA**		
Donor Lymphocytes	**TPA**	**E**	**E/TPA**	**E**	**E/TPA**		
Bone	**E/TPA**		**E/TPA**	**E**	**E/TPA**		
Tendons and Ligaments	**E**	**E**	**E/TPA**	**E**	**E/TPA**		
Pancreatic Islets	**TPA**	**E**	**E/TPA**	**E**	**E/TPA**		
Amniotic Membrane	**TPA**	**TPA**	**TPA**	**E**	**E/TPA**		
Heart Valves	**E**	**E**	**E/TPA**	**E**	**E/TPA**		
Whole Skin	**E**	**TPA**	**E/TPA**	**E**	**E/TPA**		
Ovarian Tissue	**TPA**	**E**	**E/TPA**	**E**	**E/TPA**		

Background to the establishment and description of inspection activities undertaken

The establishment is the preferred tissue supplier for NHS Scotland and is involved in procuring, testing, processing and storing various tissue types (as detailed above) for use in human application. Tissues are obtained from both living and cadaveric donors and procurement is carried out by establishment staff, or by other individuals on the establishment's behalf under the terms of Third Party Agreements (TPAs).

Microbiological and mandatory virology testing is carried out at two laboratories, one of which falls under this HTA licence, the other carrying out testing under the terms of a Third Party Agreement.

Processing is carried out at the establishment's tissue and cells processing facility in Edinburgh.

Depending on tissue type, storage is at the Edinburgh hub establishment, or at one of the establishment's satellite bone banks. The establishment has set up a National Storage Site for bone at the Aberdeen satellite and this site controls distribution of bone products to the satellite bone banks in Inverness, Aberdeen (at the same location), Dundee, Glasgow and Edinburgh.

Other tissue types are stored at the Edinburgh hub and distributed to end users as required. Tendons are only stored in Edinburgh and, for short periods prior to supply to end users, in Glasgow.

Distribution to the hub following procurement, between the hub and the satellites and to end users is carried out either by SNBTS transport staff, or by courier companies acting under a Third Party Agreement.

The establishment has been inspected on two previous occasions.

This inspection was routine, and involved the Edinburgh hub and the satellite bone bank sites at Inverness, Aberdeen (including the National Storage Site), Dundee and Glasgow. At each site, the inspection team carried out a visual inspection of the premises, audit, document review and interviews with key staff. In advance of the inspection, the establishment provided the HTA with Preparation Process Documents detailing the processing steps carried out in relation to the different tissue types.

No procurement sites were visited by the inspection team during the course of this inspection, but the relevant Third Party or Service Level Agreements (TPAs/SLAs) were reviewed.

Since the last inspection, items of advice and guidance provided by the HTA have been considered by the establishment and, where considered appropriate, steps have been taken to act upon it. In particular, revisions to the software programme used to record key information relating to certain tissue types have been made, the establishment has taken steps to provide for in process particle monitoring, though this had not yet been finalised, and alternative storage of archived documentary records has been arranged to remove the risk of damage from water ingress.

At each site, and audit was carried out as follows:

> Inverness: A femoral head stored in the quarantine freezer was located, its location confirmed in the electronic record held within the custom designed software programme used for tracing donations (Tissue Trace) and barcode details compared. A donated femoral head was selected in the electronic record, the corresponding bone pot located in the freezer used to store tissue available for issue, details compared and the corresponding donor documentation found and checked.

Aberdeen: The same process was followed for two donated femoral heads held in the Aberdeen Bone Bank section of the establishment. In addition, a donated femoral head was located within one of the National Storage Site freezers, details compared with the electronic log and the relevant donor documentation traced and compared.

Dundee: The same process was followed for two donated femoral heads, one in the quarantine freezer and one in the issue freezer. For the latter, relevant donor documentation was located and compared. In addition, an inventory of the samples held in an emergency freezer, used to hold tissue for use in non-elective or emergency surgery, was carried out.

Glasgow: The same process was followed for two donated femoral heads, one in the quarantine freezer and one in the issue freezer. In addition, one femoral head was located within the freezer used to hold tissue pending transport to the National Storage Site, details compared with the electronic record, and the relevant donor documentation found and checked.

Edinburgh: Three processing records (relating to Heart Valves, PBSCs and Pancreatic Islets) were reviewed for presence of authorisation documents, testing results, processing details, environmental monitoring, transport records and disposal records.

No discrepancies were found during any of the audit procedures.

Inspection findings

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

Compliance with HTA standards

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE2 Environmental controls are in place to avoid potential contamination.		
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 003/2010.	The environment in the Class A Microbiological Safety Cabinets (MSCs) to which tissues and cells are exposed during processing is monitored, as required by the Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment. The monitoring does not, however, include in process particle monitoring as required by Annex 1 to the Eudra Lex GMP guidelines. The establishment has a system of environmental monitoring which reduces the risk of contamination going undetected. This includes in-process monitoring of viable particulates in the Grade A and B environments and continuous non-viable particulate monitoring in the Grade B laboratory. However, the failure to carry out in-process non-viable particulate monitoring in the MSCs breaches HTA standards and is thus considered to be a minor shortfall. By carrying out the necessary monitoring the establishment will minimise risk of particle contamination and any compromise to the quality and safety of tissues and cells.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1b	The DI is advised to document the process followed at the Dundee Bone Bank whereby establishment staff periodically check the expiry dates of tissues held within the freezer used to hold tissue for non-elective or emergency surgery, in order to ensure that all staff are aware of the need to carry out expiry date checks and to ensure that staff are trained on the procedure.
2.	GQ1d	The DI is advised to update the SOP relating to Storage and Testing of Fresh Frozen Surgical Bone (INV BBK 10 07) to reflect the fact that the Record of Donors Book is no longer used to retain donor records and is purely now an

