HTA inspection evidence workbook: Post Mortem sector establishments

<table>
<thead>
<tr>
<th>Time*</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.00 – 9.30</td>
<td>Inspection team arrival and introductory meeting</td>
</tr>
<tr>
<td>9.30 – 12.00</td>
<td>Visual inspection of premises / commencement of audit trail</td>
</tr>
<tr>
<td>12.00 – 12.30</td>
<td>Interview with Mortuary Manager (PFE &amp; Disposal)</td>
</tr>
<tr>
<td></td>
<td>Interview Consultant Histopathologist (Consent &amp; GQ)</td>
</tr>
<tr>
<td>12.30 – 13.00</td>
<td>Document review</td>
</tr>
<tr>
<td></td>
<td>Interview with Bereavement Officer (Consent &amp; Disposal)</td>
</tr>
<tr>
<td>13.00 – 14.00</td>
<td>Working lunch and document review / completion of audit trail</td>
</tr>
<tr>
<td>14.00 – 15.00</td>
<td>Interview with Designated Individual (GQ &amp; PFE)</td>
</tr>
<tr>
<td></td>
<td>Interview with Coroner’s officer (Consent)</td>
</tr>
<tr>
<td></td>
<td>Interview with Corporate Licence Holder Contact (GQ)</td>
</tr>
<tr>
<td>15.00 – 16.30</td>
<td>Document review and inspection team debrief</td>
</tr>
<tr>
<td>16.30 – 17.00</td>
<td>Final feedback meeting</td>
</tr>
</tbody>
</table>

* all times are estimated and the order of the timetable is arranged by the inspection team.

1 please attach any ‘Conflict of interest’ questionnaire(s)

Delete this section and insert actual filled in timetable as appropriate.

---

YYYY-MM-DD [Licensing number] [Establishment name] inspection notes

Reference number: HTA-TEM-008 Last reviewed on: 19 May 2015
Version number: 15.0 Next review due: 19 May 2016
<table>
<thead>
<tr>
<th>Licensing history</th>
<th>(type of licence / how long for / number of previous inspections / accreditation)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up actions from last inspection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Pre-inspection meeting notes
Introductory meeting notes

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Visual inspection evidence

- ✔️ = evidence has been seen and meets HTA standards
- ✗ = evidence seen but does not meet HTA standards
- ☐ = evidence not seen therefore standard not assessed
- ☐ = this option applies

### Access to mortuary (PFE1/GQ1)

- Secure access to mortuary: swipe card / key / code lock / CCTV
- Record of visitors to mortuary: FDs / family of deceased / tissue retrieval team / maintenance staff
- Secure access of records
- Premises are in reasonable condition i.e. structure & cleanliness of floors, walls, entranceways

| Who checks the ID of deceased on admission? | 2 person check? Yes / No |
| Who brings bodies into the mortuary out of hours? | |
| What ID details of deceased are checked: | On admission: | On release: |

### Body storage (PFE3/PFE5)

<table>
<thead>
<tr>
<th>Number of:</th>
<th>Fridges</th>
<th>Freezers</th>
<th>Paediatric</th>
<th>Bariatric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal temperature range for:</td>
<td>fridge °C to °C</td>
<td>freezers °C to °C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trigger point:</td>
<td>fridge °C to °C</td>
<td>freezers °C to °C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alarm system is tested every ___ days / weeks / months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature monitored: manually / local alarm / external alarm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature records are reviewed for trends</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are contingency arrangements for power failure or overflow</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are temporary storage units which are alarmed/checked</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There is separate storage for infants/babies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage for paediatrics is alarmed and monitored (note any differences to adult storage below)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bodies are all covered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body bags are used for infectious cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are special measures for infectious cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are special measures for forensic (high profile) cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleaning records for body store. Date last cleaned:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference number: HTA-TEM-008
Last reviewed on: 19 May 2015
Version number: 15.0
Next review due: 19 May 2016
### Viewing room (PFE1)

