**Site visit inspection report on compliance with HTA minimum standards**

**Castle Hill Hospital**

**HTA licensing number 12174**

**Licensed for the**

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

**5-6 December 2018**

## Summary of inspection findings

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

Although the HTA found that Castle Hill Hospital (the establishment) had met the majority of the HTA standards, eight minor shortfalls were found in relation to the Governance and Quality and Premises, Facilities and Equipment standards. The shortfalls relate to the contingency plans for tissue in the event of termination of activities, audits, sample labelling, use of the Single European Code (SEC), risk assessments, transport conditions and the storage of consumables.

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.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

| Tissue Category; Tissue Type | Procurement | Processing | Testing | Storage | Distribution | Import | Export |
|---|---|---|---|---|---|---|---|
| **Musculoskeletal, Bone; Bone** | **E** | | **E** | **E** | **E*** | | |
| **Musculoskeletal, Bone; Cranial Plate** | **E** | | **E** | **E** | **E*** | | |
| **Musculoskeletal, Tendon & Ligament; Tendons** | | | **E** | | | | |

**Background to the establishment and description of inspection activities undertaken**

This report refers to the activities carried out at Castle Hill Hospital (the hub) and its two satellite sites based at the Spire Hull and East Riding Hospital (Spire) and the Hull Royal Infirmary (HRI). The establishment is licensed for procurement, donor testing, storage and distribution of human tissues and cells under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), and has been licensed since March 2007.

Femoral heads are procured from patients undergoing elective hip replacement surgery at the hub. The bone bank coordinator will identify and seek consent from potential donors, taking a past medical, social, and travel history. During their pre-assessment visit, patients are given an information sheet on elective hip surgery. Collection pots along with the bone bank number and related labels are provided by the bone bank coordinator.

Blood samples for the mandatory serological testing are taken from the donor on the day of donation by the anaesthetist. In addition, the scrub nurse will take swabs and bone chips from procured femoral heads. The femoral head is placed in a sterile tamper-evident screw-capped pot which is, in turn, placed in a second sterile tamper-evident screw-capped pot. Femoral heads are assigned a unique bone bank number. A patient ID label and a “Not For Implant” allograft sticker are applied to the pot following procurement. The blood samples are sent to the testing laboratory located at the hub and the swabs and bone chips are sent for microbiological testing at the HRI. All femoral heads are weighed and details of each procurement are entered into the bone bank register and an electronic spreadsheet prior to them being placed in the quarantine section of the bone bank -80°C freezer.

The bone bank coordinator contacts all donors after 180 days to arrange for the collection of a blood sample for the repeat mandatory serological testing; the blood sample is collected during a home visit or the during the donor’s six-month post-surgery review. The first and second serology test results, as well as the microbiology test results, are recorded on the bone bank register and electronic spreadsheet. The serology and microbiology test results are reviewed, and if all results are negative, the bone bank coordinator transfers the femoral head to the “end use” shelf of the freezer and a “For Implant” sticker is affixed to the pot. Any samples with a positive result are disposed of.

The majority of femoral heads stored at the hub are for allogeneic use. Occasionally, femoral heads are procured for autologous use and stored in a separate section of the freezer until they are needed for end use. The hub also stores and distributes tendons and menisci, which are purchased from another HTA-licensed establishment. These are stored on a separate shelf in the -80°C freezer and traceability records are maintained in a separate section of the bone bank register.

In the past femoral heads have been procured at the Spire satellite site. However, the Spire has not procured any femoral heads in the last two years and the majority of staff with experience of the process have left the satellite. At the time of the inspection, there were no arrangements, or plans, in place at the Spire site to procure femoral heads, and no collection equipment or consumables were held on site.

The other satellite site, HRI, procures cranial flaps during neurosurgery for autologous use at a later date. This procedure often takes place during emergency trauma surgery and the surgeon consents the patient when possible. However, if the patient is unable to provide

consent at the time of procurement, it is either sought after the procedure has taken place if donor is able to give consent or it may be sought from the next of kin. Alternatively, consent may be assumed as being in 'the best interest of the patient'. A blood sample, bone chips and a swab of the cranial flap are taken in the operating theatre once the surgeon confirms that the cranial flap can be stored.

Following procurement of the cranial flap, excess tissue is removed and the flap is placed in the appropriate collection pot, labelled with a hospital number, patient ID sticker, and an 'autologous use' sticker. The hub is notified and a medical courier service, under contract with the Trust, is contacted to arrange transportation of the cranial flap along with the associated paperwork to the hub. The cranial flap can be stored at the satellite in a temperature-monitored refrigerator, for up to 24 hours prior to transfer to the hub premises. The samples for serology and microbiology testing are sent to the pathology lab within HRI from where they are distributed accordingly. At the hub, the donor paperwork is filed, tissue and donor identifiers are recorded and the cranial flap is stored in a separate section of the -80°C freezer to the femoral heads. If needed at a later date for re-implantation, Castle Hill Hospital is notified and the cranial flap is returned to HRI for immediate end use. Patient records and the bone bank register are updated with traceability details.

