

**Site Inspection Report for  
Leicester Bone Bank  
Licence No. 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.**
- **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.**

**18, 25 and 26 November 2008**

## 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, and 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
  - compliance with the information and confidentiality requirements of Section 13 (1).
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. The 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

17. This report refers to the activities carried out by Leicester Bone Bank. Leicester Bone Bank is part of the University Hospitals of Leicester NHS Trust (UHL). The Bone Bank currently carries out the procurement, donor testing, processing, storage, distribution and issue of femoral heads procured from living donors and massive allografts procured from deceased donors. Leicester Bone Bank currently processes around 1,000 units per annum and has plans to increase this number in the future. They also have future plans to undertake processing of bone products at [REDACTED] site (which is currently licensed as the [REDACTED]).
18. [REDACTED] carries out donor serology testing on behalf of the establishment. While [REDACTED] is part of the same NHS Trust, the licensable activity takes place on separate unlicensed premises and is not currently under the governance of the Leicester Bone Bank.
19. Leicester Bone Bank obtains consent and stores relevant material for research which is provided to UHL research projects. Relevant material is also provided to xxxxxxxx [REDACTED] and to [REDACTED]. Relevant material for use in research is provided to UHL researchers where ethics approval has been sought from [REDACTED]. There was a substantial change made to the ethics approval application to incorporate the [REDACTED] research project by submission of their protocol. Ethical approval for this change was given. The Deputy Scientific Director stated that the material being supplied to [REDACTED] was similarly approved by way of substantial change to the ethics approval for this project. Evidence of this approval was not made available on inspection. It was also brought to the attention of the inspectors that the Principal Investigator named for all of the approved ethics submissions has subsequently died. This has not been recorded as a substantial amendment to the ethics approval and this must be done.
20. A phase two inspection of Leicester Bone Bank was carried out on the following dates:
  - 18 November 2008 – Leicester Bone Bank satellite
    - North Devon District Hospital, Barnstaple

- 25-26 November 2008 – Leicester Bone Bank hub
  - Glenfield Hospital
- 26 November 2008 – Leicester Bone Bank satellite
  - Nuffield Hospital, Leicester

21. The inspection team comprised:

- all sites/ all dates
  - [REDACTED] – Head of Regulation - HTA Lead Inspector
  - [REDACTED] – Regulation Manager – HTA Inspector
- Leicester sites / 25-26 November 2008
  - [REDACTED] – Regulation Manager – HTA Inspector

## 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.	<p>Consent is taken for storage of relevant material for research. This consent process uses a separate consent form which is in accordance with the requirements of the HT Act.</p> <p>Compliance with this standard is assessed in more detailed standards below.</p>	
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 not applicable.	N/A
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.	<p>This standard is almost met.</p> <p>The consent form shows how potential donors are identified through the list of exclusion criteria. Training records have been maintained to show who is able to take consent. However, it is difficult to clearly identify on the consent form who has taken consent from patients as only the signature and not the name of the individual is recorded. Additionally, this signature is not dated.</p> <p><b>See advice and guidance 1</b></p>	3
d) Consent forms comply with the HTA Codes of Practice.	<p>This standard is almost met.</p> <p>The consent form is informative. However, version control of consent forms (to ensure only the most up-to-date forms are being used) does not appear to be in place.</p> <p><b>See advice and guidance 1</b></p>	3
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.	Compliance with this standard is assessed in more detailed standards below.	
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 not applicable	N/A
c) Information is available in suitable formats and there is access to independent interpreters when required.	This standard is partially met.  Information is given verbally and by Patient Information Leaflet (PIL). There is access to independent interpreters, when and if necessary.  However, the PIL has been repeatedly photocopied and is difficult to read. The Nuffield Hospital Leicester satellite site is using an obsolete version of the PIL. This PIL was not updated at the same time as the consent form and does not reflect the current consent form's use of language.  <b>See advice and guidance 2</b>	2
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.	Compliance with this standard is assessed in more detailed standards below.	
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.	4
b) Training records are kept demonstrating attendance at training on consent.	This standard is fully met.	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.	Compliance with this standard is assessed in more detailed standards below.	
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.	<p>This standard is almost met.</p> <p>Documented procedures are in place.</p> <p>Staff are carrying out practices which aim to minimise the risk to patient safety but the documented procedures do not always reflect current practice.</p> <p>Documented procedures are not linked to risk assessments.</p> <p><b>See advice and guidance 3</b></p>	3
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>This standard is almost met.</p> <p>There is evidence that indicates regular governance meetings take place and minutes are recorded, however, these meetings only occur twice per year or on an ad hoc basis. The role of the DI in these meetings is unclear.</p> <p><b>See advice and guidance 4</b></p>	3
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>This standard is almost met.</p> <p>Documents are dated and signed off by an authorised person. However, in some cases, documents are authored and authorised by the same person. Documents are not reviewed in line with review dates. There is no schedule for the regular review and update of quality documents.</p> <p><b>See advice and guidance 5</b></p>	3
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.	<p>This standard is partially met.</p> <p>Procedures for tissue procurement are documented but are not adequately communicated to all procurers. Training in procurement is not adequately provided to theatre nurses carrying out procurement activities, thus safety of living donors may be compromised.</p> <p><b>See condition 4</b></p>	2