- There are out of hours viewings: Yes / No
- What arrangements are in place for safety of staff (lone working)?
  - Personal alarm / wall alarm / call to security on arrival and leaving / CCTV / other:

- Access to the rest of the mortuary is restricted: Yes / No

### PM room (PFE2/PFE5)

- Demarcation of clean and dirty areas:
  - Doors / step over barrier / lines / signage
  - Scrubs / boots / waterproof gown / hair net
  - Goggles or glasses or visor / gloves / face mask – type:

- There are cleaning records for PM room. Date last cleaned:

- There are special measures for high risk PMs

- Dedicated area for safe dissection of organs

- Sufficient space for PMs to be carried out safely

- Procedure to prevent mix up of organs:

<table>
<thead>
<tr>
<th>Object</th>
<th>Shows signs of…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fridge/freezer doors</td>
<td>rust / contamination / damage / none</td>
</tr>
<tr>
<td>Racking in fridge/freezers</td>
<td>rust / contamination / damage / none</td>
</tr>
<tr>
<td>Hydraulic trolleys</td>
<td>rust / contamination / damage / none</td>
</tr>
<tr>
<td>Post mortem tables</td>
<td>rust / contamination / damage / none</td>
</tr>
<tr>
<td>Hoists</td>
<td>rust / contamination / damage / none</td>
</tr>
<tr>
<td>Saws (manual and/or oscillating)</td>
<td>rust / contamination / damage / none</td>
</tr>
</tbody>
</table>

- There are _____ air changes per hour

- PM tables are downdraft

- Formalin is stored in a well-ventilated area

- Equipment is **not** made of porous material

- There are hand washing facilities by the exit from the mortuary
Visual inspection notes

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Storage of specimens (PFE3)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are there samples stored in the Mortuary?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Large specimens in formalin / wet tissue blocks / bloods or urine etc for toxicology</td>
<td>Other</td>
</tr>
<tr>
<td>Samples are stored in:</td>
<td></td>
</tr>
<tr>
<td>There are samples: awaiting collection for processing / awaiting courier collection for specialist analysis / forensic / permanently stored there</td>
<td></td>
</tr>
</tbody>
</table>

### Histology (PFE3)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>What types of samples are transferred?</td>
<td>Tissue contained in cassettes / wet tissue for trimming</td>
</tr>
<tr>
<td>Blocks and slides are filed in suitable cabinets in a secure area</td>
<td></td>
</tr>
<tr>
<td>Wet tissues/ trimmings are stored in a well-ventilated area</td>
<td></td>
</tr>
<tr>
<td>Samples for repatriation with deceased are highlighted</td>
<td></td>
</tr>
</tbody>
</table>

### A&E (PFE3)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples are removed in dedicated area, which ensures dignity of deceased</td>
<td></td>
</tr>
<tr>
<td>A unique identifier is assigned to the deceased and recorded on sample pots</td>
<td></td>
</tr>
<tr>
<td>Paperwork in use is current version</td>
<td></td>
</tr>
<tr>
<td>Samples are: Transferred straight away / stored unrefrigerated awaiting collection / stored in a fridge awaiting collection / stored in fixative</td>
<td></td>
</tr>
<tr>
<td>Fridge for storage of samples is: regularly monitored / alarmed</td>
<td></td>
</tr>
</tbody>
</table>

### Maternity (PFE3)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes / No</th>
</tr>
</thead>
<tbody>
<tr>
<td>A unique identifier is assigned to the deceased</td>
<td></td>
</tr>
<tr>
<td>There is a viewing area, which ensures the dignity of the deceased</td>
<td></td>
</tr>
<tr>
<td>Pregnancy remains are: Transferred to straight away / stored unrefrigerated awaiting collection / stored in a fridge awaiting collection / stored in fixative</td>
<td></td>
</tr>
<tr>
<td>Fridge for storage of pregnancy remains is: regularly monitored / alarmed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who takes deceased to the mortuary?</th>
<th>In hours:</th>
<th>Out of hours:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Visual Inspection notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

