

**Site Inspection Report for
Leicester Bone Bank, University Hospitals of Leicester NHS Trust**

Licensing number 11011

Licensed for the

- **procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, and the**
- **storage of relevant material which has come from a human body for use for Scheduled Purposes other than transplantation under the Human Tissue Act 2004**

15-16 September 2009

Introduction

1. The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes such as research, transplantation, education and training and public display. The requirements of the HTA are set out in the Human Tissue Act 2004 (HT Act) and the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. There are supplementary requirements for those establishments storing tissue for transplantation and they are summarised in HTA Directions 001/2006, 002/2007 and 004/2007.
2. The Human Tissue Authority is also the designated Competent Authority for the purposes of the European Union Tissue and Cells Directives (the Directives) so far as they relate to tissues and cells for use in human application. On 5 July 2007 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations) came into force. The Regulations formally transposed the Directives into UK law. Under the Regulations the HTA regulates and licences the procurement, testing, processing, storage, distribution, import or export of tissues or cells intended for human application. The HTA has produced detailed Directions to complement the implementation of the Directives.
3. As part of the regulatory framework, the HTA licenses establishments and undertakes inspections to assess compliance with expected standards.
4. Under the HT Act and the Regulations, the HTA has a statutory responsibility to make judgements about the suitability of the Designated Individual, Licence Applicant (Holder), premises and practices in relation to the licensed activities. These responsibilities are set out in Part 11 and 12 of the Regulations, which is the framework for the HTA's approach to licensing and inspection.
5. The HTA must satisfy itself that the Designated Individual (DI) is a suitable person to supervise the activity to be authorised by the licence and that they will undertake the following duties:
 - secure that other persons to whom the licence applies are suitable persons to participate in the licensed activities;
 - secure that suitable practices are used in the course of carrying on the activity; and
 - secure that the conditions of the licence are complied with.
6. Designated Individuals who are licensed under the Regulations have the following additional duties:
 - secure the conditions of third party agreements, in relation to the licensed activities authorised to be carried on under his supervision; and
 - secure that the information and confidentiality requirements of Section 13 (1) are complied with.
7. The HTA must satisfy itself that the applicant for the licence is a suitable person/entity to be the holder of the licence.

8. The HTA must satisfy itself that the premises are suitable for the activity to be authorised by the licence.
9. To fulfil its statutory responsibilities, the HTA must be able to assess whether an establishment is suitable to carry out one or more of the activities regulated by the HTA. Suitability is assessed through a process of inspection. Inspections can be routine or risk based, announced or unannounced.

Inspection Process

10. HTA defines inspection as a process encompassing desk-based review, on-site assessment and analysis of relevant written, numerical, verbal and visual information to evaluate the establishment's compliance with expected standards. Desk-based reviews, described as phase one inspections, focus on the evaluation of the compliance report submitted by the Licence Applicant and Designated Individual, as well as any additional information provided by the establishment at the request of the HTA. On-site assessments, described as phase two inspections, focus on a review of the establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. Where the inspection process identifies that a standard is not being met, additional conditions may be placed on an establishment's licence to ensure that appropriate action is taken to address the non-compliance/s.
11. Both desk-based review and on-site assessments may lead to advice and guidance for improving practice in one or more areas.

Judgements

12. To enable the HTA to make effective judgements about the suitability of the DI and the Licence Holder, the suitability of the premises, the suitability of the practices taking place under the supervision of the DI and the activity or activities carried out under a third party agreement made in accordance with Directions 002/2007, the HTA standards were developed under four high-level headings:
 - Consent
 - Governance and Quality
 - Premises, Facilities and Equipment
 - Disposal
13. The evidence gathering during inspection focuses on these standards, with particular emphasis on any areas identified as requiring special attention in phase one of the inspection, as detailed above.
14. Throughout the inspection process, standards are assessed using the same four-point numerical scale used by the DI in the completion of the initial compliance report.

Numerical scale	Interpretation
1	Standard not met
2	Standard partially met
3	Standard almost met
4	Standard fully met or exceeded

15. The information gathered throughout the inspection process informs the HTA's licensing decisions within the regulatory framework. Where the HTA is not presented with evidence that the establishment meets the requirements of a standard/s, it works on the premise that a lack of evidence indicates non-compliance. There are varying degrees of non-compliance. The action an establishment will be required to make following the identification of a non-compliance is based on the HTA's assessment of risk to patient safety and/or tissue integrity and/or a breach of the HT Act or associated Directions.