<p>f) There are procedures for tissue and / or cell procurement, which ensure the dignity of deceased donors.</p>	<p>This standard is partially met.</p> <p>In practice, personnel are working to procedures that are not documented. There is no documented standard operating procedure (SOP) for the procurement of massive allografts from deceased donors. This procurement takes place in an operating theatre and not in a mortuary setting. On this basis, it could not be determined if there is provision for the dignity of deceased donors.</p> <p><b>See condition 5</b></p>	<p><b>2</b></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 partially met.</p> <p>In practice, staff take receipt of tissue. However, there is no procedure to verify that bone received meets specifications and is appropriately labelled.</p> <p><b>See condition 6</b></p>	<p><b>2</b></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 partially met.</p> <p>There are procedures to ensure quarantined material is stored separately from tissue that has been issued for human application.</p> <p>However, quarantined (freshly procured) and non-quarantine (released for use in patients following full testing results) tissue is stored in the same operating theatre freezer at the hub. It is unclear whether this practice also takes place at satellite sites.</p> <p><b>See Special Directions</b></p> <p>Non-conforming consignments such as those with compromised pots are repackaged and assigned for irradiation; however, this process has not been documented or validated.</p> <p>Fresh frozen femoral heads that lacked test results at donation were not disposed of.</p> <p><b>See condition 7</b></p>	<p><b>2</b></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 almost met.</p> <p>There are systems in place to keep tissues quarantined until the 180 day testing is complete, after which tissues are released and are moved to a separate freezer. However, full testing as required by Directions 001/2006 is not conducted at donation.</p> <p><b>See condition 8</b></p> <p>The coloured sticker coding system for quarantine/non-quarantine material is not documented or included in SOPs.</p> <p><b>See advice and guidance 6</b></p>	<p><b>3</b></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 not met.</p> <p>Consumables are not kept in a controlled, monitored environment.</p> <p>Batch numbers of broths and bone jars are not recorded and neither are expiry dates. This is a particular issue given that jars and broth bottles are distributed to satellites and allocated to theatre stores without expiry information.</p> <p>Acceptance criteria have not been established for critical materials and reagents. There is no assurance that these materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.</p> <p>Sterilisation of critical consumables is carried out in an unaccredited sterilisation service department. This department is also not subject to internal UHL audits. It cannot be guaranteed that these consumables are adequate to maintain the quality and safety of tissues. Leicester Bone Bank has not performed a validation of the sterilisation process for these consumables.</p> <p><b>See condition 9</b></p>	<p><b>1</b></p>
<p>k) There is a procedure for handling returned products.</p>	<p>This standard is fully met.</p>	<p><b>4</b></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 fully met.</p>	<p><b>4</b></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 partially met.</p> <p>Allocation of tissue is on a size, blood type and rhesus factor matching basis. However, this is performed in an ad hoc fashion by the Scientific Director and Deputy Scientific Director. This procedure is not documented, nor does it reflect any written policy.</p> <p><b>See condition 10</b></p>	<p><b>2</b></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>Leicester Bone Bank does not import from non EEA states.</p>	<p><b>N/A</b></p>
<p>o) There is a complaints system in place.</p>	<p>This standard is fully met.</p>	<p><b>4</b></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>There have previously been written agreements in place with ██████████, however this has recently been retracted and there is currently no third party agreement in place for the irradiation of bone.</p> <p><b>See Special Directions and condition 3</b></p>	<p><b>3</b></p>

q) There is a record of agreements established with third parties.	This standard is fully met.	4
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 002/2007.	This standard is fully met.	4
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.	This standard is fully met.	4
t) There are procedures for the provision of service in an emergency.	This standard is fully met.	4
GQ2 There is a documented system of quality management and audit.	Compliance with this standard is assessed in more detailed standards below.	
a) There is a quality management system which ensures continuous and systematic improvement.	This standard is partially met. The quality management system is present, but not complete. Documents are reviewed on dates specified, however, there is little evidence of a comprehensive review system or necessary substantive changes to procedures as a result of this review. <b>See advice and guidance 7</b>	2
b) There is an internal audit system for all licensable activities.	This standard is not met. There is no documented system for internal audits. Satellites are not regularly audited. Audits of only two satellites have been documented. Audits are not scheduled and do not appear to be ongoing. Current auditing systems are incomplete and inadequate to capture non-compliance at the hub or satellite sites. <b>See condition 11</b>	1
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.	This standard is partially met. There is some evidence of external audits. However, these appear to only be undertaken at the hub. The frequency of external audits is undefined. There is no evidence that all actions were followed up as a result of audit findings. <b>See advice and guidance 8</b>	2

<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>Procedures that relate to processes affecting the quality and safety of bone have not undergone regular evaluation. Some procedures are absent and some do not reflect current practice. e.g. procedures for positive swab results at end-user sites and the colour sticker system.</p> <p><b>See advice and guidance 3</b></p> <p>Documented processes relating to the procurement of massive bone allografts from deceased donors are missing.</p> <p><b>See condition 2</b></p> <p>There is no documented procedure indicating when tissue is irradiated following a positive result for microbiological contamination. The process of irradiation has not been validated to determine whether tissue which has been irradiated following a positive result for microbiological contamination is safe for human application</p> <p><b>See Special Direction and condition 3</b></p>	<p><b>2</b></p>
<p>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.</p>	<p>Compliance with this standard is assessed in more detailed standards below.</p>	
<p>a) There are clearly documented job descriptions for all staff.</p>	<p>This standard is fully met.</p>	<p><b>4</b></p>
<p>b) There are orientation and induction programmes for new staff.</p>	<p>This standard is partially met.</p> <p>The current induction programme does not involve competency based assessment of staff following training.</p> <p><b>See condition 12</b></p>	<p><b>2</b></p>
<p>c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.</p>	<p>This standard is not met.</p> <p>Staff procuring on behalf of the establishment do not have regular updates in training. Training of procurement staff is not adequately recorded.</p> <p><b>See condition 4</b></p> <p>There is no planning for and limited access to CPD and training. There is no time allocated to this in the bone bank staff job descriptions.</p> <p><b>See condition 12</b></p>	<p><b>1</b></p>
<p>d) There is annual documented mandatory training (e.g. health and safety and fire).</p>	<p>This standard is fully met.</p>	<p><b>4</b></p>

<p>e) Personnel are trained in all tasks relevant to their work and their competence is recorded.</p>	<p>This standard is partially met.</p> <p>There are limited training procedures in place. Staff based at the hub have been carrying out procedures for a number of years. It is unclear whether they have been trained in all aspects relevant to their work.</p> <p><b>See condition 12</b></p> <p>Theatre nurses undertaking procurement are not trained appropriately and their competence is not recorded.</p> <p><b>See condition 4</b></p>	<p><b>2</b></p>
<p>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.</p>	<p>This standard is partially met.</p> <p>The training programme for staff is not documented other than for the training in taking consent. Training records are incomplete. Training relies on staff reading SOPs and does not reference the scientific, ethical and regulatory principles.</p> <p><b>See condition 12</b></p>	<p><b>2</b></p>
<p>g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.</p>	<p>This standard is not met.</p> <p>There is no documented training programme that ensures that staff understand the organisational structure and the quality systems.</p> <p><b>See condition 12</b></p>	<p><b>1</b></p>
<p>h) There is a system of staff appraisal.</p>	<p>This standard is fully met.</p>	<p><b>4</b></p>
<p>i) Where appropriate, staff are registered with a professional or statutory body.</p>	<p>This standard is fully met.</p>	<p><b>4</b></p>
<p>j) There are training and reference manuals available.</p>	<p>This standard is partially met.</p> <p>There are SOPs available for some procedures and training consists of review of the SOPs. Reference manuals are available at the hub but not widely disseminated to staff at satellites.</p> <p><b>See conditions 4 and 12</b></p>	<p><b>2</b></p>

