Inspection report on compliance with HTA licensing standards
Inspection dates: **27, 28 November 2024**

# Castle Hill Hospital

HTA licensing number 12174

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

**Licensable activities carried out by the establishment**

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.
'TPA' = Third party agreement; the establishment is licensed for this activity but another establishment (not licensed by the HTA) carries out the activity on their behalf.

| Site | Procurement | Processing | Testing | Storage | Distribution | Import | Export |
|---|---|---|---|---|---|---|---|
| **Hub**<br>**Castle Hill Hospital** | E/TPA | | E | E | E | | |
| **Satellite**<br>**Hull Royal Infirmary** | E | | E | E | | | |

**Tissue types authorised for licensed activities**

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.

| Tissue Category; Tissue Type | Procurement | Processing | Testing | Storage | Distribution | Import | Export |
|---|---|---|---|---|---|---|---|
| **Musculoskeletal, Bone; Bone** | Authorised | | Authorised | Authorised | Authorised | | |
| **Musculoskeletal, Bone; Cranial Flaps** | Authorised | | Authorised | Authorised | | | |
| **Musculoskeletal, Bone; Bone Struts** | | | | Authorised | | | |
| **Membrane, Amniotic; Amniotic Membrane** | | | | Authorised | | | |

**Summary of inspection findings**

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

Although the HTA found that Castle Hill Hospital (the establishment) had met many of the HTA's standards that were assessed during the inspection, two major and thirteen minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

One of the two major shortfalls relates to a finding from the last inspection in 2022. The HTA is concerned that adequate steps were not taken to address this finding in the intervening period and to embed suitable practices at the establishment.

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.

**Compliance with HTA standards**

***Major Shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **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. | Although an independent audit had been conducted since the last inspection, it was limited in scope. For example, the independent audit did not include a review of activities at the satellite site, the third-party procurement organisation or the testing laboratory, or a review of primary records such as donor records, temperature monitoring data and mandatory serology testing results.<br><br>As a result, the audit did not verify compliance with protocols and all applicable HTA standards.<br><br>*This is a recurrent issue. It was identified at the previous inspection and has not been fully addressed. This finding is therefore classified as a major shortfall.* | **Major** |

| GQ7 There are systems to ensure that all adverse events 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. | The establishment's policy requires incidents to be recorded electronically on the Trust's incident reporting software. The Bone Bank Manager also keeps a paper-based record of incidents that may affect the quality and safety of the tissue products.<br><br>During the inspection a selection of five representative incidents were reviewed that related to the tissues. Four out of five incidents reviewed were not recorded on the Trust's incident reporting software, as per Trust policy. For one of these incidents the information recorded within the paper-based incident reporting system was not sufficient to enable the affected unit to be tracked from donor to recipient. Also, key information, such as corrective actions taken that related to the incidents, was not consistently recorded. The fifth incident reviewed was not traceable to paper records.<br><br>Furthermore, the establishment's satellite has no documented procedure in place for the identification and reporting of serious adverse events and reactions (SAEARs). Staff at the virology laboratory were unaware of the SAEARs reporting requirements. | **Major** |

***Minor Shortfalls***

| 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.** | | |
| c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes. | Although the DI meets with staff working under the licence, there are no minuted governance meetings. | **Minor** |
| k) There is a procedure for handling returned products. | During the inspection, establishment staff described a process where femoral heads can be returned to the -80°C storage freezer, providing the transport box remains unopened and the time from issue to return to the freezer is less than two hours. This procedure is not documented.<br>Furthermore, records do not capture whether tissue has been issued and returned, or the number of times this has happened for any given sample. | **Minor** |

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| 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. | The establishment has put an agreement in place with the third-party undertaking procurement of femoral heads on its behalf. The agreement sets out specific criteria that the third party must meet in order to ensure the quality and safety of the reagents used and the tissue products procured.<br><br>The agreement sets out that the consumables used for femoral head procurement will be temperature-monitored and the storage of the femoral heads by the third party will not exceed 24 hours. However, the storage temperature of the consumables and the femoral heads is not defined within the agreement, or in any operational documents that must be followed under the terms of the agreement. | **Minor** |
| **GQ2 There is a documented system of quality management and audit.** | | |
| b) There is an internal audit system for all licensable activities. | Internal audits do not cover the full range of activities carried out by the establishment under its licence. | **Minor** |