YYYY-MM-DD [Licensing number] [Establishment name] inspection notes

Reference number: HTA-TEM-008  Last reviewed on: 19 May 2015
Version number: 15.0  Next review due: 19 May 2016
**Audits (GQ6)**

**Body store audit trail 1**

Adult / Paediatric  
Received from: Community / Ward / Police (Suspicious death)

Name:  
DOB: / /  
Date of death: / /  

NHS/ Hospital unique identifier:  
Mortuary unique identifier:  

Storage location in mortuary register:  
Storage location on white board:  
Actual location of deceased:  

Identity bracelet on:  
Wrist:  Yes  No  
Foot:  Yes  No  

Details on ID bracelet:  Name / DOB / NHS number / Hospital number / Mortuary ID / Address  

Additional info  
e.g. hazard label / awaiting tissue return etc / shroud  

---

**Body store audit trail 2**

Adult / Paediatric  
Received from: Community / Ward / Police (Suspicious death)

Name:  
DOB: / /  
Date of death: / /  

NHS/ Hospital unique identifier:  
Mortuary unique identifier:  

Storage location in mortuary register:  
Storage location on white board:  
Actual location of deceased:  

Identity bracelet on:  
Wrist:  Yes  No  
Foot:  Yes  No  

Details on ID bracelet:  Name / DOB / NHS number / Hospital number / Mortuary ID / Address  

Additional info  
e.g. hazard label / awaiting tissue return etc / shroud  

---

**Body store audit trail 3**

Adult / Paediatric  
Received from: Community / Ward / Police (Suspicious death)

Name:  
DOB: / /  
Date of death: / /  

NHS/ Hospital unique identifier:  
Mortuary unique identifier:  

Storage location in mortuary register:  
Storage location on white board:  
Actual location of deceased:  

Identity bracelet on:  
Wrist:  Yes  No  
Foot:  Yes  No  

Details on ID bracelet:  Name / DOB / NHS number / Hospital number / Mortuary ID / Address  

Additional info  
e.g. hazard label / awaiting tissue return etc / shroud  

---
PM examination audit 1

Date of PM: / / Adult / Paediatric

Name: _______________________________ DOB: / / Date of death: / /

NHS/ Hospital unique identifier: __________________ Mortuary unique identifier: __________________

Type of PM: □ Hospital consented □ Forensic □ Coroner’s □ Limited □ Whole

Hospital consent form reviewed: □ Yes □ No Compliant with HTA standards: □ Yes □ No

Type of Tissue samples collected: __________________ No. of blocks: _______ No. of slides: _______

Sent for Histo/Tox/Specialist analysis: □ Yes □ No

Sent to: _______________________________

Wishes of bereaved from Coroners officer form state tissue to be:

□ Repatriated □ Stored for Scheduled Purpose □ Disposed of sensitively

Discrepancies: ___________________________

Histology

Date samples received in Histology: / / No. of blocks: _______ No. of slides: _______

Residual tissue: __________________________

Location: _______________________________

Discrepancies: ___________________________

Disposal/ Repatriation

Tissue samples: □ Disposed of sensitively □ Repatriated Date: / / Samples sent for specialist analysis: □ Yes □ No

Sent to: _______________________________

Date of return: / / Evidence of receipt: __________________________

Discrepancies: ___________________________

YYYY-MM-DD [Licensing number] [Establishment name] inspection notes

Reference number: HTA-TEM-008 Last reviewed on: 19 May 2015
Version number: 15.0 Next review due: 19 May 2016
### PM examination audit 2