<p>k) The establishment is sufficiently staffed to carry out its activities.</p>	<p>This standard is not met.</p> <p>The establishment does not appear to have sufficient staff resource based on the non-compliance with HTA standards observed during the site-visit inspection. The establishment has expanded its activities to multiple sites and there is no evidence that suitable staffing needs analyses have been performed in order to ensure adequate ability to perform licensable activities. In particular:</p> <ul style="list-style-type: none"> <li>• staff levels at the hub are not adequate to enable governance of the large number of satellite sites</li> <li>• the DI does not have an appropriate amount of protected time to dedicate to his responsibilities at the establishment</li> <li>• the volume of material being received and distributed at the hub does not appear commensurate with the number of staff</li> <li>• inadequate systems mean that staff at the hub spend a disproportionate amount of time undertaking menial tasks, such as accessing records.</li> </ul> <p><b>See Special Directions and condition 2</b></p>	<p><b>1</b></p>
<p>GQ4 There is a systematic and planned approach to the management of records.</p>	<p>Compliance with this standard is assessed in more detailed standards below.</p>	
<p>a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.</p>	<p>This standard is almost met.</p> <p>Procedures are in place but are not documented.</p> <p><b>See advice and guidance 10</b></p>	<p><b>3</b></p>
<p>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.</p>	<p>This standard is partially met.</p> <p>There is evidence of some audit of records and their content, however this does not appear to be regularly scheduled, documented or systematic. Discrepancies in record keeping were noted and requested records were not found at site.</p> <p><b>See condition 13</b></p>	<p><b>2</b></p>

<p>c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.</p>	<p>This standard is not met.</p> <p>Information recorded in the day book is incomplete, often illegible and inappropriately linked to associated paper records.</p> <p>Consent documentation does not have space to record the name of the person taking consent and signatures cannot be reliably linked to records of persons trained in taking consent.</p> <p>Material issue sheets held at satellites are used to record reservations and cancellations of bone. These sheets were observed to be unclear as to which specimen were being reserved after multiple cancellations/reissues had been recorded. Legibility and accuracy of these records is an issue.</p> <p>Donor data sheets cannot be photocopied or faxed due to shaded boxes and are thus not reproducible. Legibility and accuracy of these records is an issue.</p> <p>Computerised records were unvalidated.</p> <p><b>See condition 13</b></p>	<p><b>1</b></p>
<p>d) There is a system for back-up / recovery in the event of loss of computerised records.</p>	<p>This standard is fully met.</p>	<p><b>4</b></p>
<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 partially met.</p> <p>There is a system in place that combines use of computerised databases with paper records. The electronic records keeping system does not reliably match the day book system. The 'fate date' recording method is not reliably linked to paper records. Overall the record keeping/registering system is complex, undocumented and could lead to errors and failure of traceability.</p> <p>It is noted that a new electronic data management system is proposed.</p> <p><b>See condition 13</b></p>	<p><b>2</b></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><b>4</b></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><b>4</b></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>Raw data relating to the tissues are kept for an appropriate length of time. Raw data relating to consumables (expiry dates and batch numbers) that affect the quality and safety of tissue are not recorded or retained appropriately.</p> <p><b>See condition 9</b></p>	<p><b>3</b></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 almost met.</p> <p>The hub retains minimum data to ensure that 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. Recipient patient case notes, however, do not reflect any information regarding transplanted bone and traceability cannot be established from these records.</p> <p><b>See condition 14</b></p>	<p><b>3</b></p>
<p>j) Records are kept of products and material coming into contact with the tissues and / or cells.</p>	<p>This standard is not met.</p> <p>Batch numbers and expiry dates are not recorded for consumables coming into contact with tissues.</p> <p><b>See condition 9</b></p>	<p><b>1</b></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 partially met.</p> <p>Documented agreements are in place but sites have failed to record bone details in patient case notes.</p> <p>See GQ4 (i) above.</p> <p><b>See condition 14</b></p>	<p><b>2</b></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 not met.</p> <p>The acceptance or rejection of tissue following positive microbial culture is determined on an ad hoc basis by the Scientific Director and/or Deputy Scientific Director. There is no documented policy, procedure or rationale regarding the acceptance or rejection of tissue.</p> <p><b>See condition 15</b></p>	<p><b>1</b></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 fully met.</p>	<p><b>4</b></p>

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.	Compliance with this standard is assessed in more detailed standards below.	
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.	This standard is fully met.	4
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.	This standard is partially met. The majority of required tests are carried out at donation and again after 180 days, however, HbV core antigen and HTLV testing is not undertaken at the time of donation. An appropriate risk assessment regarding HTLV is not carried out for donors. <b>See condition 8</b>	2
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.	This standard is fully met.	4
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.	This standard is fully met.	4
e) Testing of donor samples is carried out using CE marked diagnostic tests.	This standard is fully met.	4
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.	This standard is fully met.	4
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.	Compliance with this standard is assessed in more detailed standards below.	
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.	This standard is fully met. Advice and guidance is offered. <b>See advice and guidance 11</b>	4
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.	This standard is almost met. An audit trail is maintained but the numerous paper records do not facilitate easy audit. <b>See condition 13</b>	3

<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 partially met.</p> <p>Traceability is maintained up until transplant has occurred. Recipient patient case notes do not reflect any information regarding transplanted bone and traceability cannot be ensured from these records.</p> <p><b>See condition 14</b></p>	<p><b>2</b></p>
<p>GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.</p>	<p>Compliance with this standard is assessed in more detailed standards below.</p>	
<p>a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.</p>	<p>This standard is partially met.</p> <p>Some (but not all) non-compliances are documented. Non-compliances, including adverse events and reactions, are not graded for severity.</p> <p>There is no documented procedure for dealing with non-compliances and adverse events and reactions. There is also no policy to define what should be recorded as a non-compliance.</p> <p><b>See condition 16</b></p>	<p><b>2</b></p>
<p>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.</p>	<p>This standard is fully met.</p>	<p><b>4</b></p>
<p>c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.</p>	<p>This standard is almost met.</p> <p>The responsibilities of personnel are defined in practice but are not documented by the establishment.</p> <p><b>See advice and guidance 12</b></p>	<p><b>3</b></p>
<p>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.</p>	<p>This standard is partially met.</p> <p>There are no documented procedures detailing the assessment and fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.</p> <p><b>See condition 16</b></p>	<p><b>2</b></p>
<p>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.</p>	<p>This standard is fully met.</p>	<p><b>4</b></p>

