Site visit inspection report on compliance with HTA minimum standards

SNBTS Tissue Establishment

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**

18-20 March 2014

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.

SNBTS Tissue Establishment (the establishment) was found to have met all HTA standards.

Since the last inspection, the establishment has been affected by various changes. The DI has changed and licensing arrangements have been rationalised, so that there is now one hub establishment and five satellites.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

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

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

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

Licensable activities carried out by the establishment

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

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

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
PBSC	**E/TPA**	**E**	**E/TPA**	**E**	**E**		
Bone Marrow	**E/TPA**						
Cord Blood	**E**	**E**	**E/TPA**	**E**	**E**		
Donor Lymphocytes	**E/TPA**	**E**	**E/TPA**	**E**	**E**		
CD133 PBSC	**E/TPA**	**E**	**E/TPA**	**E**	**E**		
Bone	**E/TPA**		**E/TPA**	**E**	**E**		
Tendons and Ligaments	**E**	**E**	**E/TPA**	**E**	**E**		

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Pancreatic Islets	**TPA**	**E**	**E/TPA**	**E**	**E**		
Amniotic Membrane	**TPA**	**TPA**	**TPA**	**E**	**E**		
Corneas		**E**		**E**			
Limbal Stem Cells		**E**		**E**			
Heart Valves	**E**	**E**	**E/TPA**	**E**	**E**		
Whole Skin	**E**	**E**	**E/TPA**	**E**	**E**		
Ovarian Tissue	**E/TPA**	**E**	**E/TPA**	**E**	**E**		

Background to the establishment and description of inspection activities undertaken

SNBTS Tissue Establishment (the establishment) is the principal 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.

The hub part of the establishment is based in Edinburgh and recent licensing changes mean that there are now five satellite establishments, four in other Scottish cities and one located on the outskirts of Edinburgh. The satellites are:

- Dundee - East of Scotland Tissue and Cell Bank (ESTCB)
- Aberdeen – North East of Scotland Tissue and Cell Bank (NESTCB)
- Inverness – North of Scotland Tissue and Cell Bank (NSTCB)
- Glasgow – West of Scotland Tissue and Cell Bank (WSTCB)
- Edinburgh – Scottish Centre for Regenerative Medicine (SCRM)

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). When a tissue cannot be supplied by the establishment, it is purchased from another HTA licensed establishment.

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.

Each donation is allocated a unique number, the establishment using ISBT 128 barcoded labelling. Traceability is maintained in paper records and also, depending on tissue or cell type, on a custom-designed software database. The latter has protections built in to prevent release of stored materials where full processing and testing results are not available or where results are unsatisfactory.

Processing of most tissues and cells is carried out at the hub and at three satellite sites, SCRM, NESTCB and WSTCB. Processing is carried out within cleanrooms or in laboratories if a closed process can be used. Environmental monitoring is carried out in accordance with Annex 1 of Eudralex, and examination of contact and settle plates is carried out by the quality team at the establishment or by agreement with local specialist laboratories.

Depending on tissue type, storage is at the hub, or at one of the satellite tissue banks. NESTCB also acts as the national storage site for bone, and controls distribution of bone products to the satellite tissue and cell banks.

PBSCs are stored at the NESTCB, ESTCB, WSTCB and at the hub. Cord blood is stored within the national storage facility at WSTCB. Bone products for end use are stored at all locations.

Other tissue types are stored at the hub and distributed to end users as required. Storage environments depend on the type of tissue or cells stored, but in all cases, storage equipment is validated and calibrated regularly, subject to scheduled maintenance, and monitored and alarmed.

Prior to release, each donor file is reviewed by trained members of staff and signed off for product release by medical or nursing staff following a review of donor selection, testing, processing, environmental monitoring, transport and storage records.

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 TPA. When distributed to end users, the establishment insists on this being on a “named patient basis” and therefore details of the recipient are retained on the secure tissue database, ensuring traceability from donor to recipient.

The hub establishment has been inspected on three previous occasions. This was the first inspection following a period of rationalisation and licensing changes. Several former hub sites became satellites during this reorganisation and the inspection team visited the hub site and three of the five satellite sites, ESTCB, WSTCB and SCRM.

With particular regard to ESTCB, only those activities related to bone storage were inspected, as the PBSC activity carried out under that establishment’s own licence had been subject to an HTA inspection during the previous 12 months.

At each site, the inspection team carried out a visual inspection of the premises, audit of traceability, document review and interviews with key staff. The DI was interviewed In advance of the inspection.

With particular reference to the clean rooms at SCRM, these had been the subject of a recent visit by a Good Manufacturing Practice (GMP) inspector from another UK regulator. The results of that inspection were shared with the HTA in advance of this inspection and the HTA took the proportionate view that the clean rooms at SCRM need not form part of this inspection. However, during the document review, the HTA noted the establishment’s response letter to the findings of the GMP inspector.

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

The licence rationalisation has been carried out as part of on-going plans for the building of a single national Scottish centre dealing with tissues and cell products, and on completion of this it is likely that all activities (other than procurement) will be carried out at that single site. The WSTCB will remain as a distribution centre for the west of Scotland.The HTA’s future inspection planning with regard to SNBTS will be informed by progress towards that goal.