The Inspection Report

16. The inspection report represents the findings from the evidence supplied during phase one and phase two of the inspection process, that is, from the initial compliance report, any additional documentation provided prior to the site-visit and the evidence obtained through interview and observation during the site-visit. Future inspections may identify other areas of non-compliance if new evidence is obtained. Where full compliance with a standard has been established, this is noted. Where standards have been found to be non- or partially compliant, details are included of the evidence for this finding.

Inspection Report for Leicester Bone Bank, University Hospitals of Leicester NHS Trust

17. This report refers to the activities carried out by the Leicester Bone Bank, University Hospitals of Leicester NHS Trust (the establishment). The establishment currently carries out the procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application. The vast majority of the establishment's work relates to the procurement, testing, storage and distribution of femoral heads and, infrequently, massive bone allografts and tendons. In addition, the establishment occasionally stores and uses heart valves which have been procured, processed, tested and distributed by HTA licensed establishments, including the [REDACTED].
18. A routine inspection of the establishment was carried out in November 2008, led by [REDACTED], Head of Regulation. This inspection found significant areas of non-compliance, reflected in Special Directions SD/2008/004 being issued and an additional 19 conditions being placed on the licence. Compliance information had been submitted for all 19 conditions during 2009. Notwithstanding this, given the high number of additional conditions, the HTA considered it appropriate and proportionate to schedule a non-routine inspection to assure itself of continued compliance with all standards.
19. The establishment's hub is situated at Glenfield Hospital in Leicester. At the time of inspection, there were nine satellites, all licensed for the procurement, processing, testing, storage, distribution and import/export of human tissues and cells for human application, namely:
 - Leicester General Hospital
 - Spire Hospital, Leicester
 - Nuffield Hospital Leicester
 - Nuffield Orthopaedic Centre
 - Milton Keynes General Hospital
 - Pilgrim Hospital

- Lincoln County Hospital
- PHG NHS Treatment Centre
- Broomsfield Hospital

In addition, immediately following the site visit inspection, the establishment applied for a satellite licence for Horton Treatment Centre, Banbury.

20. The establishment procures over 1,000 femoral heads per annum from the hub and satellite sites. The infrequent procurement of massive bone allografts and tendons take place in the surgical theatres at the hub, following consent taken by [REDACTED] staff. All human bone is quarantined at the hub while testing takes place. All serology and microbiological testing is undertaken at [REDACTED], except for the following:
- a. microbiological testing of bone donated at Milton Keynes General Hospital is carried out at Milton Keynes General Hospital;
 - b. microbiological testing of bone donated at Pilgrim Hospital is carried out at Pilgrim Hospital;
 - c. microbiological testing of bone donated at Lincoln County Hospital is carried out at [REDACTED]. [REDACTED] is not a satellite of the Leicester Bone Bank.

Once bone has been released from quarantine, it is used by surgeons at the hub or distributed for end use to the satellites or to any hospital with whom the establishment has an end user agreement.

21. A phase two inspection of the establishment's hub and Spire Hospital, Leicester satellite site was carried out on 15 and 16 September 2009.

22. The inspection team comprised:

- [REDACTED], Regulation Manager - Lead Inspector
- [REDACTED], Regulation Manager - Inspector
- [REDACTED], Regulation Manager - Observer

23. A traceability audit was carried out on four independent consignments of bone stored in the quarantine and release freezers at the hub to ensure that traceability was maintained through the establishment's records systems. A discrepancy was found where a femoral head was located in Freezer 3 however the storage database stated it was being stored in Freezer 17. Following instruction from the HTA, an audit was carried out by the establishment and appropriate corrective and preventative actions put into place. Further detail can be found in the assessment of Governance and Quality Systems standard 6.

