Inspection report on compliance with HTA licensing standards
Inspection dates: **17-18 May 2022**

# Royal Gwent Hospital

HTA licensing number 11130

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

**Licensable activities carried out by the establishment**

**Licensed activities – Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**

'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 |
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| **Royal Gwent Hospital** | E/TPA | | E/TPA | 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 | | |

**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 Royal Gwent Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, two major and nine minor shortfalls were found against standards for Consent, Governance and Quality, and Premises, Facilities and Equipment.

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 |
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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.** | During an audit in 2020, the establishment identified an occasion where an incorrect femoral head was released for human application. This was reported to the HTA as a serious adverse event (SAE). The corrective and preventative actions (CAPAs) undertaken to prevent recurrence of this event included the implementation of a two-person check when transferring FH from the quarantine (F3) freezer to the release (F2) freezer following release by the Medical Director. Although establishment procedures were updated and the check was implemented, it was not maintained. At the time of the inspection, two-person checks at the point of transfer were not being routinely undertaken.<br><br>During a review of internal incident records, two recent incident records were reviewed in which the record had been signed off as completed before all of the identified CAPAs had been completed. The establishment does not have a separate system to monitor progress of the completion of open CAPAs. | **Major** |
| i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded. | | |
| **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 | | |

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| any corrective or preventative actions. | | |
| **GQ2 There is a documented system of quality management and audit.** | | |
| a) There is a quality management system which ensures continuous and systematic improvement. | During a visit to the Royal Gwent Hospital virology laboratory, it was determined that although donor serological samples are initially received and spun down at the laboratory, serology testing activities have transferred to the Grange Hospital, another hospital within the Trust. The change had not been communicated to, or identified by, the establishment. The new laboratory's premises and procedures have not been audited and no alternative steps have been taken to ensure the arrangements are suitable.<br><br>The establishment's internal audit records are not sufficiently documented to provide assurance that all CAPAs have been identified and robustly addressed before the audit record is closed. | **Major** |

***Minor Shortfalls***

| Standard | Inspection findings | Level of shortfall |
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| **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 | Consent for donation is taken either in pre-operation clinics or on the day of surgery by trained nurses. A review of records demonstrated that the | **Minor** |

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| take informed consent in accordance with the requirements of the HT Act and Code of Practice on Consent. | consent training for ward nurses had expired. | |
| **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. | Since the last inspection, the establishment has agreed an arrangement with an end user whereby distributed bone can be stored by the end user at -20°C for up to 48 hours before use. The establishment's governance documents, such as agreements and the information provided to end users, have not been updated to reflect this new arrangement and the specific requirements needed to ensure the quality and safety of the distributed bone in this scenario. | **Minor** |
| 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 does not have an agreement in place with the third party testing laboratory that undertakes specialist serological testing of donor samples on occasions where the donor's medical history indicates that additional tests to support the assessment of donor suitability are required.<br><br>The establishment's written agreement with the third party laboratory that undertakes routine HTLV testing does not require the third party to maintain records of raw data in accordance with regulatory requirements. | **Minor** |
| r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021. | | |

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| **GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.** | | |
| e) Personnel are trained in all tasks relevant to their work and their competence is recorded. | The establishment's procedures for documenting staff training, particularly in the context of the reading of updated procedures, do not satisfactorily demonstrate that staff receive such training prior to undertaking the related activity. | **Minor** |
| **GQ4 There is a systematic and planned approach to the management of records.** | | |
| j) Records are kept of products and material coming into contact with the tissues and / or cells. | The establishment does not have a system in place to record the lot numbers of swabs coming into contact with femoral heads during procurement. | **Minor** |
| **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. | The establishment's bone donor medical history form requires updating to properly capture donor selection information in accordance with Directions 001/2021. For example, questions relating to diseases of unknown aetiology are limited to inflammatory diseases only, and the form does not explicitly prompt the donor to report medical history that could indicate a risk of immunosuppression or systemic infection. | **Minor** |
| b) The testing of donors by the establishment or a third party on behalf of the establishment is carried | The manufacturers of kits used to undertake serological testing require that samples are spun down within 24 hours of being collected. The laboratory does not record the time at which samples are centrifuged, and was therefore unable to demonstrate that this requirement had been met. | **Minor** |