At each site, an audit was carried out. The HTA chose not to remove any tissues and cells from storage for audit where they were autologous, highly matched or where there was a greater likelihood of packaging being subject to thermal shock damage. As the traceability systems used were the same in each case this was not considered to affect the validity of the audit, as follows:

- WSTCB: two femoral heads were located within the issue freezer and one within the quarantine freezer. Traceability details were checked against the electronic and paper records available, including unique number, location record, rhesus status and expiry date.

  One further femoral head was identified on the electronic record and its location and traceability details checked. The donor file was reviewed for the presence of consent and donor selection records, virology and bacteriology results and storage records.

  The electronic records for one cord blood sample were compared to the donor and processing records to confirm presence of consent documentation, traceability records, virology and bacteriology results and storage location. The related plasma and red cell samples were located within the storage freezer and their location compared with the paper and electronic records.

  The electronic record for one cord blood sample which had been discarded were accessed for details of traceability and processing and disposal records and the corresponding paper file reviewed.

- ESTCB: two femoral heads were located within the issue freezer and one within the quarantine freezer. Traceability details were checked against the electronic and paper records available, including unique number, location record, rhesus status and expiry date.

  One further femoral head was identified on the electronic record and its location and traceability details checked. The donor file was reviewed for the presence of consent and donor selection records, virology and bacteriology results and storage records.

- SCRM: the donor and batch processing file for one CD 133 PBSC case was reviewed for the presence of consent documentation, traceability and processing records. The storage location was noted and this was subsequently confirmed on the electronic record at the hub storage location.

- Hub: one tendon and one femoral head were located within the storage freezer and location details, expiry dates and rhesus status compared against the corresponding electronic record. The corresponding paper donor file for the tendon was reviewed for the presence of donor selection details, consent records, mandatory testing results and, as this was from a multi-tissue donor, the processing records, environmental monitoring results and traceability records for all tissue types procured were reviewed with a member of staff.

Only one minor discrepancy was noted. One femoral head was in the wrong storage location within the issue freezer at ESTCB, but was quickly located within an adjacent rack allocated to the same rhesus group.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C3a	The DI is advised to consider whether an observation audit of establishment staff seeking consent could be introduced alongside the current practice whereby staff carry out simulated consent taking as part of refresher training.
2.	GQ1r	The DI is advised to ensure that, during the rolling revision and signing of TPAs, all references to HTA Directions are to Directions 003/2010. He is also advised to consider how schedules to the TPAs, detailing the obligations of each party, may be legally incorporated as part of the document.
3.	GQ2d	The DI is advised to consider the use of cord blood samples which otherwise would be discarded because of a failure to meet criteria for processing, for the purposes of process qualification and validation, prior to discard.

Concluding comments

The HTA saw various examples of good practice during the inspection. The quality systems used are consistent across all sites, meaning staff are familiar with processes used at each location, and local changes are minimal.

The establishment has developed an electronic system to record donor details, relevant results and traceability, and has built in protections to prevent the release of tissues or cells where there is any non conformity with expected results. The same system automatically allocates a short expiry date to tissues issued for use.

Where this is practical, the establishment has robust procedures in place for the return of unused tissues and cells, involving the use of data-loggers, security tabs and validated boxes, so that only tissues and cells which meet defined acceptance criteria can be returned to stock.

The establishment has set up a system recording the transfer of bone products which have been labelled for release into “virtual freezers” on the database when being transported between sites, and this means full traceability is maintained throughout transfers.

Tissues and cells are supplied to end users on a “named recipient” basis so that traceability information to end user is maintained by the establishment. End user agreements and documents contain clear information on how end users should report serious adverse events or reactions.

Staff in the pancreatic islets programme telephone transplant clinicians in the days following transplant of islets to check for any post transplant reactions.

Laboratory staff are encouraged to attend the clinical procedures where tissues and cells issued by the establishment are used to help put the importance of the quality systems in context.

Cord blood consent staff use a “mini consent” form, being consent to the cord blood collection only, where a mother is already in labour and not able to complete the full consent process. Full consent for processing and testing is then sought after the mother has recovered from the birth.

For certain critical entries of information into the database, the establishment uses a “double blind” entry system, where two members of staff separately enter the same information into the database and any inconsistency triggers a non conformance warning.

Heart valves which have been processed, but for which full virology and bacteriology results are not available, are placed in a pre-quarantine storage Dewar linked to the equipment monitoring system. These are only moved to the larger quarantine freezer when full results have been obtained. Tissues are moved to issue freezers only when all test results are available and all quality and clinical checks have been completed, the process folders signed off and final labelling applied.

Evidence was seen of comprehensive risk assessments relating to the moving of a process from one location to another. Similarly, evidence was seen of risk assessments being carried out for change of equipment or consumable supplies.

The establishment sets rigid parameters for the follow up and closing of any incidents and the HTA saw evidence of autologous tissue being subject to external, independent, quality testing following an incident to determine whether it was suitable for storage, rather than simply being disposed of.

The HTA has given advice to the Designated Individual with respect to audit of consent procedures, process validation and some elements of documentation.

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

Report sent to DI for factual accuracy: 7 April 2014

Report returned from DI: 15 April 2014

Final report issued: 17 April 2014

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.