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.	Compliance with this standard is assessed in more detailed standards below.	
a) There are documented risk assessments for all practices and processes.	This standard is partially met.  Not all practices and processes have been risk assessed. The risk assessments that have been done are cursory and do not identify and control all the risks to the quality and safety of tissues.  <b>See condition 17</b>	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.	This standard is partially met.  Staff at the hub can access those risk assessments which have been performed but there is no evidence that these are available at satellite sites.  <b>See condition 17</b>	2
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 not applicable.  N.B. A documented risk assessment should be carried out for determining the fate of tissues with incomplete test results.	N/A

## Premises, Facilities and Equipment

Standard	Assessment	Score
PFE1 The premises are fit for purpose.	Compliance with this standard is assessed in more detailed standards below.	
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	This standard is not met. Operating theatres at the hub are not risk assessed as procurement sites. Satellite sites are not appropriately risk assessed. <b>See condition 17</b>	1
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.	This standard is almost met. Office space is limited, which may impact on the ability of staff to carry out their roles. Storage of temperature restricted consumables in the office is not appropriate as this is not a controlled and monitored environment. <b>See advice and guidance 13</b>	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.	Compliance with this standard is assessed in more detailed standards below.	
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.	<p>This standard is partially met.</p> <p>There is appropriate storage of stocks of tissues at the hub, which are stored in designated quarantine or release freezers.</p> <p>However, quarantined (freshly procured) and non-quarantine (released for use in patients following full testing results) tissue is stored in the same operating theatre freezer at the hub. It is unclear whether this practice also takes place at satellite sites. This is an unacceptable risk to the integrity of tissues and cells.</p> <p><b>See condition 1</b></p>	<b>2</b>
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	<b>N/A</b>
c) There are procedures for cleaning and decontamination.	This standard is fully met.	<b>4</b>
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.	<p>This standard is almost met.</p> <p>SOPs detail that all staff should be wearing lab coats in tissue bank areas. This was not observed.</p> <p>Gloves are available in tissue storage areas but staff failed to use them or advise inspectors to do so.</p> <p><b>See advice and guidance 14</b></p>	<b>3</b>
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.	Compliance with this standard is assessed in more detailed standards below.	
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination	<p>This standard is partially met.</p> <p>Freezers are located in secure access locations at the hub and at satellites. However, the freezers in the theatres at the hub and at the Nuffield Hospital Leicester satellite site are not lockable.</p> <p><b>See advice and guidance 14</b></p>	<b>2</b>
b) There are systems to deal with emergencies on a 24 hour basis.	<p>This standard is almost met.</p> <p>Freezers in the theatre at the Nuffield Hospital Leicester satellite site are not alarmed. It is not clear how an incident regarding these freezers would be dealt with out of hours.</p> <p><b>See advice and guidance 15</b></p>	<b>3</b>

c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	This standard is almost met.  Whilst the storage and theatre freezers themselves are sufficient to maintain tissue integrity. Some satellite freezers only alarm locally. A failure to quickly rectify a reported temperature recording error at the North Devon District Hospital satellite site was observed.  <b>See advice and guidance16</b>	<b>3</b>
d) There is a documented, specified maximum storage period for tissues and / or cells.	This standard is fully met.	<b>4</b>
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.	Compliance with this standard is assessed in more detailed standards below.	
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 almost met.  The conditions for the release of tissue do not accurately reflect the full range of donor testing that is required in the Directions.  <b>See conditions 7 and 8</b>	<b>3</b>
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.	This standard is fully met.	<b>4</b>
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.	This standard is fully met.	<b>4</b>
d) Records are kept of transportation and delivery.	This standard is fully met.	<b>4</b>
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 almost met.  Femoral heads are stored in a glass jar placed inside a plastic jar, both of which are autoclaved prior to use. Tissues to be transported are placed in an appropriately labelled secondary package.  However, the jars the tissues are stored in are not validated as fit for purpose. Packaging for massive allografts is not validated as fit for purpose.  <b>See condition 9</b>	<b>3</b>
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.	<b>4</b>
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.	This standard is fully met.	<b>4</b>

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 not met. Primary packaging is not labelled with the information required by Directions. <b>See condition 18</b>	1
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.	This standard is fully met.	4
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	Compliance with this standard is assessed in more detailed standards below.	
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.	This standard is fully met.	4
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	This standard is fully met.	4
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.	This standard is fully met.	4
d) New and repaired equipment is validated before use and this is documented.	This standard is almost met. There is no evidence that a repaired freezer detailed in a non-compliance report was validated before recommissioning. <b>See advice and guidance 17</b>	3
e) There are documented agreements with maintenance companies.	This standard is fully met.	4
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	This standard is fully met.	4
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.	This standard is fully met.	4

h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.	This standard is fully met.	4
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.	<p>This standard is not met.</p> <p>The identities of authorised staff carrying out activities are not documented.</p> <p>Individual theatre numbers/names where procurement takes place are not recorded as part of the procurement process.</p> <p><b>See advice and guidance 18</b></p> <p>Batch numbers and expiry dates for consumables are not recorded.</p> <p><b>See condition 5</b></p>	1
k) There are contingency plans for equipment failure.	This standard is fully met.	4

## Disposal

Standard	Assessment	Score
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.	Compliance with this standard is assessed in more detailed standards below.	
a) The disposal policy complies with HTA's Codes of Practice.	<p>This standard is partially met.</p> <p>Tissue from the deceased is not disposed of separately to other clinical waste.</p> <p><b>See proposed condition 19 in draft report</b></p>	2
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.	<p>This standard is not met</p> <p>There is no specific disposal procedure to ensure there is no cross contamination. The Trust is drafting a disposal policy that does not take this into consideration.</p> <p><b>See proposed condition 19 in draft report</b></p>	1

D2 The reasons for disposal and the methods used are carefully documented.	Compliance with this standard is assessed in more detailed standards below.	
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 almost met.  There are disposal logs and records for tissue that is not implanted, however, they do not accurately reflect the reason for disposal.  <b>See advice and guidance 19</b>	<b>3</b>
b) Disposal arrangements reflect (where applicable) the consent given for disposal.	This standard is fully met.	<b>4</b>

## Conclusions

22. 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

23. The Designated Individual (DI) is technically suitable for the role. However, the DI has a limited operational role in the bone bank and as a consultant orthopaedic surgeon does not have protected hours in which to conduct his role. The level of non-compliance observed during inspection indicates that the DI has not suitably ensured compliance with HTA standards via oversight and governance of the licensable activities occurring at the establishment.