| **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.** | | |
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| 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. | The establishment's training procedures for staff carrying out licensable activities do not include parts covering HTA requirements and the regulatory context for the work carried out under the authority of the establishment's HTA licence. | **Minor** |
| k) The establishment is sufficiently staffed to carry out its activities. | The majority of the bone bank activities are carried out by the Bone Bank Co-ordinator, including:<br>• arranging and taking the repeat donor blood samples after an interval of 180 days;<br>• the review of the serology and microbiology test results;<br>• updating the bone bank paperwork; and<br>• transferring the femoral heads from the "quarantine" to the "issue for use" compartments of the -80°C freezer.<br>There is no staff contingency for the bone bank work and the activity stops during periods of annual leave and sickness. | **Minor** |

| GQ4 There is a systematic and planned approach to the management of records. | | |
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| 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. | The third party that procures tissue on behalf of the establishment has a record retention policy that sets out that data must be stored for eight years after the patient's death or last appointment. This is not aligned with regulatory requirements.<br><br>The establishment has not taken other steps to ensure that records are retained for the required timeframes. | **Minor** |
| i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells. | | |

| GQ5 There are documented procedures for donor selection and exclusion, including donor criteria. | | |
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| a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021. | Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) establishments procuring tissues and cells for human application must ensure that donors are selected based on an analysis of risks relating to transmissible diseases. This assessment must include consideration of the donor's travel and exposure history and local infectious disease prevalence.<br><br>A part of its donor evaluation process, the establishment asks potential donors about whether they have ever travelled outside Western Europe, North America or Canada, and whether they have ever spent time in a region where malaria is endemic.<br><br>The establishment was not able to provide evidence of a robust process that underpins this approach to the evaluation of donor travel risks. For example, the establishment's governance documents do not set out in which countries malaria is endemic, or where such information could be found, or what steps to take in the event that a potential donor indicates that they have travelled outside of the specified regions. Furthermore, the establishment was unable to describe how new and emerging travel risks would be identified and incorporated into its selection procedures. | **Minor** |

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| **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. | The scope of the risk assessments is limited and does not cover all processes and activities. | **Minor** |
| **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. | The establishment has not carried out a premises risk assessment at the neurosurgery and ophthalmology departments located at the satellite site. | **Minor** |

| 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. | The swabs and pots used for femoral head and cranial flap procurement must be stored between 10-25°C and 10-35°C, respectively, according to the manufacturer's instructions. Staff at the hub only record the temperature of the trolley where the pots and swabs are stored on a monthly basis, but the data review is limited to the temperature data of the day.<br><br>Establishment staff at the satellite, where cranial flaps are procured and stored, record the minimum and maximum temperature of storage of the consumables. However, there were several gaps identified in the recording of the temperature monitoring data.<br><br>The amniotic membrane product stored at the satellite site must be stored between 2-25°C, according to the manufacturer's instructions. Whilst staff record the temperature of the storage area daily, minimum and maximum temperatures are not recorded. | **Minor** |
| c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity. | The establishment's procedure at the satellite for managing temperature deviation alarms within the fridge where the cranial flaps are stored, sets out that staff will re-set the probe and check the temperature within one hour.<br><br>Several examples were identified where the procedure for reporting out of range alarms was not followed and staff did not record if the temperature returned back within range following the temperature excursion. | **Minor** |

| PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored. | | |
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| b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions. | The -80°C freezer temperature monitoring probes at the hub, and the fridge and ambient temperature probes at the satellite site, have not been calibrated in accordance with the manufacturer's recommendations.<br>Also, the establishment uses scales to weigh the femoral heads. The scales have not been calibrated to ensure accurate measurements. | **Minor** |

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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.

**Advice**

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

| Number | Standard | Advice |
|---|---|---|
| 1. | GQ1b | Although the procedure for managing serious adverse events and reactions was recently updated, a reference to the previous DI was identified. The establishment is advised to review all documentation to ensure it includes up-to-date references and contact details of the new DI. |
| 2. | GQ1c | In addressing the shortfall above against GQ1c, the DI is advised to include in the agenda for the governance meetings the work undertaken by the establishment, any updates from the HTA, incidents, and issues that may have arisen. Also, the results of all audit findings, and actions taken, should be |