<table>
<thead>
<tr>
<th>Date of PM:        /       /</th>
<th>Adult / Paediatric</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name: ______________________</th>
<th>DOB: / / /</th>
<th>Date of death: / / /</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>NHS/ Hospital unique identifier:</th>
<th>Mortuary unique identifier:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type of PM: [ ] Hospital consented</th>
<th>[ ] Forensic</th>
<th>[ ] Coroner’s</th>
<th>[ ] Limited</th>
<th>[ ] Whole</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hospital consent form reviewed: [ ] Yes</th>
<th>[ ] No</th>
<th>Compliant with HTA standards: [ ] Yes</th>
<th>[ ] No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type of Tissue samples collected:</th>
<th>No. of blocks:</th>
<th>No. of slides:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sent for Histo/Tox/Specialist analysis: [ ] Yes</th>
<th>[ ] No</th>
</tr>
</thead>
</table>

Sent to:

Wishes of bereaved from Coroners officer form state tissue to be:

- [ ] Repatriated
- [ ] Stored for Scheduled Purpose
- [ ] Disposed of sensitively

Discrepancies:

### Histology

<table>
<thead>
<tr>
<th>Date samples received in Histology: / /</th>
<th>No. of blocks:</th>
<th>No. of slides:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Residual tissue:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Location:</th>
</tr>
</thead>
</table>

Discrepancies:

### Disposal/ Repatriation

<table>
<thead>
<tr>
<th>Tissue samples: [ ] Disposed of sensitively</th>
<th>[ ] Repatriated</th>
<th>Date: / /</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Samples sent for specialist analysis: [ ] Yes</th>
<th>[ ] No</th>
</tr>
</thead>
</table>

Sent to:

<table>
<thead>
<tr>
<th>Date of return: / /</th>
</tr>
</thead>
</table>

Evidence of receipt:

Discrepancies:
PM examination audit 3

Date of PM: / /  
Adult / Paediatric

Name:  
DOB: / /  
Date of death: / / 

NHS/ Hospital unique identifier:  
Mortuary unique identifier:  

Type of PM:  
- Hospital consented  
- Forensic  
- Coroner’s  
- Limited  
- Whole

Hospital consent form reviewed:  
- Yes  
- No

Compliant with HTA standards:  
- Yes  
- No

Type of Tissue samples collected:  
No. of blocks:  
No. of slides:  

Sent for Histo/Tox/Specialist analysis:  
- Yes  
- No

Sent to:

Wishes of bereaved from Coroners officer form state tissue to be:

- Repatriated  
- Stored for Scheduled Purpose  
- Disposed of sensitively

Discrepancies:

Histology

Date samples received in Histology:  / / 
No. of blocks:  
No. of slides:  
Residual tissue:  
Location:  
Discrepancies:

Disposal/ Repatriation

Tissue samples:  
- Disposed of sensitively  
- Repatriated  
Date: / / 

Samples sent for specialist analysis:  
- Yes  
- No

Sent to:

Date of return:  / / 
Evidence of receipt:
Discrepancies:

Reference number: HTA-TEM-008  
Last reviewed on: 19 May 2015
Version number: 15.0  
Next review due: 19 May 2016
## Document Review

Please complete the name, version number and date due for review of each of your documents next to the appropriate headings below. Please ensure that the documents listed below are available on the day of the site visit inspection.

<table>
<thead>
<tr>
<th>HTA standard</th>
<th>Title of document</th>
<th>Version</th>
<th>Review date</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C1:</strong> Consent (C):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1: PM consent policy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1: PM consent SOP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C1: Hospital PM consent form (Adult/Paediatric)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HTA review notes:**

| C2: | Patient information sheet on PM consent, PM consent information in Braille/other languages | | | |

**HTA review notes:**
<table>
<thead>
<tr>
<th>C3:</th>
<th>Consent training programme (e.g. PowerPoint presentation, handouts, external course), consent training records</th>
<th></th>
</tr>
</thead>
</table>

**HTA review notes:**

Agreements with other Trusts for appropriate consent

<table>
<thead>
<tr>
<th>Date signed:</th>
<th></th>
</tr>
</thead>
</table>

**HTA review notes:**

**Governance and Quality Systems (GQS)**

<table>
<thead>
<tr>
<th>GQ1:</th>
<th>Policies relating to the licensable activity (e.g. COSHH, H&amp;S)</th>
<th></th>
</tr>
</thead>
</table>