24. The Licence Holder (University Hospital of Leicester NHS Trust) is considered suitable.

### Suitability of the Premises

25. The HTA has some concern about the premises. The HTA has identified areas where action is required to ensure that the establishment fully meets the requirements of HTA standards.

### Suitability of Practices

26. The practices being carried out under the licence are deficient in several areas. The HTA has identified areas where action is required to ensure that the establishment fully meets the requirements of HTA standards.

### Summary comment

27. The HTA is satisfied that the establishment is suitable to be licensed for the purposes that it has set out. Improvements are required in several areas: see sections below.

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

28. There were no conditions on the licence at the time of inspection.

**Proposed conditions (requirements) related to areas of non-compliance identified during the inspection process and removed following receipt of compliance information before publication of final report**

29. The regulatory reference is noted so the DI can refer back to relevant standards in the Human Tissue Act 2004, the Q and S Regulations 2007, the Compliance Report and Directions or Codes of Practice.

No	Regulatory reference	Conditions (including reasons for conditions)	Compliance Information Provided
1	GQ1(h) PFE2(a)	<p><b>Condition</b></p> <p>The DI and the LH shall immediately: ensure that quarantined human tissue is not placed in the same freezer as non-quarantined material at the hub or any satellite sites.</p> <p>By 31 January 2009, the DI and the LH shall; assess the hub and all satellite sites to establish the storage arrangements for quarantined (freshly procured) and non-quarantined (released for use in patients following full testing results) human tissue. prepare, introduce and enforce a written standard operating procedure for the storage of non-quarantined and quarantined material at the hub and satellite sites that ensures compliance with HTA Directions 002/2007 (43). provide written confirmation and copies of relevant documentation to the Human Tissue Authority (“the HTA”) when the requirements set out in (a) (i) – (iii) have been fully met.</p> <p>This information should be sent to <a href="mailto:licensing.enquiries@hta.gov.uk">licensing.enquiries@hta.gov.uk</a> or to the HTA offices marked ‘Compliance’.</p> <p><b>Reason</b></p> <p>At the hub, tested and released femoral heads are stored in the same operating theatre freezer that is used to store freshly procured (untested) femoral heads. This presents an unacceptable risk to the integrity of tissues and cells. It is unclear whether this practice also takes place at satellite sites</p>	<p>Email from establishment states:</p> <p>The Hub and all satellite sites have been assessed to establish storage arrangements for both quarantined and non-quarantined bone. See Appendix A</p> <p>2. Standard operating procedures have been written governing the storage of tissue at both Hub and satellite sites. See Appendix B</p>

6	<b>GQ1(g)</b>	<p><b>Condition</b> By 01 July 2009, the Designated Individual will put in place a documented system to verify that bone received by the establishment meets documented specifications and is labelled appropriately. This verification should include an assessment of the integrity of containers as well as the completeness of information included on the label and on donor information sheets.</p> <p><b>Reason</b> There is no procedure to verify that bone received meets specifications and is appropriately labelled.</p>	Establishment has provided new SOP and labeling information.
19	<b>D1(a)</b> <b>D1(c)</b>	<p><b>Condition</b> By 01 June 2009, the Designated Individual will put in place a documented policy and associated procedure for the disposal of tissue from deceased donors that is generated in the procurement of massive allografts. This procedure will ensure at a minimum that tissue from the deceased is disposed of separately to all other clinical waste.</p> <p><b>Reason</b> Tissue from deceased donors is not disposed of separately to other clinical waste. There is no specific disposal procedure documented</p>	<p>Email from establishment states:</p> <p>A new Standard Operating Procedure concerning the discard of tissues has now been completed. See Appendix D.</p>

**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 Q and S Regulations 2007, the Compliance Report and Directions or Codes of Practice.

No	Regulatory reference	Conditions (including reasons for conditions)
1.		<b>Proposed condition not applied following receipt of compliance information</b>

