Site visit inspection report on compliance with HTA minimum standards

SNBTS Tissue Establishment-Satellite

The North East of Scotland Tissue and Cell Bank (NESTCB)

HTA licensing number 11010

Licensed for the

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

26 June 2018

Summary of inspection findings

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

Although the HTA found that NESTCB (the satellite) had met the majority of the HTA standards, four minor shortfalls were found in relation to Governance and Quality. These relate to the requirement for the establishment's risk assessment to be reviewed; the procedures required to minimise the risk of contamination; terms of end user agreement; review of risk assessments and defining the exposure time of tissues and cells to cryoprotectant before cryopreservation.

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.

Tissue category; tissue type	Procurement	Processing	Testing	Storage	Distribution	Export
Musculoskeletal, Bone; Bone				**E**	**E**	
Musculoskeletal, Tendon & Ligament; Tendons				**E**	**E**	
Progenitor Cell, Hematopoietic, PBSC*; PBSC	**E**	**E**	**E**	**E**	**E**	

* peripheral blood stem cells

Background to the establishment and description of inspection activities undertaken

The North East of Scotland Tissue and Cell Bank (NESTCB), based in Aberdeen, procures, processes and stores PBSCs. NESTCB is a satellite of the Scottish National Blood Transfusion Service (SNBTS, the hub) based in Edinburgh. Consultants undertake donor assessment and seek consent for the procurement of PBSCs from autologous, adult donors

within the haematology department at Aberdeen Royal Infirmary which is adjacent to the satellite site. There are three apheresis machines, which are used in rotation. The machines are cleaned once a week if not used.

Donor blood samples for mandatory serology testing are taken no longer than 30 days prior to the day of harvest. The blood samples are sent to the hub in Edinburgh for analysis. If there is no capacity in Edinburgh, samples may then be sent to the Glasgow satellite for analysis. All results are sent electronically. On the day of the procurement, CD34 counts are checked to determine whether the donor can commence apheresis. The CD34 counts are performed by the processing laboratory. PBSC procurement is undertaken by apheresis nurses who confirm the identity of the patient against their medical records. Each collection is assigned a unique code, which ensures traceability from procurement through to processing, storage, distribution and end-use or disposal.

Apheresis kits and the anticoagulant Acid**-**Citrate**-**Dextrose Formula A (ACD-A) are stored in secure, temperature-monitored cabinets which are monitored continuously. There is a daily review of the temperature, the data is backed-up weekly and the temperature probes are calibrated every six months.

Staff from the processing laboratory collect the PBSC units in a transport box which is kept cool for a minimum time frame in a refrigerator prior to use. In between use the box is cleaned. The units are usually processed on the same day; however, if this is not possible the unit is placed in a temperature-monitored refrigerator overnight. In the event that the PBSCs have been collected from two patients on the same day then the units are placed on different shelves.

Prior to processing the PBSC units are weighed. Processing of the cells takes place within a dedicated clean room facility. Until recently, the establishment undertook closed processing in a Grade A over D environment. However, the establishment has recently moved to open processing and has taken steps to ensure that this occurs in a Grade A over B environment.

All critical, open processing takes place within the microbiological safety cabinets. Whenever processing occurs, the environmental monitoring includes settle plates and particle monitoring in the cabinets as well as broth samples for sterility testing; settle plates in the grade B area and finger dabs for processing staff. Plates and broths for microbiological testing are incubated and analysed in the microbiology department of the Aberdeen Royal Infirmary.

After the addition of the cryoprotectant the units are frozen using a controlled-rate freezer and then stored in the vapour phase of liquid nitrogen tanks. The laboratory is informed via a ‘stem cell planner’ when the frozen PBSC units are required for infusion. The stem cell deputy manager or the quality manager will review the processing records and a medical review of the mandatory serology markers and sterility data is undertaken. The units are placed in a dry shipper and taken to the ward by staff from the processing laboratory. The patient identity is checked by the clinician. Units are thawed on demand and a further identity check is made against the patient’s wristband.

NESTCB is also a national holding site for bone. Bone is distributed from the SNBTS hub and stored at the satellite site in a -80°C freezer. The tissue is transported in transport boxes validated to maintain the required temperature for up to 72 hours. Each box can hold up to six bones. Bone is issued on a named patient basis to four local hospitals. When the bone is issued by NESTCB, the shelf life of the bone is reduced to six months

The NESTCB also stores tendons. These are ordered from another HTA-licensed establishment by the four local hospitals and the tendons are sent to, stored and distributed by the NESTCB.

Bone is issued on a named patient basis to the above three local hospitals. Bones are distributed in transport boxes filled with dry ice. If dry ice is not available, then the bone may be distributed provided that the shipping time is no more than four hours. Bone transported in this way cannot be returned to stock.