SOPs of licensed activities:
- PM examination
- Lone working
- Receipt/release of bodies

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Transfer of bodies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Viewings</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minutes of meetings – mortuary, pathology, senior management</td>
<td>Name of meeting:</td>
<td>Frequency:</td>
</tr>
<tr>
<td>Complaints policy, complaints SOP, records of complaints relating to licensed activities</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HTA review notes:**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GQ2:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organisational chart</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal audit schedule</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal audit reports and follow up actions</td>
<td>Area of audit:</td>
<td>Date completed:</td>
<td></td>
</tr>
</tbody>
</table>

**HTA review notes:**

Reference number: HTA-TEM-008  Last reviewed on: 19 May 2015
Version number: 15.0  Next review due: 19 May 2016
### GQ3: Job descriptions, staff qualifications

- Induction programme for new staff
- Staff appraisal records, CPD (for mortuary staff) **Staff member:**
- Mandatory training records (e.g. H&S, fire, risk management, infection control) **Staff member:**
- Training records for external courses
- Competency training

### HTA review notes:

### GQ4: Records management policy

- Policies on data protection, confidentiality, freedom of information, public disclosure (whistleblowing)
- SOPs for record creation, records access, amendment, retention and destruction
<table>
<thead>
<tr>
<th>GQ6:</th>
<th>Tissue removal forms, blocks/slides forms</th>
</tr>
</thead>
</table>

**HTA review notes:**

<table>
<thead>
<tr>
<th>GQ7:</th>
<th>Adverse incidents policy, adverse incidents SOP, adverse incidents form, adverse incidents records (including evidence of CAPAs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HTA reportable incident (HTARI) SOP, HTARI form, HTARI records</td>
</tr>
<tr>
<td></td>
<td>System to distribute local/national information</td>
</tr>
</tbody>
</table>

---

Reference number: HTA-TEM-008
Last reviewed on: 19 May 2015
Version number: 15.0
Next review due: 19 May 2016
### HTA review notes:

<table>
<thead>
<tr>
<th>GQ8:</th>
<th>Risk assessments of licensed activities</th>
<th>List risks assessed:</th>
</tr>
</thead>
</table>

### HTA review notes:
<table>
<thead>
<tr>
<th><strong>Premises, Facilities and Equipment (PFE)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PFE1:</strong> Risk assessment of premises</td>
</tr>
<tr>
<td>SOP for safety of staff and authorised visitors</td>
</tr>
<tr>
<td>SOP for security</td>
</tr>
</tbody>
</table>

*HTA review notes:*

<table>
<thead>
<tr>
<th><strong>PFE2:</strong> Cleaning and decontamination SOP cleaning schedule and records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air ventilation records (PM room)</td>
</tr>
</tbody>
</table>

*HTA review notes:*

Reference number: HTA-TEM-008  Last reviewed on: 19 May 2015
Version number: 15.0  Next review due: 19 May 2016
<table>
<thead>
<tr>
<th>PFE3:</th>
<th>Fridge temperature monitoring records</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Contingency plan for power failure, body overflow</td>
</tr>
</tbody>
</table>

**HTA review notes:**

<table>
<thead>
<tr>
<th>PFE4:</th>
<th>Transportation SOP, transportation risk assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A system to ensure that traceability of bodies, organs, tissues is maintained during transportation</td>
</tr>
<tr>
<td></td>
<td>Transportation and delivery records</td>
</tr>
<tr>
<td></td>
<td>Agreements with Trusts receiving bodies, organs, tissues</td>
</tr>
<tr>
<td></td>
<td>Agreements with couriers, transport companies, funeral directors</td>
</tr>
<tr>
<td></td>
<td>Date signed:</td>
</tr>
</tbody>
</table>