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| out in accordance with the requirements of Directions 001/2021. | | |
| **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 establishment's defined temperature limits for areas in which femoral head storage pots and the swabs used in microbiological testing are stored is not aligned with the storage temperature range stipulated by the manufacturer of the swabs.<br><br>The temperature of the St Woolos Hospital theatre area where a stock of swabs and pots are stored is monitored by a stand-alone temperature and humidity probe. The establishment has not provided calibration certification to demonstrate that the probe is suitably calibrated. In addition, a review of records taken using the probe identified several errors and occasions in which only the humidity measurement had been recorded. This indicated that recent staff refresher training had not been successfully embedded. Gaps were also identified in monitoring records relating to the storage area at St Joseph's Hospital.<br><br>The temperature monitoring form does not identify the equipment number of the probe used in each location, and examples were reviewed in which the section of the form identifying the location being monitored had not been completed. | **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 establishment was unable to provide requested service records for the laminar flow within which microbiological samples are processed, or an incubator within which microbiological plates are incubated. | **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 |
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| 1. | C1a, GQ5a | The DI is advised to define a maximum time between the taking of consent and donor selection and the day of procurement to ensure the patient's medical history and consent are reconfirmed on occasions where planned surgeries have been postponed for extended periods. |
| 2. | C3a | The establishment is considering whether to restrict the taking of consent to clinic sessions prior to the day of planned surgery. If this change is approved, the DI is advised to ensure standard operating procedures are updated to reflect the change, ensuring arrangements at the third party procurement hospitals are also checked to confirm that they remain suitable and accurately documented. |

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| 3. | GQ1c, GQ2b, GQ5b | The DI is advised to appoint Persons Designated (PDs) to represent the establishment's microbiology and virology laboratories and include these representatives in establishment governance meetings. This would help to strengthen lines of communication between the teams so that topics relevant to activities under the licence are reported and discussed.<br><br>The DI is further advised to put a system in place to circulate governance meeting minutes by email to all invited attendees, to ensure those absent on the day are kept informed of items relevant to activities under the licence. |
| 4. | GQ4f,g | Establishment staff create an entry in the bone bank database for a procured femoral head once the consent form linked to the donation event has been received into the bone bank office. However, the form may not be received until several weeks after the bone has been placed into the quarantine freezer and the serology and microbiology tests have been completed. Although the bone is not released for human application until all the necessary information has been collated and reviewed, the DI is advised to review the current system to ensure that it is suitable and does not create a risk to the security of records or the establishment's ability to manage incidents relating to procured bone that may occur before the database entry is created. |
| 5. | PFE3a | The DI is advised to redesign the temperature monitoring form used to record the temperature and humidity of theatre areas, to assist staff in recording the readings correctly and as a reminder to reset the probe after each daily reading has been taken. |

## Background

The establishment has been licensed by the HTA since March 2007. This was the establishment's seventh inspection; the last inspection took place in February 2019.

Femoral heads are procured at Royal Gwent Hospital and two other local hospitals, St Woolos Hospital and St Joseph's Hospital, under the terms of third party agreements (TPAs). Consumables, including swabs and storage containers, are supplied by the establishment.

Consent and the donor questionnaire are completed during pre-admission clinics or pre-operatively on the day of procurement. Blood samples for mandatory donor serology testing are taken at the same time as consent and repeated at least 180 days after procurement. Establishment procedures require femoral heads to be placed in quarantine storage at Royal Gwent within four hours of procurement. After receipt of the donor consent form, establishment staff will open a new patient file in the Bone Bank database and generate a unique identification number for the bone to maintain traceability. Microbiological testing of bone swabs and 'nibbles', as well as donor serological testing, is undertaken at the Royal Gwent UKAS-accredited laboratory, with the exception of HTLV testing, which is undertaken under the terms of a TPA.

Release from quarantine is undertaken by the Medical Director following review of the medical history form and the relevant microbiology and serology results.

Since the last inspection mandatory serological testing activities undertaken by the Trust laboratories have relocated to a different hospital within the Trust.

**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*

The inspection included a review of policies and procedural documents relating to licensed activities, servicing records, agreements, audits, risk assessments, incidents, meeting minutes, temperature monitoring records, and staff training records.

*Visual inspection*

The inspection included a visual inspection of the establishment's locked and air-conditioned freezer storage area at Royal Gwent Hospital, which is also the room within which the main stock of consumables associated with procurement are stored. The inspection also

included visits to the theatres (within which some consumables are stored) at both Royal Gwent and St Woolos Hospital, and a visit to the establishment's microbiology and virology laboratories, within which donor serological testing and microbiological testing of bone swabs and 'nibbles' are undertaken.

*Audit of records*
The visual inspection included a review of three selected femoral heads in storage within the quarantine and release freezers against the entries within the associated bone back ledgers. The movement of bone from quarantine storage to release, as documented in the establishment's ledgers, was reviewed. Records of consent, donor selection, microbiology and virology assessment and release by the Medical Director were reviewed for three femoral heads, including one that was used in human application.

*Meetings with establishment staff*
Round table discussions were held with the DI, who is the establishment's Medical Director, the Deputy Medical Director, the establishment's Governance Manager and the Bone Bank Co-ordinator. The inspection also includes discussions with representatives of the microbiology and virology testing laboratories.

**Report sent to DI for factual accuracy: 17 June 2022**

**Report returned from DI: 28 June 2022**

**Final report issued: 29 June 2022**

**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: 21 November 2023**

## 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. |
| 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. |

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| 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. |

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| 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. |
| 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. |

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| 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 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. |

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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. |
| 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. |