Compliance with Standards, Codes of Practice and Directions

Consent

Standard	Assessment	Score
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.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
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 and the HTA's Codes of Practice	This standard is fully met.	4
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 Regulations 2007 and the HTA's Codes of Practice.	This standard is fully met. ██████ staff obtain consent on behalf of the establishment for the procurement of massive bone allografts. A Service Level Agreement outlining roles and responsibilities is in place.	4
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.	This standard is fully met. All persons attending pre-assessment for primary hip revision surgery are considered as donors. Lists of personnel trained to take consent are maintained at the hub and each satellite.	4
d) Consent forms comply with the HTA Codes of Practice.	This standard is fully met.	4
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.	This standard is fully met.	4
C2 Information about the consent process is provided and in a variety of formats.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2006 is included.	This standard is fully met.	4

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 001/2006 is included.	This standard is fully met. ██████ staff obtain consent on behalf of the establishment for the procurement of massive bone allografts. A Service Level Agreement outlining roles and responsibilities is in place.	4
c) Information is available in suitable formats and there is access to independent interpreters when required.	This standard is fully met. Information is provided in written and verbal formats. Potential donors also have access to interpreters through the hospital they are attending.	4
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.	This standard is fully met.	4
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
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.	This standard is fully met. The establishment has put into place a thorough training programme for those people taking consent which covers the essential elements of taking informed consent. Annual training is in place.	4
b) Training records are kept demonstrating attendance at training on consent.	This standard is fully met. Records are maintained at the hub and each satellite of who is trained in taking consent.	4

Governance and Quality

Standard	Assessment	Score
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.	This standard is fully met.	4
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.	This standard is fully met.	4

<p>c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.</p>	<p>This standard is fully met.</p> <p>The Medical Director, Scientific Director and Deputy Scientific Director meet on a fortnightly basis. Other staff working under the licences meet on a weekly basis.</p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met.</p> <p>Documents are reviewed and updated by the Scientific Director and authorised by the Medical Director.</p> <p>The original SOP in the quality manual is signed to show it is the master copy. Secondary copies are not signed.</p> <p>General advice and guidance has been offered against this standard (see advice and guidance 2).</p>	<p>4</p>
<p>e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.</p>	<p>This standard is fully met.</p> <p>Liaison officers examine any tissue received by the establishment and sign to show that the packaging has been verified as appropriate and intact.</p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met.</p> <p>All tissue is quarantined for at least 180 days. Non-conforming consignments or tissue with incomplete test results are discarded as detailed in relevant procedures.</p>	<p>4</p>
<p>i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.</p>	<p>This standard is fully met.</p> <p>The Scientific Director signs off when tissues are released from quarantine.</p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met.</p>	<p>4</p>

<p>k) There is a procedure for handling returned products.</p>	<p>This standard is almost met.</p> <p>There is a procedure that states that no returns shall be accepted unless authorised by the Scientific Director. The acceptance criteria on which the Scientific Director authorises such returns are not documented.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 3).</p>	<p>3</p>
<p>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.</p>	<p>This standard is almost met.</p> <p>The establishment is currently in negotiations with the ██████████ ██████████ to put a contingency agreement in place.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 4).</p>	<p>3</p>
<p>m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.</p>	<p>This standard is fully met.</p> <p>Bone is allocated on the basis of size, and in the case of females of child bearing age, on the basis of ± Rhesus factor.</p>	<p>4</p>
<p>n) The establishment ensures imports from non EEA states meet the standards of quality and safety set out in Directions 001/2006 and 002/2007.</p>	<p>This standard is not applicable.</p> <p>The establishment does not import from non-EEA states.</p>	<p>N/A</p>
<p>o) There is a complaints system in place.</p>	<p>This standard is fully met.</p>	<p>4</p>

<p>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.</p>	<p>This standard is almost met.</p> <p>Written agreements are in place with two courier companies used to transport bone to end users.</p> <p>Donor virology testing is carried out by the [REDACTED], however an agreement has not been put in place with this HTA-licensed establishment for the provision of testing services. The HTA acknowledges that this issue was raised but not resolved during the prior routine inspection of the establishment.</p> <p>The majority of microbiology testing is carried out by the [REDACTED] or satellite sites as described in paragraph 20 above. However, microbiological testing for bone donated at Lincoln County Hospital is carried out at [REDACTED], which is not a satellite of the bone bank.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 5-7).</p> <p>The HTA notes that the establishment has ceased the irradiation of bone following positive microbiology results since November 2008. The HTA reminds the establishment that should they wish to recommence this activity, a suitable Third Party Agreement as set out in Directions 002/2007 must be in place, the practice must be risk assessed, and all procedures must be documented. Additionally, validation of irradiation of massive bone allografts must be carried out. The HTA notes that a validation of irradiation of femoral heads has already been carried out.</p>	<p>3</p>
<p>q) There is a record of agreements established with third parties.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2007.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.</p>	<p>This standard is fully met.</p>	<p>4</p>