**HTA review notes:**
<table>
<thead>
<tr>
<th>PFE5: Maintenance contracts for equipment, service records</th>
<th>List equipment:</th>
<th>Date maintained:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contingency plans for equipment failure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HTA review notes:**

---

**Disposal (D)**

<table>
<thead>
<tr>
<th>D1: Disposal policy</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Agreement with disposal contractors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agreements with Coroner</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HTA review notes:**
<table>
<thead>
<tr>
<th>D2:</th>
<th>Disposal SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Disposal records</td>
</tr>
<tr>
<td></td>
<td>Coroner's Officer retention/disposal forms</td>
</tr>
</tbody>
</table>

**HTA review notes:**

**General:**

- Inspection report from external auditors (e.g. CPA)

**HTA review notes:**
<table>
<thead>
<tr>
<th>Additional documentation review notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Additional documentation review notes

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference number: HTA-TEM-008  
Last reviewed on: 19 May 2015  
Version number: 15.0  
Next review due: 19 May 2016
Additional documentation review notes

<table>
<thead>
<tr>
<th>Reference number: HTA-TEM-008</th>
<th>Last reviewed on: 19 May 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version number: 15.0</td>
<td>Next review due: 19 May 2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional documentation review notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Additional notes

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**YYYY-MM-DD [Licensing number] [Establishment name]** inspection notes

**Reference number:** HTA-TEM-008  **Last reviewed on:** 19 May 2015

**Version number:** 15.0  **Next review due:** 19 May 2016
### Additional notes

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### HTA licensing standards

**Key for completion of licensing standards:**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️</td>
<td>= evidence has been seen and meets HTA standards</td>
</tr>
<tr>
<td>✗</td>
<td>X = evidence seen but does not meet HTA standards</td>
</tr>
<tr>
<td></td>
<td>No - Ring no if assessment not carried out or write N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual</td>
</tr>
<tr>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
</tr>
</tbody>
</table>

Ring for location of evidence

Visual = in visual inspection notes; Verbal = in interview notes; Doc = in documentation reviewed

(Where evidence is in another pack provide inspectors initials)

### Consent standards

**C1 Consent is obtained in accordance with the requirements of the Act and as set out in the Codes of Practice**

<table>
<thead>
<tr>
<th>There is a documented policy which covers consent for PM examination &amp; tissue retention which reflect the Act &amp; the code on consent.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>There is a documented SOP which details the consent process (incl. who can take consent, training required, &amp; information to be given to those giving consent)</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>There is written information about the consent process for those giving consent which reflects the Act &amp; the code on consent.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

**C2 Information about the consent process is provided and in a variety of formats**

<table>
<thead>
<tr>
<th>Relatives are given an opportunity to ask questions.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relatives are given an opportunity to change their minds and it is made clear who should be contacted in this event.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>There is written information which contains clear guidance on options for how tissue may be handled after the PM examination.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>There is written information on consent in different languages &amp; formats, or access to interpreters/translator.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the Act and HTA code of practice on consent.

Refresher training is available (e.g. annually).

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Attendance at consent training is documented.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

If untrained staff are involved in taking consent, they are always accompanied by a trained individual.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Deviations from documented SOPs are recorded and monitored.

Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:

- post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
- record keeping
- receipt and release of bodies, which reflect out of hours arrangements
- lone working in the mortuary
- transfer of bodies and tissue (including blocks and slides) to other establishments or off site
- ensuring that tissue is handled in line with documented wishes of the relatives
- disposal of tissue (including blocks and slides)

(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Policies and procedures are regularly reviewed (for example, every 1-3 years).