The NESTCB was last inspected in 2012. During this routine inspection, a visual inspection of the premises, an audit of a set of PBSC processing records, a document review and roundtable discussions were undertaken. Tissue traceability was assessed for two bone samples and although no discrepancies were found it was noted that the transport form used for the distribution of tissue was auto-populated and there was no record of whether a courier or hospital porter was used.

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.	Overshoes are donned in an unclassified area. Staff then proceed though a corridor, open to general laboratory traffic, to enter the change area of the clean room. Staff, then wear sterile overalls whilst still wearing the same overshoes.	**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 time limit from the addition of cryoprotectant to the PBSC units to the commencement of cryopreservation has not been defined and documented.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.		
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.	NESTCB provides bones to a private hospital. The agreement between NESTCB and the hospital stipulates that Serious Adverse Events and Serious Reactions (SAEARs) are reported to the HTA without delay and not as required within 24 hours of discovery.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
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.	The establishment's risk assessment was last reviewed two years ago and does not reflect the move to open processing.	**Minor**

Advice

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

No.	Standard	Advice
1	GQ1b	The establishment's standard operating procedure (SOP) for CD34 enumeration includes a manual calculation for the final CD34 viability count. The DI is advised to ensure that the SOP accurately reflects all the steps undertaken for the CD34 calculation as well as documenting the requirement for a two-person for the calculation. The DI is also advised to amend the SOP for processing PBSCs to include the new environmental monitoring alert limits to reflect the move to open processing in a Grade A over B environment.
2	GQ1h	If bone, received from the hub or returned from local hospitals, does not meet the required standards the bone is kept on the top shelf of the -80°C freezer. The DI is advised to create a designated area for quarantining such

		products.
3	GQ1i	The DI is advised to ensure that there is an appropriate ongoing quality monitoring programme to assess the potency of PBSC units post thaw, given the ten year storage period.
	GQ1k	Only one member of staff, who was not available for the inspection, was familiar with the procedures for receipting of musculoskeletal tissue. The DI is advised to ensure all staff are aware of procedures to log and review the available tissue products.
4	GQ1t	If there is a failure of the clean room plant during processing staff will continue to process the tissue and cells to completion. The DI is advised to ensure that these units are marked as tissue for concessionary release.
5	GQ3k	There is one fully trained member of staff for the processing of PBSCs and will be re-deployed to the hub. The establishment is in the process of reorganising its services including moving processing to the hub but no specific date has been defined. The DI is advised to ensure that the remaining staff complete their training to safeguard this activity.
6	PFE3a	It was noted that the room where the bone bank freezers are located was open and that the bone bank freezers are not locked. The DI is advised to ensure access to the bone bank freezer is secured.
7	PFE3a	The storage temperature for the cryoprotectant is defined by the manufacturer as being between 20°C to 30°C. However, the room temperature alarm is set at 18°C - 25°C. The DI is advised to ensure that the temperature of the stock room reflects the storage temperature recommended by the manufacturer.
8	PFE4d	Blank forms used to record the transport of bone from the NSCTB to local hospitals were auto-populated. In addition, for some of the records of delivered bone there was no indication whether a courier or hospital porter delivered the bone. The DI is advised to ensure that transport forms are only completed on the day bone is distributed and details of who undertook the delivery of the tissue.
9	PFE5a	The PBSC units are weighed prior to processing to determine their volume and hence the volume of cryoprotectant required. The balance is checked against a calibrated, one kilogram weight but this is not documented. The DI is advised to implement a procedure for documenting the check of the balance prior to use, obtain calibrated weights that reflect the actual weight ranges of the PBSC units and to ensure that the weights remain calibrated.
10	PFE5b	The DI is advised to review maintenance reports to make sure all relevant sections of the documents are completed by the contractor.
11	PFE5f	The DI is advised to ensure that batch numbers of all cleaning reagents are also recorded in the environmental cleaning log.

Concluding comments

There are a number of areas of practice that require improvement, resulting in four minor shortfalls. These relate to the requirement for the establishment's risk assessment to be reviewed; to procedures required to minimise the risk of contamination; terms of end user

agreements; review of risk assessments and defining the exposure time of tissues and cells to cryoprotectant before cryopreservation. In addition, the HTA has given advice to the Designated Individual with a view to helping the establishment further develop its working practices.

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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 31 July 2018

Report returned from DI: 5 September 2018

Final report issued: 21 September 2018

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 2 January 2019

Appendix 1: HTA standards

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

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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
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 002/2018 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 Directions 002/2018 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
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 002/2018.
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 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
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 002/2018 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 002/2018.
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 002/2018.
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 002/2018.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.

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 002/2018.
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 002/2018.
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 shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions,

   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 breach in the relevant Codes of Practices, the HT Act and other relevant professional and statutory guidelines;

or

A shortfall which indicates a failure to carry out satisfactory procedures 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.

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.