<p>t) There are procedures for the re-provision of service in an emergency.</p>	<p>This standard is almost met.</p> <p>The establishment is currently in negotiations with ██████████ ██████████ to put a contingency agreement in place.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 4).</p>	<p>3</p>
<p>GQ2 There is a documented system of quality management and audit.</p>	<p>The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection</p>	<p>N/A</p>
<p>a) There is a quality management system which ensures continuous and systematic improvement.</p>	<p>This standard is fully met.</p> <p>The quality management system is documented in a quality manual and supported by policies, audits and risk assessments.</p> <p>A system has been implemented for each satellite to store a site file at pre-assessment (consent) and theatres (procurement) which details all of the relevant information for that satellite, including training records. The hub holds site files on each satellite. This system has been noted by the HTA as an example of good practice.</p> <p>General advice and guidance has been offered against this standard (see advice and guidance 8-10).</p>	<p>4</p>

<p>b) There is an internal audit system for all licensable activities.</p>	<p>This standard is almost met.</p> <p>Audits of the hub and satellites are undertaken at least annually by the Scientific Director.</p> <p>At the time of inspection, audits did not cover checking the transcription of traceability data from the Bone Bank log book into the electronic database.</p> <p><i>Following inspection by the HTA, the establishment conducted an audit of traceability data from the Bone Bank log book into the electronic database. Of 20 records checked, no discrepancies were found. Additionally, the establishment has put in place an SOP for systematically checking the correlation of the log book and the electronic database.</i></p> <p>A recent audit of the Spire Hospital, Leicester satellite site did not identify a discrepancy in the satellite's site file that stated that the -80°C quarantine freezer should be run at -35°C.</p> <p>Advice and guidance has also been offered against this standard (see advice and guidance 11-12).</p>	<p>3</p>
<p>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.</p>	<p>This standard is fully met.</p> <p>The establishment employs ██████████, Quality Manager, ██████████ to undertake external audits.</p>	<p>4</p>
<p>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.</p>	<p>This standard is partially met.</p> <p>The jars used to store bone have been validated by the establishment as fit for purpose.</p> <p>The Sterile Services Unit situated at Glenfield Hospital is not accredited. A report shown to the HTA states that the service does not meet all required standards. Validation data for their sterilisation service was not seen on inspection.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 13).</p>	<p>2</p>

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) There are clearly documented job descriptions for all staff.	This standard is fully met.	4
b) There are orientation and induction programmes for new staff.	This standard is fully met.	4
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.	This standard is fully met.	4
d) There is annual documented mandatory training (e.g. health and safety and fire).	This standard is fully met.	4
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	This standard is fully met.	4
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.	This standard is fully met. The establishment has introduced thorough training programmes for staff taking consent and procuring. Competency of these staff members is assessed by the Scientific Director and Deputy Scientific Director. The training programmes cover the wider scientific and ethical principles of the work, as well as the regulatory context. The HTA received very positive feedback from staff who had undertaken the training that it was useful and enjoyable.	4
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.	This standard is fully met.	4
h) There is a system of staff appraisal.	This standard is fully met.	4
i) Where appropriate, staff are registered with a professional or statutory body.	This standard is fully met.	4
j) There are training and reference manuals available.	This standard is fully met.	4

k) The establishment is sufficiently staffed to carry out its activities.	This standard is fully met. During inspection in 2008, the HTA identified an issue with staffing levels at the establishment. Following internal review by HR, a recommendation was made that two extra staff members were employed, or workload was reduced. The establishment took steps to reduce workload by increasing efficiency in existing processes and reducing the number of satellites.	4
GQ4 There is a systematic and planned approach to the management of records.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.	This standard is almost met. The required procedures were not clearly documented. Advice and guidance has been offered against this standard (see advice and guidance 14).	3
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.	This standard is fully met. At the time of inspection, audits did not cover checking the transcription of traceability data from the Bone Bank log book into the database. <i>Following inspection by the HTA, the establishment conducted an audit of traceability data from the Bone Bank log book into the electronic database. Of 20 records checked, no discrepancies were found. Additionally, the establishment has put in place an SOP for systematically checking the correlation of the log book and the electronic database.</i>	4
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.	This standard is fully met.	4
d) There is a system for back-up / recovery in the event of loss of computerised records.	This standard is fully met.	4