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

There is a system for recording that staff have read and understood the latest versions of these documents.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Deviations from documented SOPs are recorded and monitored.
### GQ2 There is a documented system of quality management and audit

<table>
<thead>
<tr>
<th>There is a quality manual which includes mortuary activities.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Policies and SOPs are version controlled (and only the latest versions available for use).</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Audits include compliance with documented procedures, records (for completeness) and traceability.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>There is a complaints system in place.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

<table>
<thead>
<tr>
<th>Staff are appropriately trained/qualified or supervised.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staff have annual appraisals.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staff are given opportunities to attend training courses, either internally or externally.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attendance by staff at training events is recorded.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>There is a documented training programme for new mortuary staff (e.g. competency checklist).</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Visual</td>
</tr>
</tbody>
</table>
### GQ4 There is a systematic and planned approach to the management of records

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>No</td>
<td>Verbal</td>
</tr>
<tr>
<td></td>
<td>Doc</td>
</tr>
</tbody>
</table>

There is a systematic and planned approach to the management of records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

There are documented SOPs for record management.

### GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

Bodies are tagged/labelled upon arrival at the mortuary.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

Organs and tissue samples taken during PM examination are fully traceable.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

Details of organs retained and the number of wax blocks and tissue slides made are recorded.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

The traceability system includes the movement of tissue samples between establishments.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

Details are recorded of tissue that is repatriated or released with the body for burial or cremation.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family’s wishes. Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

### GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
<tr>
<td>Doc</td>
<td></td>
</tr>
</tbody>
</table>

Staff are trained in how to use the incident reporting system.
<table>
<thead>
<tr>
<th>Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**GQ8 Risk assessments of the establishments practices and processes are completed regularly and are recorded and monitored appropriately**

<table>
<thead>
<tr>
<th>All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
## Premises, facilities and equipment standards

### PFE1 The premises are fit for purpose

<table>
<thead>
<tr>
<th>Description</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is sufficient space for the activities to be carried out.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>Refrigerated storage units are in good working condition and well maintained.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>Surfaces are made of non-porous materials.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).</td>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### PFE2 Environmental controls are in place to avoid potential contamination

<table>
<thead>
<tr>
<th>Description</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>There is appropriate PPE available and routinely worn by staff.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>There is adequate critical equipment and/or PPE available for high risk post mortems.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>There are documented cleaning and decontamination procedures.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

<table>
<thead>
<tr>
<th>Description</th>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is sufficient capacity for storage of bodies, organs and tissues.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>Temperatures of fridges and freezers are monitored on a regular basis.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
<tr>
<td>There are documented contingency plans in place should there be a power failure, or overflow.</td>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>
### Bodies are shrouded whilst in storage.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary). (Note that coroners usually have their own agreements with external parties for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

#### Items of equipment in the mortuary are in a good condition and appropriate for use:

- fridges / Freezers
- hydraulic trolleys
- post mortem tables
- hoists
- saws (manual and/or oscillating)
- PPE for high risk cases (e.g. respirators)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

The use of porous materials is kept to a minimum and has been risk assessed.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation. (Note that these records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>

### Disposal Standards

### D1 There is a clear and sensitive policy for disposing of human organs and tissue

There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Visual</td>
</tr>
</tbody>
</table>
The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
</tbody>
</table>

### D2 Post Mortem tissue is disposed of if consent is not given for its storage and use for scheduled purposes

There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
</tbody>
</table>

Tissue is disposed of in accordance with the documented wishes of the deceased person's family.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
</tbody>
</table>

Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
</tbody>
</table>

There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Visual</td>
<td>Verbal</td>
</tr>
</tbody>
</table>
Compliance with licensing standards notes:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference number: HTA-TEM-008    Last reviewed on: 19 May 2015
Version number: 15.0            Next review due: 19 May 2016
Feedback
Summary:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DI suitability:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LH / CLH suitability:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

YYYY-MM-DD [Licensing number] [Establishment name] inspection notes

Reference number: HTA-TEM-008  Last reviewed on: 19 May 2015
Version number: 15.0  Next review due: 19 May 2016
## HTA standards

### Consent

### Governance and quality systems
## Premises, facilities and equipment

<table>
<thead>
<tr>
<th>Evidence workbook completed by:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Disposal

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference number: HTA-TEM-008  Last reviewed on: 19 May 2015
Version number: 15.0          Next review due: 19 May 2016