2.	<b>GQ3(k)</b>	<p><b>Condition</b></p> <p>By 31 March 2009, the DI and the LH shall;</p> <ul style="list-style-type: none"> <li>(i) undertake an evaluation of staffing needs at the establishment (hub and all satellites) to ensure that staffing arrangements are adequate in order for the establishment to fully comply with the Human Tissue (Quality and Safety for Human Application) Regulations 2007. This evaluation should assess how any needs can be met without imposing undue workload on existing individual members of staff. The evaluation should include the production of a proposed action plan and timeline to address any shortfall identified and should give consideration as to whether the current activity level is manageable with existing staff numbers.</li> <li>(ii) provide written confirmation and copies of relevant documentation to the HTA when the evaluation has been completed and provide copies of any proposed action plan and timeline.</li> </ul> <p>This information should be sent to <a href="mailto:licensing.enquiries@hta.gov.uk">licensing.enquiries@hta.gov.uk</a> or to the HTA offices marked 'Compliance'.</p> <p><b>Reason</b></p> <p>The establishment does not appear to have sufficient staff resource based on the non-compliance with HTA standards observed during the site-visit inspection. The establishment has expanded its activities to multiple sites and there is no evidence that suitable staffing needs analyses have been performed in order to ensure adequate ability to perform licensable activities. In particular:</p> <ul style="list-style-type: none"> <li>• staff levels at the hub are not adequate to enable governance of the large number of satellite sites</li> <li>• the DI does not have an appropriate amount of protected time to dedicate to his responsibilities at the establishment</li> <li>• the volume of material being received and distributed at the hub does not appear commensurate with the number of staff</li> <li>• inadequate systems mean that staff at the hub spend a disproportionate amount of time undertaking menial tasks, such as accessing records.</li> <li>• There has been no provision of CPD or ongoing training for staff due to the level of their activity</li> </ul> <p>Theatre staff undertaking procurement have not been appropriately trained nor has their training been updated</p>
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3.	<b>GQ2(d)</b> <b>GQ1(p)</b>	<p><b>Condition</b></p> <p>The DI and the LH shall immediately:</p> <ul style="list-style-type: none"> <li>(i) cease the issue of any human tissue which has been irradiated following a positive result for microbiological contamination.</li> </ul> <p>By 31 March 2009, the DI and the LH shall;</p> <ul style="list-style-type: none"> <li>(i) validate as effective the use of irradiation in rendering such tissue safe for human application and document this validation.</li> <li>(ii) produce a standard operating procedure setting out when tissue should be irradiated and when it should be disposed of following a positive result for microbiological contamination. This procedure must include documented sign off by an authorised person.</li> <li>(iii) ensure a third party agreement (as described in HTA Directions 002/2007 (117 - 119)) is put in place with an irradiation provider.</li> <li>(iv) complete a risk assessment for all tissue currently in storage which has been irradiated following a positive result for microbiological contamination to determine whether it is safe for human application and if not, ensure that it is disposed of in accordance with the procedure in (c)(iii) above.</li> <li>(v) provide written confirmation and copies of relevant documentation to the HTA when the requirements set out in c (i) – (v) have been fully met.</li> </ul> <p>This information should be sent to <a href="mailto:licensing.enquiries@hta.gov.uk">licensing.enquiries@hta.gov.uk</a> or to the HTA offices marked 'Compliance'.</p> <p><b>Reason</b></p> <p>There is no standard operating procedure for the irradiation or disposal of tissue following a positive result for microbiological contamination. Current records do not include documented sign off by an authorised person when contaminated bone is sent for irradiation or returned to the establishment. Validation has not been carried out for this process.</p> <p>An agreement for the irradiation of bone is not in place. This practice may result in contaminated or endotoxin containing bone being issued. This poses an unacceptable threat to patient safety.</p>
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4.	<b>GQ1(e)</b> <b>GQ3 (c)</b> <b>GQ3 (e)</b> <b>GQ3(j)</b>	<p><b>Condition</b></p> <p>By 01 July 2009, the Designated Individual will put in place a documented training programme for those theatre nurses procuring femoral heads from living donors. This training programme will include a competency based assessment of all staff that have been trained. Records of training must be made and copies of the records will be retained at the hub and originals kept at the procurement sites. This training must be regularly updated in line with an ongoing training schedule.</p> <p>The Designated Individual will also put in place a system for recording the name of the individual procuring femoral heads and the Designated Individual will ensure a periodic audit is carried out to provide assurance that those individuals procuring femoral heads have been trained and that their training is current. Any discrepancies found from the audit will be documented and appropriate corrective measures will be implemented./</p> <p><b>Reason</b></p> <p>Procedures for tissue procurement are documented but are not adequately communicated to all procurers.</p> <p>Training in procurement is not adequately provided to theatre nurses carrying out procurement activities. The competence in procurement of theatre nurses is not recorded, and potentially safety of patients and the quality and safety of tissue may be compromised. Staff procuring on behalf of the establishment do not have regular updates in training or access to procedures.</p>
5.	<b>GQ1(f)</b>	<p><b>Condition</b></p> <p>By 01 July 2009, the Designated Individual will put in place a documented training programme for those theatre nurses procuring massive bone allografts from deceased donors, which ensures the dignity of deceased donors. This training programme will include a competency based assessment of all staff that have been trained. Records of training must be made and copies of the records will be retained at the hub. This training must be regularly updated in line with an ongoing training schedule.</p> <p>The Designated Individual will also put in place a system for recording the name of the individual procuring massive bone allografts and the Designated Individual will ensure a periodic audit is carried out to provide assurance that those individuals procuring femoral heads have been trained and that their training is current. Any discrepancies found from the audit will be documented and appropriate corrective measures will be implemented.</p> <p><b>Reason</b></p> <p>There is no documented SOP for the procurement of massive allografts from deceased donors. This procurement takes place in an operating theatre and not in a mortuary setting. On this basis, it could not be determined if there is provision for the dignity of deceased donors or that tissue is procured in a way that ensures the relevant quality and safety.</p>
6.		<p><b>Proposed condition not applied following receipt of compliance information</b></p>

7.	<b>GQ1(h)</b> <b>PFE4(a)</b>	<p><b>Condition</b></p> <p>By 01 July 2009, the Designated Individual will audit all records relating to bone that is currently in storage and identify any bone that lacks complete test results at donation. A documented risk assessment of bone that has been identified as lacking complete test results must be made and this bone must be either be disposed of or re-issued, as appropriate.</p> <p>The Designated Individual will put in place a documented policy and procedure for the repackaging, irradiation and subsequent re-issue of femoral heads following the identification of non-conformances with packaged bone, such as compromised pots.</p> <p><b>Reason</b></p> <p>Fresh frozen femoral heads that lacked test results at donation were not disposed of.</p> <p>Non-conformances such as compromised pots are repackaged and assigned for irradiation; however, this process is not documented or validated.</p>
8.	<b>GQ1(i)</b> <b>GQ5(b)</b> <b>PFE4(a)</b>	<p><b>Condition</b></p> <p>By 01 March 2009, the Designated Individual shall ensure that full donor testing as required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and HTA Directions 002/2006 is carried out for all bone before release to patients.</p> <p>The Designated Individual will put in place a policy and procedure for risk assessment of donors regarding HTLV testing and ensure that future HTLV testing of samples is informed by this risk assessment and any associated changes in policy or procedures.</p> <p>The Designated Individual will identify any stored bone that has incomplete testing and undertake a documented risk assessment of these units and either dispose of or authorise for release as dictated by the results of this risk assessment.</p> <p><b>Reason</b></p> <p>The majority of required tests are carried out at donation and again after 180 days, however, HbV core antigen and HTLV testing are not undertaken at the time of donation.</p> <p>An appropriate risk assessment regarding HTLV is not carried out for donors.</p> <p>The conditions for the release of tissue do not accurately reflect the full range of donor testing that is required in the Directions.</p>

9.	<b>GQ1(j)</b> <b>GQ4(h)</b> <b>GQ4(j)</b> <b>PFE4(e)</b>	<p><b>Condition</b></p> <p>By 01 April 2009, the Designated Individual will establish criteria for the acceptance of consumables used for the storage and testing of bone, such as bone jars and test media. Consumables received must be accepted only in accordance with these criteria. Records (type, batch/lot numbers and expiry dates) of all consumables used must be made and retained. Temperature sensitive consumables must be stored in an appropriate controlled and monitored environment. Consumables issued to satellites must be appropriately labelled with type, batch/lot numbers and expiry dates and must be stored at satellite sites in an appropriate controlled and monitored environment. The use of these consumables at satellite sites must also be appropriately recorded.</p> <p>The Designated Individual shall put in place a procedure for validating the sterility of consumables that have been autoclaved by the UHL sterile services. The Designated Individual shall satisfy himself that the sterilisation service can provide a suitably reliable service and has been appropriately audited or accredited and shall make a record of this and provide a copy to the HTA.</p> <p>The Designated Individual will undertake a validation suitability to maintain quality and safety for inner and outer jars used to store femoral heads and packaging for massive allografts.</p> <p><b>Reason</b></p> <p>Consumables critical to the testing and procurement of femoral heads are not stored in a controlled, monitored environment.</p> <p>Batch numbers of broths and bone jars are not recorded and neither are expiry dates. This is a particular issue given that jars and broth bottles are distributed to satellites and allocated to Theatre stores without expiry information.</p> <p>Acceptance criteria have not been established for critical materials and reagents. There is no assurance that these materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.</p> <p>Sterilisation of critical consumables is carried out in an unaccredited sterilisation service department. This department is also not subject to internal UHL audits. It cannot be guaranteed that these consumables are of sufficient quality to maintain the quality and safety of tissues. There is no validation of the sterilisation process for these consumables performed by Leicester Bone Bank.</p> <p>Inner and outer jars used to store femoral heads and packaging for massive allografts have not been validated as fit for purpose.</p>
10.	<b>GQ1(m)</b>	<p><b>Condition</b></p> <p>By 01 April 2009, the Designated Individual shall put in place a documented policy and procedure for the assignment of tissue to patients based on blood type, rhesus factor (where appropriate) and a surgeons' request for allograft size. The reason for assignment of bone to patients must be recorded.</p> <p><b>Reason</b></p> <p>Allocation of tissue is on a size, blood type and rhesus factor matching basis and is performed in an ad hoc fashion which is reliant on the specific knowledge of the Scientific Director and Deputy Scientific Director. This procedure is not documented, nor does it reflect any written policy.</p>