<p>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.</p>	<p>This standard is fully met.</p> <p>Registers are kept in an electronic database which shows tissue being stored at the hub and satellite sites. Disposal of tissue is also recorded on electronic spreadsheets, which are kept on the Trust's IT system and subject to regular back-up.</p> <p>The HTA notes that the establishment is currently considering the procurement of a custom-built system to manage the stored material.</p>	<p>4</p>
<p>f) There are procedures to ensure that donor documentation, as specified by Directions 001/2006, is collected and maintained.</p>	<p>This standard is fully met.</p> <p>The Donor Data Sheets have been updated since the HTA site visit inspection in 2008 and capture the required information in a systematic fashion.</p>	<p>4</p>
<p>g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2006 and 002/2007.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>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.</p>	<p>This standard is almost met.</p> <p>Not all raw data critical to the safety and quality of tissues and cells, e.g. temperature logs, are being kept for 10 years.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 15).</p>	<p>3</p>
<p>i) The minimum data to ensure traceability from donor to recipient as required by Directions 002/2007 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>j) Records are kept of products and material coming into contact with the tissues and / or cells.</p>	<p>This standard is fully met.</p> <p>Batch numbers, lot numbers and expiry dates of the bone jars are retained.</p>	<p>4</p>
<p>k) There are documented agreements with end users to ensure they record and store the data required by Directions 002/2007.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met.</p> <p>The reason for rejection is recorded on the establishment's disposal logs.</p>	<p>4</p>

<p>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.</p>	<p>This standard is almost met.</p> <p>The establishment is currently in negotiations with ██████████ ██████████ to put a contingency agreement in place.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 4).</p>	<p>3</p>
<p>GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.</p>	<p>The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection</p>	<p>N/A</p>
<p>a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2006.</p>	<p>This standard is fully met.</p> <p>Donors are selected on the basis of a thorough medical questionnaire.</p>	<p>4</p>
<p>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 001/2006.</p>	<p>This standard is almost met.</p> <p>All required tests are being carried out by the establishment.</p> <p>Agreements with testing laboratories have not been put into place.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 5-7).</p>	<p>3</p>
<p>c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>e) Testing of donor samples is carried out using CE marked diagnostic tests.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.</p>	<p>This standard is fully met.</p> <p>Samples taken for donor testing are labelled with the hospital's unique identifier, which is linked to a unique bone bank code through the establishment's donor database.</p>	<p>4</p>

<p>GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.</p>	<p>The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection</p>	<p>N/A</p>
<p>a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.</p>	<p>This standard is fully met. A unique bone bank code is allocated to each donation.</p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met. Information is available regarding donor and recipient data, the location of the tissues when in storage and records of disposal or use as required. As identified in paragraph 23 above, an audit trail undertaken at the establishment found a discrepancy where a piece of bone was located in a different freezer from what was stated on the register. <i>Following inspection by the HTA, the establishment conducted an audit of the entire holdings of the establishment to ensure the location of every piece of bone was correctly recorded in the register. The audit identified a number of pieces of bone that were located in a different location to what was listed on the register. The register was updated to reflect the correct location of each piece of bone, and staff will be retrained in the establishment's procedures for moving bone and updating the register on 3 November 2009. A visual reminder to assist staff has been placed on each freezer. Further audit will be undertaken in three months' time.</i></p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met. Traceability is maintained from donation through to end use. The surgeon completes a Recipient Information Sheet, which is returned to the establishment. Failure to return this information results in the end user being unable to buy further bone from the establishment. The establishment has facilitated traceability through to end users by supplying a sticker to be included in recipient patient notes identifying that bone transplant has taken place. Use of this sticker is required in each end user agreement.</p>	<p>4</p>

GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.	This standard is almost met. Documented procedures for the identification, investigation and follow up for adverse events are in place. However, the HTA found that staff were not fully aware of these procedures or their implications. Advice and guidance has been offered against this standard (see advice and guidance 16).	3
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.	This standard is fully met.	4
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.	This standard is fully met.	4
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.	This standard is fully met.	4
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.	This standard is fully met.	4
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.	This standard is fully met.	4
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.	This standard is fully met.	4
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.	This standard is fully met.	4

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) There are documented risk assessments for all practices and processes.	<p>This standard is partially met.</p> <p>Risk assessments of some practices and processes have been put into place.</p> <p>However, risk assessments are broad and do not clearly identify individual risks and hazards that staff working under the licence should be aware of.</p> <p>Risk scores, made up of likelihood and impact ratings, did not appropriately reflect the actual risk of an event occurring.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 17).</p>	2
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.	This standard is fully met.	4
c) Staff can access risk assessments and are made aware of local hazards at training.	<p>This standard is fully met.</p> <p>Staff can access risk assessments from the relevant site files.</p>	4
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.	This standard is fully met.	4