The -80°C freezer at the hub is connected to an uninterruptible power supply. The storage temperature is recorded by a wheel chart which is reviewed and replaced weekly. The freezers are alarmed to the switchboard, which will notify the bone bank coordinator or other nominated staff both in and out of hours in the event of a deviation from the required storage temperature.

This is the sixth routine inspection of the establishment and included a visual inspection of the premises, both at the hub and two satellite sites, an interview with the DI and discussions with the bone bank coordinator (a PD on the licence) and the PD with oversight of each satellite facility.

In addition to a review of documentation relevant to the establishment's licensable activities a traceability audit was carried out which included two cranial flaps (one in quarantine and one released for use), two femoral heads (one in quarantine and one released for use) and a tendon that were currently in storage. The establishment occasionally source tendons for surgical procedures from a third party, and are licensed for storage of such tissue. During the inspection, it was noted that there was a tendon stored for possible autologous use that had been collected at the establishment. The bone bank coordinator had utilised the existing consent forms and processes, including mandatory testing, to ensure that the tendon was tracked and stored appropriately. All material was cross-checked against the bone bank register and patient notes. A total of six sets of patient records, including records for procurement and testing of two cranial flaps and four femoral heads, from the last two years (donor and linked recipient; where applicable) were reviewed to ensure that they contained all the relevant documentation, including serology and microbiology test results. There was a minor anomaly identified within the notes, specifically with regards to the lack of a microbiology test result from the swab of an implanted cranial flap, as it was not received at the testing lab.

The Spire satellite is not currently undertaking any licensable activity and has not procured femoral heads since the last inspection. The patient records for the one recipient of a femoral head were reviewed and no anomalies were found. As Spire transfers records to an offsite

storage archive after two years there were no other records available for review. Due to recent staff turnover there were no individuals on site experienced in, or trained, to procure femoral heads. It was also noted that there were no clinical areas set aside for the procurement of femoral heads, and no collection materials were currently held on site. The PD for Spire indicated that should this process be reinitiated in the future then training would be sought from the bone bank coordinator.

## 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. | | |
| 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. | The establishment has an agreement to transfer tissue to a Research Tissue Bank (RTB) licensed by the HTA in the event of termination of activities. As the RTB is licensed under the Human Tissue Act 2004 they will not be able to store or release tissues for patient use should it be required. | **Minor** |
| GQ2 There is a documented system of quality management and audit. | | |
| 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. | The establishment does conduct an independent audit. However, the audit does not include an assessment of compliance with HTA standards. | **Minor** |
| GQ5 There are documented procedures for donor selection and exclusion, including donor criteria. | | |
| f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code. | Establishment staff do not always label samples for donor testing with the time the sample was taken. Notes in several patient records indicated there was no date or time on the sample, and the date recorded was when the sample was received in the testing laboratory. | **Minor** |

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| GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail. | | |
| d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018. | The establishment do not record the SEC associated with tissue sourced from another HTA licensed establishment. | **Minor** |
| 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. | Staff at HRI reported that they did not have any documented risk assessments in place.<br>While the establishment has a number of risk assessments in place at the hub they do not address the potential risks associated with all practices and processes. For example, the establishment did not have risk assessments addressing the risks associated with:<br>- using external couriers to transport material<br>- transferring samples to the testing laboratory for mandatory testing | **Minor** |
| 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 policy is to review risk assessments every two years.<br>In addition, several of the risk assessments provided for review had passed their required review date. These included, but were not limited to, the risk assessments for:<br>- 'Autologous bone stored in the bone bank being incorrectly implanted', due for review 23/5/2018<br>- 'Contaminated or poor quality/damaged bone being implanted', due for review 23/5/2018<br>- 'Risk of Contaminating Bone by incorrect use at the Spire', due for review 24/5/2018 | **Minor** |

**Premises, Facilities and Equipment**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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. | Ambient storage areas at the hub and HRI were not temperature-monitored. This does not provide assurance that consumables have been kept at an appropriate temperature range. The microbial swabs used at both sites required storage at 5-25ºC while the pre-packed collection kits for cranial flaps, at HRI, required storage at 10-35ºC. | **Minor** |
| PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination. | | |
| g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented. | The establishment have not documented the critical transport conditions required to maintain the properties of cranial flaps during transport from HRI to the hub.<br><br>Cranial flaps are transported at ambient temperature after storage for up to 24 hours, at temperatures between 2-10ºC. The establishment have not performed a validation, or assessment, to ensure these conditions are suitable to maintain the quality and integrity of the cranial flaps. | **Minor** |