11.	<b>GQ2(b)</b>	<p><b>Condition</b></p> <p>By 01 September 2009, the Designated Individual will put in place a schedule of regular audits of the hub and of all satellites. This audit schedule must include an annual audit of the hub and an audit of each satellite site at least every two years. The audits must be documented and made available on inspection. Non-compliances that are identified by audits must be followed up with appropriate corrective and preventative actions and the implementation of these corrective and preventative actions must be verified and recorded in the audit documentation.</p> <p><b>Reason</b></p> <p>There is no documented system for internal audits. Satellites are not regularly audited. Audits of only two satellites have been documented. Audits are not scheduled and do not appear to be ongoing. Current auditing systems are incomplete and inadequate to capture non-compliance at the hub and satellite sites.</p>
12.	<b>GQ3(b)</b> <b>GQ3(c)</b> <b>GQ3(e)</b> <b>GQ3(f)</b> <b>GQ3(g)</b> <b>GQ3(h)</b> <b>GQ3(j)</b>	<p><b>Condition</b></p> <p>By 01 September 2009, the Designated Individual will put in place a formal induction programme for all new staff at the hub and new staff conducting licensable activities at the satellites.</p> <p>A training programme will be introduced that ensures staff are familiar with the organisational structure of and the quality systems used by the bone bank.</p> <p>The Designated Individual will ensure that training relating to procurement is conducted as outlined in Conditions 1 and 2. In addition, the Designated Individual will identify all other areas of licensable activity where training is not conducted or sufficiently documented and shall put in place a training schedule for all staff regarding these activities that is documented and regularly updated. This will include a competency based assessment of all staff conducting licensable activities.</p> <p>The Designated Individual shall put in place a policy, schedule and allocate time for the ongoing training and continuing professional development (CPD) of staff employed by the bone bank.</p> <p><b>Reason</b></p> <p>The current induction programme does not involve competency based assessment of staff following training.</p> <p>There are limited training procedures in place and the training programme for staff is not documented other than for training in taking consent. Training records are incomplete.</p> <p>There is no documented training programme that ensures that staff understand the organisational structure and the quality systems.</p> <p>There are SOPs available for some procedures and training consists of reviewing those SOPs. Reference manuals are available at the hub but not widely disseminated to staff at satellites.</p> <p>There is no planning for and limited access to CPD and training. There is no time is allocated to this in the bone bank staff job descriptions.</p>

13.	<b>GQ4(b)</b> <b>GQ4(c)</b> <b>GQ4(e)</b> <b>GQ6(b)</b>	<p><b>Condition</b></p> <p>By 01 September 2009, the Designated Individual will conduct an audit of the establishment's paper and electronic records to ensure that these accurately reflect the bone that is in storage and that has been issued. This audit should pay particular attention to the following areas:</p> <ul style="list-style-type: none"> <li>• The legibility and traceability of records especially those records contained in the 'Day Book'. An assessment of the appropriateness of the 'Day Book' system should be made.</li> <li>• Records of who has taken consent for given samples and crosschecking this with records of those trained to take consent.</li> <li>• Material issue sheets at satellites and the systems for recording reservation and subsequent cancellation of bone assigned for use at the satellites.</li> <li>• The reproducibility and legibility of donor information sheets, particularly when photocopied or faxed.</li> <li>• Cross checking the paper and electronic record systems for accuracy and for the ease of tracing boner from donor to recipient and vice-versa.</li> </ul> <p>The Designated Individual will put in place a scheduled audit of records at the bone bank that ensures any discrepancies found from the audit will be documented and appropriate corrective / preventative measures will be implemented.</p> <p><b>Reason</b></p> <p>There is evidence of some audit of records and their content, however this does not appear to be regularly scheduled, documented or systematic. Discrepancies in record keeping were noted and requested records were not found at site.</p> <p>Information recorded in the day book is incomplete, often illegible and inappropriately linked to associated paper records.</p> <p>Consent documentation does not have space to record the name of the person taking consent and signatures cannot be reliably linked to records of persons trained in taking consent.</p> <p>Material issue sheets held at satellites are used to record reservations and cancellations of bone, which become unclear as to which specimen is being reserved after multiple cancellations/reissues. Legibility and accuracy of these records is an issue.</p> <p>Donor data sheets cannot be photocopied or faxed due to shaded boxes and are thus not reproducible. Legibility and accuracy of these records is an issue.</p> <p>There is a system in place that combines use of computerised databases with paper records. The electronic records keeping system does not reliably match the day book system. The fate date recording method is not reliably linked to paper records. Overall the record keeping/registering system is complex, undocumented and could lead to errors and failure of traceability.</p> <p>An audit trail is maintained but the numerous paper records do not facilitate easy audit.</p>
14.	<b>GQ4(i)</b> <b>GQ4(k)</b> <b>GQ6(c)</b>	<p><b>Condition</b></p> <p>By 01 September 2009, the Designated Individual shall implement a system for the incorporation into recipient patient notes the information regarding the bone that has been transplanted into patients. A procedure for recording this information shall be communicated to end users and an audit of the recording of this information should be conducted periodically.</p> <p><b>Reason</b></p> <p>Recipient patient case notes do not reflect any information regarding transplanted bone and traceability cannot be ensured from these records.</p>