		archive record.
3.	GQ1d	The DI is advised to update the SOP relating to Labelling/Verification of Bone for Clinical Use (GLAS TSD 2310 09) to include reference to the need to generate and use product label verification stickers, therefore reflecting the practice carried out.
4.	GQ1d	The DI is advised to ensure that the Read and Understood sheets attached to departmental copies of SOPs are signed consistently in accordance with the relevant governance procedures.
5.	GQ1d	The DI is advised to review the SOP detailing clean room clothing procedures to ensure it matches the practice being carried out, with particular reference to the use of Tyvek suits over long sleeved undergarments.
6.	GQ1r	The DI is advised to update the Third Party Agreement template used to ensure that reference is made to the Guide to Quality and Safety Assurance of Tissues for Patient Treatment, rather than to the superseded HTA Directions, so that when TPAs are reviewed the format is correct.
7.	GQ7g	The DI is advised to consider modifying the documentation supplied to clinicians with processed Pancreatic Islet cells to ensure that there is early reporting of any Serious Adverse Event or Reaction which could potentially have resulted from issues with the quality and safety of the supplied cells.
8.	GQ7h	The DI is advised amend the SOP for Quarantine or Recall of Tissue Products (NATS TSD 035 07) to ensure there is provision for notification of any Serious Adverse Event or Reaction to the HTA within required timescales, and to ensure that staff are updated on the changes.
9.	GQ8b	The DI is advised to consider how Q Pulse should be used to schedule update of risk assessments, taking into consideration the processes to which assessments apply and the practicalities of updating same in relation to relative patient risk.
10.	PFE2b	The DI is advised to review how the extrapolation of exposure times of settle plates is managed to ensure compliance with Eudra Lex GMP Annex 1, taking into consideration processes where processing time is less than 4 hours.
11.	PFE3a	The DI is advised to ensure that blood sample tubes stored within the Dundee Bone Bank freezer room are maintained at the temperature required by the supplier.

Concluding comments

The HTA saw various examples of good practice.

Consent training is regularly updated and those taking consent are subject to regular competency checks. Similarly, staff undertaking procurement of tissues or cells are subject to regular competency checks.

The Tissue Trace software package which has been custom designed to record details relating to donors and tissues is also used to record details of the recipient patient, providing

complete traceability from donor to recipient in one location. The establishment manages recipient information by using tissue request forms, to be completed by end users, which require recipient details, and graft recipient forms which are returned following use of tissues or cells, and can be used to update records in cases where, as a result of illness, the identity of the recipient changes.

Several examples were seen where incident investigation or assessment of processes had led to change to procedures. For example, staff now use barcode scanners, rather than handwriting of details, to record the transfer of bone from issue freezers to transport containers following an incident where incorrect recording of the identification number of a femoral head in transit was discovered. The style of clean room clothing was changed following a review of environmental monitoring results, to minimise particulate generation. The location of secure anti-tamper seals on transport boxes was altered to minimise the risk of unrecorded opening of same, following an incident where a femoral head was removed from a transit box for use and the anti-tamper seal left unbroken.

The establishment has a very strict key performance indicator time for the closing off of incident reports following investigation and the carrying out of corrective actions, and these are consistently met.

As part of the audit process, suppliers have been audited to ensure they are meeting required standards. Similarly, as part of the audit of satellite sites, where there are SLAs or TPAs in place with others, for example hospital operating theatres, the quality team from the establishment visit the sites to ensure they meet agreed requirements.

Staff are well motivated and a culture of quality is evident. Staff are enthusiastic with regard to the quality procedures in place, seeing them as a way to evolve and improve practice rather than as a burden. As an example of this, the inspection team found no documents where changes had been made in a way contrary to the SOP detailing the procedures to be followed for amendment.

Personal training records seen by the inspection team were uniformly carefully maintained and up to date, again exhibiting the approach staff take to the quality systems in place.

The audit programme is well established and it is clear that a great deal of thought has been applied to how audits are scheduled, the recording of audits and the actions taken after audit.

Despite the wide geographical range of location of the satellites, communication was seen to be excellent and great efforts have been made to ensure uniformity of practices and related documentation, with local situations or practices taken into account.

There is an area of practice that requires improvement, resulting in one minor shortfall. This relates to environmental monitoring during critical processing and the establishment is in the course of meeting the necessary requirements, in implementation of advice and guidance provided at the last inspection.

The HTA has also given advice to the Designated Individual with respect to storage of blood tubes and to the content of various documents.

The HTA requires that the Designated Individual addresses the shortfall 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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 3 April 2012

Report returned from DI: 18 April 2012

Final report issued: 24 April 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: 01 August 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.