## Advice

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

| No. | Standard | Advice |
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| 1. | GQ1b | In order to facilitate consistency, standard operating procedures (SOPs) and other documents are shared across the hub and two satellite facilities. Documents require minor modifications to make them site-specific. The DI is advised to review these documents to ensure that the required modifications have been made and are accurate. For example, the SOP S1 'Creation and retention of bone bank records for femoral head harvesting' (Spire) retains the reference that 'A signed consent form allows the Trust to harvest and store the donated bone' even though the Spire is a private hospital and not part of the Trust. |
| 2. | GQ1r and GQ1s | Tissue is transferred from HRI to the hub using a courier service under an agreement with the Trust. The DI is advised to retain a current version of the |

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| | | agreement to assure himself that it continues to detail any storage conditions required during transport and that the requirement to report any incidents to the DI within a specific time frame is included. |
| 3. | GQ3k | The DI is responsible for reporting SAEARs to the HTA. He is advised to consider training the PD in this process to provide support and cover for when he is absent. |
| 4. | GQ4h | While the refrigerator used for the temporary storage of cranial flaps at HRI is continuously monitored, staff manually record current and minimum/maximum refrigerator temperatures. A review of the reporting log identified a number of instances where the daily log had either been left blank or had been annotated with the statement 'Not Working'. The inspection team were informed that this phrase indicate that staff were not working in the theatre on that day and the log had not been completed, rather than indicating the refrigerator or other equipment was 'Not Working'. The DI is advised to introduce a standardised process where blank fields are annotated to explain why they are blank, the phrase 'Not Working' is replaced with something more specific, and that there are processes in place for the long-term storage of these records. |
| 5. | GQ4h | The establishment uses chart recorders to record the temperature of their -80ºC freezer. The DI is advised to consider annotating any temperature excursions on the chart, when it is removed for storage, in order to assure himself that any excursions can be accounted for in the future. |
| 6. | GQ5a | During the consent seeking process, the establishment completes a questionnaire with the donor which includes information on travel outside of Western Europe, Canada and North America. Due to the risk of exposure to infection within these regions, the DI is advised to develop procedures to consider these risks when recruiting potential donors. |
| 7. | GQ6d | The establishment does not currently distribute tissues or cells to other organisations. However, this type of distribution may occur in the future. The DI should ensure procedures are put in place for application of the Single European Code (SEC) should this activity commence. |
| 8. | GQ7a | The DI is advised to review the SOPs relating to reporting Serious Adverse Events and Reactions to ensure that they reflect current practice. The SOPs should clearly state that the 24 hour reporting time frame is from discovery of the Event or Reaction, and have no ambiguity regarding who reports the event or reaction to the bone bank coordinator /Designated Individual. |

## Concluding comments

Several areas of good practice were noted during the inspection. Overall, the hub and satellite facilities worked well together to provide and well-organised patient orientated service. There was good collaboration across the different sites, with the same SOPs and documents being shared across each site in order to facilitate processes and ensure consistency.

There were a number of areas of practice identified during the inspection that require improvement, resulting in eight minor shortfalls under the Governance and Quality standards, and the Premises, Facilities and Equipment standards. These shortfalls related to a lack of adequate contingency for storage of material in the event that the establishment terminates activity, the lack of an appropriate independent audit against the HTA standards, labelling of

samples for serology and microbiology testing, documentation of systems to protect the quality and integrity of tissue during transport, failure to record the SEC on purchased tissues and cells, and risk assessments. There was also a minor shortfall related to the storage of consumables at ambient temperatures. In addition, there are some areas of practice that may benefit from further improvement and HTA has given advice to the Designated Individual with respect to these.

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: 08 January 2019**

**Report returned from DI: 24 January 2019**

**Final report issued: 01 February 2019**

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

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| 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. |
| 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 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. |

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| 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. |

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| 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. |
| 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. |

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| 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** |
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| PFE1 The premises are fit for purpose. |
| a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose. |
| b) There are procedures to review and maintain the safety of staff, visitors and patients. |
| c) The premises have sufficient space for procedures to be carried out safely and efficiently. |
| e) There are procedures to ensure that the premises are secure and confidentiality is maintained. |
| f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities. |
| PFE2 Environmental controls are in place to avoid potential contamination. |
| a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine. |
| 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. |

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| 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. |

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|---|
| 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.