Premises, Facilities and Equipment

Standard	Assessment	Score
PFE1 The premises are fit for purpose.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	<p>This standard is almost met.</p> <p>The hub premises have been risk assessed, and each satellite is being risk assessed to ensure that the premises are fit for purpose at the same time that an internal audit is being undertaken. However, these audits are still ongoing.</p> <p>Further consideration should be given to the risk assessment process in light of the advice and guidance offered against standard GQ8a.</p>	3
b) There are procedures to review and maintain the safety of staff, visitors and patients.	This standard is fully met.	4
c) The premises have sufficient space for procedures to be carried out safely and efficiently.	<p>This standard is almost met.</p> <p>Space, particularly for storage, is limited. The HTA is advised that no additional space is currently available.</p> <p>The HTA notes the important service that the Bone Bank is operating and considers that staff have worked well to make best use of the space available to ensure the quality and safety of the tissues are maintained. However, the limited space available results in the continual shuffle of bone through various quarantine and release freezers, which poses a risk to the traceability of the tissue. This was highlighted in the audit undertaken on the freezers (see standard GQ6b).</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 18).</p>	3
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.	This standard is fully met.	4
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.	This standard is fully met.	4

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.	This standard is fully met.	4
PFE2 Environmental controls are in place to avoid potential contamination.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.	This standard is fully met.	4
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 002/2007.	This standard is not applicable. The establishment does not undertake processing.	N/A
c) There are procedures for cleaning and decontamination.	This standard is almost met. Cleaning of the storage areas occurs in a systematic fashion, however this is not documented. Advice and guidance has been offered against this standard (see advice and guidance 19).	3
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.	This standard is fully met.	4
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.	This standard is fully met.	4
b) There are systems to deal with emergencies on a 24 hour basis.	This standard is fully met.	4
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	This standard is fully met. Tissue is stored in designated freezers whose temperature is recorded.	4

d) There is a documented, specified maximum storage period for tissues and / or cells.	This standard is fully met. Each piece of bone has an expiry date of 5 years. This expiry is written onto the bone jar label when it is booked into the establishment.	4
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2006 and 002/2007.	This standard is fully met.	4
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.	This standard is almost met. Packaging used for transportation has been validated. However, transport has not been risk assessed. Advice and guidance has been offered against this standard (see advice and guidance 17).	3
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.	This standard is fully met.	4
d) Records are kept of transportation and delivery.	This standard is fully met.	4
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.	This standard is fully met.	4
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.	This standard is fully met.	4
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.	This standard is fully met. Packaging used for transport has been validated.	4
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.	This standard is fully met.	4
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.	This standard is fully met.	4

<p>j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.</p>	<p>This standard is almost met.</p> <p>Standard information sheets are provided with each piece of bone distributed, however the information should differ slightly for bone sent for immediate use and bone sent for storage pending end use.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 21).</p>	<p>3</p>
<p>PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.</p>	<p>The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection</p>	<p>N/A</p>
<p>a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>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.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>d) New and repaired equipment is validated before use and this is documented.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>e) There are documented agreements with maintenance companies.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.</p>	<p>This standard is almost met.</p> <p>Freezers are defrosted bi-annually. There were no procedures for decontamination of freezers.</p> <p>Advice and guidance has been offered against this standard (see advice and guidance 22).</p>	<p>3</p>
<p>g) Instruments and devices used for procurement are sterile, validated and regularly maintained.</p>	<p>This standard is fully met.</p>	<p>4</p>
<p>h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.</p>	<p>This standard is fully met.</p>	<p>4</p>

i) Staff are aware of how to report an equipment problem.	This standard is fully met.	4
j) For each critical process, the materials, equipment and personnel are identified and documented.	This standard is fully met.	4
k) There are contingency plans for equipment failure.	This standard is fully met. Hub freezers have carbon dioxide backup that will temporarily keep the bone at an appropriate temperature if the power supply should fail. Freezer failure at satellite sites would be addressed by collection of the bone by establishment's staff or discard of the bone if collection is not viable.	4