15.	<b>GQ4(l)</b>	<p><b>Condition</b></p> <p>By 01 June 2009, the Designated Individual shall implement a documented policy and procedure for the acceptance or rejection of tissue</p> <p><b>Reason</b></p> <p>There is no documented policy, procedure or rationale regarding the acceptance or rejection of tissue.</p>
16.	<b>GQ7(a)</b> <b>GQ7(d)</b>	<p><b>Condition</b></p> <p>By 01 September 2009, the Designated Individual shall put in place a procedure for the recording of suspected adverse events and reactions that includes the grading of their severity. This procedure will thereby identify suspected serious adverse events and/or reactions and include a mechanism for informing the HTA of such events and include an assessment and designation of the fate of tissues and / or cells affected by an adverse event or reaction.</p> <p>The Designated Individual will put in place a procedure for the recording of non-conformances that includes grading the severity of non-conformances. This procedure should include a system for putting in place corrective and preventative actions following non-conformances and include a mechanism to ensure that these actions have been undertaken in a timely fashion. A risk assessment of bone affected by a non-conformance should be made and a determination as to the fate of bone affected by any deviation from the required quality and safety standards should be made.</p> <p><b>Reason</b></p> <p>Non-compliances, including adverse events and reactions, are not graded for severity.</p> <p>There is no documented procedure for dealing with non-compliances and adverse events and reactions. There is also no policy to define what should be recorded as a non-compliance.</p> <p>There are no documented procedures detailing the assessment and fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.</p>
17.	<b>GQ8(a)</b> <b>GQ8(c)</b> <b>PFE1(a)</b>	<p><b>Condition</b></p> <p>By 01 September 2009, the Designated Individual shall undertake a comprehensive risk assessment of all practices and procedures undertaken at the hub and at satellite sites, with respect to the quality and safety of bone. These risk assessments should be made available to staff at the hub and at all satellite sites where the respective procedures take place.</p> <p><b>Reason</b></p> <p>Not all practices and processes have been risk assessed. The risk assessments that have been done are cursory and do not identify and control all the risks to the quality and safety of tissues at the hub or at satellites. Staff at the hub can access those risk assessments which have been performed but there is no evidence that these are available at satellite sites.</p>
18.	<b>PFE4(i)</b>	<p><b>Condition</b></p> <p>By 01 June 2009, the Designated Individual will implement a documented procedure to ensure that the primary packaging used for bone is labelled with the information required by the HTA Directions 002/2007.</p> <p><b>Reason</b></p> <p>Primary packaging is not labelled with the information required by HTA Directions.</p>

19.	<b>D1(a)</b> <b>D1(c)</b>	<b>Proposed condition not applied following receipt of compliance information</b>	
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### Advice and guidance

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

No.	Regulatory reference	Advice
1.	<b>C1(c)</b> <b>C1(d)</b>	The DI is advised to consider amending consent forms to include space for the consent taker to record their name clearly as well as their signature and date. This will allow verification that those taking consent have been appropriately trained. The DI should also consider version control of consent forms to ensure that all sites only use the current form.
2.	<b>C2(c)</b>	The DI is advised to consider updating the patient information leaflets to reflect current consent procedures and the language used on the consent form. They should be printed and not photocopied in order to ensure legibility. The legibility of the font used should also be considered. The DI should also consider version control of patient information leaflets to ensure that all sites only use the current form.
3.	<b>GQ1 (b)</b>	The DI is advised to consider reviewing and updating standard operating procedures. Procedures should detail all processes which may affect the quality and safety of human tissue and reflect current practice at the establishment. A regular evaluation date should be established for each procedure to ensure that procedures are up to date and fit for purpose.
4.	<b>GQ1(c)</b>	The DI is advised to consider increasing the frequency of governance meetings and review his involvement in governance, such as through these meetings.
5.	<b>GQ1(d)</b>	The DI is advised to consider a review of policies and SOPs in line with their recorded review dates. Policies and SOPs should be authored and authorised by different staff members.
6.	<b>GQ1(i)</b>	The DI is advised to consider a review and update of the standard operating procedure to include the colour coded sticker system used to identify quarantined material and material released for issue .
7.	<b>GQ2(a)</b>	The DI is advised to consider undertaking assessment and revision of the quality management system in order to ensure its completeness and that it reflects current practice at the establishment.
8.	<b>GQ2(c)</b>	The DI is advised to consider ensuring that an audit is conducted in an independent manner at least every two years and that this verifies compliance with protocols and HTA standards. The results of the audit should be documented and any actions implemented.

9.	<b>GQ2(d)</b>	The DI is advised to consider undertaking a full and complete audit of all paper based records held at the hub to ensure completeness and to identify incomplete records and non-compliances, such as material where donor testing information has been omitted. Material non-compliances noted in the audit should be followed by a risk assessment of the material in question.
10.	<b>GQ4(a)</b>	The DI is advised to ensure procedures are put in place for the creation, identification, maintenance, access, amendment, retention and destruction of records.
11.	<b>GQ6(a)</b>	The DI is advised to consider assigning an establishment code to its product, to allow easy traceability from recipient case notes. The DI should consider revising the numbering system as it was unclear how it would cope as of 2010.
12.	<b>GQ7(c)</b>	The DI is advised to ensure the specific responsibilities and roles of staff investigating adverse events related to licensable activities in the establishment are clearly outlined and documented.
13.	<b>PFE1(c)</b>	The DI is advised to ensure the storage conditions required to maintain the quality of consumables critical to the licensable activity should be determined. The current storage arrangements should be reviewed in light of this information. Consideration should also be given to the adequacy of current office space.
14.	<b>PFE2(d)</b>	The DI is advised to ensure that staff should follow appropriate procedures for the use of protective clothing and equipment.
15.	<b>PFE3(b)</b>	The DI is advised to ensure freezers are adequately alarmed and procedures are in place for dealing with emergencies on a 24 hour basis.
16.	<b>PFE3(c)</b>	The DI is advised to consider introducing procedures to ensure that errors in recording controlled environments are dealt with quickly.
17.	<b>PFE5(d)</b>	The DI is advised to consider introducing procedure to ensure new and repaired equipment is validated before use or recommissioning and that this is documented.
18.	<b>PFE5(j)</b>	The DI is advised to consider documenting the identities of authorised staff carrying out activities and individual theatre details where procurement takes place.
19.	<b>D2(a)</b>	The DI is advised to consider amending the disposal log to include the recording of the reason for disposal.

**Report sent to DI for factual accuracy: 05 January 2009**

**Report returned from DI: 22 January 2009**

**Final report issued: 05 February 2009**