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| | | formally recorded and discussed at governance meetings, to ensure continuous improvement of processes and practices.<br><br>This will help raise awareness among staff involved in this work of the associated regulatory requirements, and facilitate the integration of the licensable activities into the governance and quality management system used by the establishment. |
| 3. | GQ4b | An example of overwriting was observed during the review of records. When correcting errors in documentation, the DI is advised to ensure that staff follow good practice by crossing through with a single line, signing, and dating the error. |
| 4. | GQ4b | During the audit of the records, a few examples were observed where not all sections of the harvest forms and paperwork were filled in. The DI is advised to review the content of the harvest forms and paperwork to ensure these remain relevant to the activities undertaken.<br><br>The DI is also advised to review the establishment's approach to the audit of records to assure himself these are sufficiently robust and able to identify any issues with completion of records and ensure appropriate remedial actions are taken, when required. |
| 5. | GQ5a | As part of the donor assessment process consideration is given to whether the bone donor is taking any medication. In addressing the shortfall against GQ5a, the DI is advised as part of the donor assessment process to include more specific, follow up questions to the initial one on whether the donor is taking immunosuppressive medication and/ or pre- and post- exposure prophylaxis medication for people at risk of HIV. |

**Background**

Castle Hill Hospital (the establishment) is licensed for the procurement, testing and storage of femoral heads and cranial flaps, and the distribution of femoral heads. Procurement of femoral heads takes place at the establishment and another hospital under a third-party

agreement, whilst procurement of cranial flaps takes place at the satellite, Hull Royal Infirmary. Donor testing for mandatory serology markers and microbiology testing of both cranial flaps and femoral heads is undertaken at the satellite. The establishment is also licensed to store amniotic membrane and bone struts.

The establishment has been licensed by the HTA since March 2007. This was the establishment's eighth inspection; the last inspection was a "focused" inspection, where only a limited number of HTA standards were assessed and took place in October 2022.

Since the previous inspection the establishment has changed the CLHc, the DI and added a new Person Designated (PD). Two new tissue types, amniotic membrane and bone struts, have been added to the licence under the authorisation relating to its storage activities. There have been no other changes to the licence arrangements or activities carried out under the licence since the previous inspection.

**Description of inspection activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The following areas were covered during the inspection:

*Review of governance documentation*

A review of a selection of documentation relevant to the establishment's licensable activities and quality management system was undertaken, including a review of policies and procedural documents, audits, risk assessments, temperature monitoring records for the -80°C freezer, 2-8°C fridge and the ambient temperature storage area used to store consumables, staff training records and reported incidents.

*Visual inspection*

A review of facilities was conducted at the establishment, including areas where receipt and storage of tissue products takes place. The inspection also included the satellite, where procurement and storage of cranial flaps and storage of amniotic membrane products takes place. The testing laboratory at the satellite was also visited. A visual inspection of the microbiology lab at the satellite was not undertaken as part of this inspection. The inspection team also visited the hospital that is procuring femoral heads under the authority of a third-party agreement with the establishment.

*Audit of records*
Representative records relating to two cranial flaps and three femoral heads were reviewed, including, where applicable: records related to procurement dates and times, testing for the mandatory serology markers, microbiology sterility testing results, storage and end use or disposal.

A traceability audit was undertaken for a femoral head and a cranial flap in the “ready to use” compartment of the -80°C freezer and three femoral heads in quarantine. The electronic record of a cranial flap was also cross-checked against the bone bank logbook. No discrepancies were identified.

*Meetings with establishment staff*
Discussions were held with the DI, the PDs and staff carrying out licensable activities at the hub, the satellite, the testing lab and the hospital operating under a third-party agreement.

**Report sent to DI for factual accuracy: 2025 – 02 – 20**

**Report returned from DI: 2025 – 03 – 03**

**Final report issued: 2025 – 04 – 03**

## Appendix 1: The HTA's regulatory requirements

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

The statutory duties of the DI 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.

## Appendix 2: Classification of the level of shortfall

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 Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 (as amended) 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 on-site 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 the final inspection report. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

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

## Appendix 3: 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 (as amended)

### 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 (as amended) 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 (as amended) 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 Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) 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. |

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| 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 001/2021 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 001/2021 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. |
| b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination. |

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| 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 Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA). |
| 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. |

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| 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 001/2021. |
| 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. |
| 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. |

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| 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 001/2021, is collected and maintained. |

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| g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021. |
| 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 001/2021 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 001/2021. |
| 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 001/2021. |
| 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 001/2021. |
| 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. |

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| e) Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021. |
| 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. |

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| 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. |

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| 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. |
| 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. |

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| 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 001/2021. |
| 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 001/2021. |
| j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021. |
| 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. |

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| 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** |
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| 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. |
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| 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. |