Disposal

Standard	Assessment	Score
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) The disposal policy complies with HTA's Codes of Practice.	This standard is fully met. The updated policy for disposal clearly describes that surplus tissue from the deceased is to be placed back into the body or, if disposed of, to be separated from other clinical waste.	4
b) The disposal procedure complies with Health and Safety recommendations.	This standard is fully met.	4
c) There is a documented procedure on disposal which ensures that there is no cross contamination.	This standard is fully met.	4
D2 The reasons for disposal and the methods used are carefully documented.	The establishment's licence for storage for a scheduled purpose was not assessed during this non-routine inspection	N/A
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.	This standard is fully met.	4
b) Disposal arrangements reflect (where applicable) the consent given for disposal.	This standard is not applicable.	N/A

Conclusions

24. During the inspection process, the HTA has made judgements about the suitability of the Designated Individual, the Licence Holder, the premises and the practices taking place under the licence.

Suitability of DI and LH

25. The Designated Individual (DI) , [REDACTED], is the Medical Director of the Leicester Bone Bank. He has the appropriate qualifications and experience to fulfil this role.

The HTA's inspection of the establishment in November 2008 raised concerns over the suitability of the DI due the availability of time to discharge his duties. The HTA is satisfied that these concerns have been addressed. The DI now has protected time to dedicate to the establishment's work, and he attends regular governance meetings with the Scientific Director and Deputy Scientific Director of the establishment. The DI is suitable.

The Licence Holder (LH) is the University Hospitals of Leicester NHS Trust; [REDACTED], Director of Clinical Quality, is the named Licence Holder representative. The LH is suitable.

Suitability of the Premises

26. The HTA is satisfied that the premises are suitable for the activities being undertaken by the establishment.

Suitability of Practices

27. The HTA is satisfied that the practices are suitable for the activities being undertaken.

Summary comment

28. The HTA is satisfied that the establishment is suitable to be licensed for the purposes that it has set out.

The HTA would like to commend the establishment's staff for their obvious commitment to the work of the Bone Bank and acknowledges the considerable amount of work that staff have undertaken since the HTA's inspection in November 2008.

Conditions (requirements) on the licence at the time of the site visit inspection.

29. There were no conditions on the licence at the time of the site visit inspection.

Conditions (requirements) related to areas of non-compliance identified during the inspection process

30. The regulatory reference is noted so the DI can refer back to relevant standards in the Human Tissue Act 2004, the Compliance Report and Directions or Codes of Practice.

No conditions have been proposed as a result of the inspection process.

Advice and guidance

31. Below are matters which the HTA advises the DI to consider.

No	Regulatory reference	Advice and guidance
1.	N/A	The DI is advised to nominate appropriate Persons Designated at each satellite site to deputise for the DI in his absence. Each PD should be provided with copies of relevant minutes from relevant governance meetings as they occur.
2.	GQ1d	The DI could consider additional document control measures to ensure staff are always using up-to-date copies of SOPs, for example, by watermarking them with "Do Not Copy".
3.	GQ1k	The DI is advised to document the acceptance criteria by which returned consignments are accepted back into the establishment. This will enable staff and end users to clearly see on what basis bone can be returned to the establishment.
4.	GQ1l GQ1t GQ4m	The DI is advised to ensure that contingency arrangements in the event of termination are formalised and documented.
5.	GQ1p GQ5b	The DI is advised to put documented agreements in place between the establishment and any HTA-licensed testing laboratory (i.e. ██████████, ██████████, Milton Keynes General Hospital and Pilgrim Hospital) for testing services provided to the establishment. Each agreement should cover the roles and responsibilities of each party and clearly set out what tests are to be carried out and on what basis, as well as how results are to be communicated to the establishment. The agreement should request that the testing laboratories make the establishment aware of any deviations from standard operating procedures or adverse events that occur in the course of carrying out testing on behalf of the establishment.
6.	GQ1p GQ5b	The Designated Individual is advised to ensure that the testing laboratories at the establishment's satellite sites (i.e. Milton Keynes General Hospital and Pilgrim Hospital) are audited as part of the establishment's schedule of ongoing satellite audits. This will provide the necessary assurance that testing services carried out at these laboratories are being undertaken in line with the agreements described in advice and guidance 5 above.
7.	GQ1p GQ5b	The Designated Individual is advised to put a third party agreement in place with ██████████ for the provision of testing services. ██████████ is providing the establishment with a service that could affect the quality and safety of the tissues and cells, therefore this agreement should comply with paragraph 119 of HTA Directions 002/2007.
8.	GQ2a	The DI is advised to review the title of the SOP on "Interviewing a potential donor" to reflect that it is the establishment's documented process for obtaining informed consent, rather than an interview.
9.	GQ2a	The DI is advised to review references to "next of kin" and "relatives" in procedures relating to deceased donors. These references should reflect the requirement for consent to be obtained from people in a qualifying relationship as set out in the Human Tissue Act 2004 and described in the HTA's code of practice on Consent.

10.	GQ2a	The DI is advised to review references to the European Union Tissues and Cells Directives (EUTCD) in the quality manual and where appropriate, change these to reflect the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The DI is reminded that as the EUTCD have been transposed into UK law, the relevant legislation under which the HTA regulates is the abovementioned Regulations.
11.	GQ2b	The DI is advised to audit the SOPs at all satellites storing bone to ensure that correct storage temperatures are documented. The expiry date of each piece of bone is dependent on storage being maintained between -40°C and -100°C. Having an SOP documenting the incorrect storage temperature could affect the quality and safety of the stored bone.
12.	GQ2b	The DI is advised to consider an additional field on each non-conformance record to identify the possible impact of each non-conformance on the quality and safety of the bone.
13.	GQ2d	<p>The DI is advised to obtain validation data from the Sterile Services Unit for internal testing of the equipment used to sterilise the establishment's bone jars. This data should be used to assure the DI that sterility is achieved after each sterilisation cycle. If the data obtained does not assure the DI that sterility is achieved during each cycle, consideration should be given to obtaining sterilisation services from an accredited unit. The validation data should be retained in the quality manual and made available to the HTA during the next on-site inspection.</p> <p>The HTA acknowledges that the non-accreditation of the Sterile Services Unit was raised by the HTA at the previous inspection of the establishment. The establishment's staff addressed this by undertaking an audit of the SSU, however the report produced states that the SSU is not in compliance with all required standards. The DI should therefore take additional steps to ensure that sterility is achieved on each sterilisation cycle, to ensure that all bone is being put into sterile pots.</p>
14.	GQ4a	The DI is advised to produce a document that clearly defines the establishment's chosen procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records. This will ensure that all members of staff are aware of how to manage records on behalf of the establishment.
15.	GQ4f	<p>The DI is advised that all raw data which are critical to the safety and quality of tissues and cells must be retained in some format for 10 years after the use, expiry or disposal of the tissue. At a minimum, the raw data would include (but not be limited to):</p> <ul style="list-style-type: none"> ○ Freezer temperature records ○ Consumables batch numbers ○ Room temperature data for areas where controllable consumables are stored ○ Delivery and transport records
16.	GQ7a	The DI is advised to ensure that all staff involved in any of the licensable activities are aware of the procedures for identification, reporting, investigating and recording adverse events and reactions. Staff should be aware that any person can report an adverse event and who it should be reported to. Staff should also be aware of what they can expect from the establishment once a potential adverse event or reaction has been identified e.g. will they receive a follow up telephone call, do they have to complete a non-conformance form etc., as staff expressed to the HTA that they would like some kind of closure after reporting such an event.

17.	GQ8a PFE4b	The DI is advised to ensure that risk assessments are completed for all licensable activities, including transport of tissues and/or cells. Risk assessments should clearly identify individual risks so that staff members can easily identify these. Careful consideration should be given to the likelihood and impact ratings to ensure that the risk score is an appropriate reflection of the actual risk. Updated risk assessments should be included in all applicable site files.
18.	PFE1c	The DI is advised to review the current storage arrangements to determine if space could be utilised in a more effective way.
19.	PFE2c	The DI is advised to document the procedures for cleaning and decontamination of the storage areas, and maintain records of cleaning.
20.	PFE3a	The DI is advised to consider whether freezers at satellites are appropriately secure or whether the freezers should be locked.
21.	PFE4j	The DI is advised to review the current Information and Handling Sheet to ensure that it is relevant for bone distributed for (a) immediate end use or (b) storage pending end use.
22.	PFE5f	The DI could consider decontaminating the storage freezers at the time of defrosting. The appropriate decontaminant and method of decontamination should be documented and made available to staff as an SOP. Records of decontamination should be maintained.

Report sent to DI for factual accuracy: 13 October 2009

Factual accuracy information received from DI: 21 October 2009

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