**Site visit inspection report on compliance with HTA licensing standards**

**Basingstoke & North Hampshire Hospital**

**HTA licensing number 12362**

**Licensed under the Human Tissue Act 2004 for the**

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

**8th & 9th August 2018**

## Summary of inspection findings

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

Although the HTA found that Basingstoke and North Hampshire had met the majority of the HTA's standards, five major and ten minor shortfalls were found against the Consent, Governance and Quality systems, Traceability and the Premises, Facilities & Equipment standards. These related to the standard operating procedure (SOP) for seeking of consent for post-mortem (PM) examination; training for seeking of consent for PM examination; SOPs; audits; risk assessments; the use of three identifiers; traceability of tissues; premises and equipment and body store alarms.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

**The HTA's regulatory requirements**

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

**Background to the establishment**

Basingstoke and North Hampshire Hospital (the establishment) is part of the Hampshire Hospitals NHS Foundation Trust. This report describes the activities carried out in the mortuary at the establishment, which is managed by Cellular Pathology. The DI is a Consultant Microbiologist and the Corporate Licence Holder contact is the Chief Executive of the Trust. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: making of a post-mortem examination; removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation, and; storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes.

The establishment receives approximately 1300 bodies each year from deaths in the hospital and the community, and performs around 430 PM examinations annually for HM Coroner for Hampshire. The total figure for PM examinations undertaken includes high-risk (up to category three) cases. The establishment have not performed any hospital (consented) PM examinations in the last three years, however, mortuary staff have undertaken some training in seeking consent for PM examination (see shortfall against C2(a)) and receive support from trained staff from another licensed establishment within the same Trust. Consent for paediatric/perinatal PM examinations is sought at the establishment by senior clinicians who may have received some training in the seeking of consent (see shortfall against C2(a)). More recently, midwives have undertaken some training for PM consent seeking at the licensed establishment where the PM examinations take place.

The establishment have a total of 55 refrigerated body spaces, including 15 spaces for bariatric bodies and can utilise a temporary refrigerated body store during periods of peak activity. There is a dedicated refrigerated unit for the storage of fetuses and neonatal bodies (see shortfall against PFE2(e)). Although the establishment has freezer storage, this can no longer be used due to the age of the units. There is currently no contingency freezer storage available at the second licensed establishment within the Trust, or formal documented agreements with other licensed establishments (see shortfall against PFE2(c))

Standard key, code lock and key fob access is required for all external doors to the mortuary and are covered by CCTV that is readily available for the mortuary staff to visually verify who is requesting access. In addition, the mortuary has a separate security alarm which is set out-of-hours. The entrance to the corridor leading the mortuary is screened by double doors and is shared with another hospital department. It was noted during the inspection that these doors are frequently left open, allowing hospital staff and visitors to see directly in to the body store when this area is being accessed (see shortfall against PFE2(a)).

Portering staff transfer and admit all hospital bodies using a concealment trolley. All bodies are transferred to the mortuary with a triplicate copy ‘Notification of Death’ (NOD) form; a

copy of the form is attached to the outside of the body bag and on the shroud of the body, in addition to the identification bands. Upon admission, an appropriately sized fridge is selected. The mortuary register and certain fridge door whiteboard details are completed by the porters. The mortuary staff complete body identification checks as soon as possible on the day, or the next working day if the body was admitted out of hours, completing the fridge door whiteboard details and assigning the mortuary register 'Unique Reference Number' (URN), to each body and associated documentation. Community bodies are transferred to the mortuary by the Coroner's contracted funeral directors and admitted by mortuary staff, including out-of-hours. A triplicate copy 'Community Death Form' is completed for each body; a copy of the form is attached to the outside of the body bag and on the shroud or clothing of the body. The details of all bodies are entered in to the electronic computer system. Bodies may be released from the mortuary using one or two identifiers (see shortfall against T1(c)).

Training in mortuary practice and procedures has been provided to the portering services supervisors by the mortuary staff. This training is then cascaded to the wider portering team.

The PM suite contains three PM tables and one dissection unit. When removing bodies from refrigerated storage, APTs carry out initial identification checks against coronial or consent documentation and again with the pathologist prior to the external examination and evisceration commencing. Pathologists complete each PM examination before commencing the next case to help mitigate against any risk of a mix-up of organs and tissue samples between cases. All PM cases are recorded in a dedicated book which includes a record of specimens, if they have been retained for further analysis. All PM histology specimens retained are recorded in a dedicated book and taken to the histopathology laboratory on site but are transferred for processing at another HTA licensed establishment. Tissue slides are returned to the establishment for the histopathologists based at the establishment to review, or sent to 'visiting' pathologists (see shortfall against T1(g)). Tissue blocks are stored at the processing establishment (see *Advice*, item 11).

Four Consultant Histopathologists, three of which are based at the establishment, fulfil the PM service.

Following the recent retirement of the Mortuary Manager, one Lead Anatomical Pathology Technologist (APT), two APTs (including a locum APT) and one Trainee APT staff the mortuary.

The establishment has a maternity unit, where there is a fridge for the storage of pregnancy remains, fetuses and stillbirths in a secure room (see shortfall against PFE2(e)). There are well documented polices for the management of pregnancy remains, fetuses and stillbirths. There is a dedicated 'shared' spreadsheet that can be accessed by the maternity unit staff and mortuary staff to help provide assurance that traceability of these cases are maintained.

In addition to the storage activities described above, the removal of tissue samples from the body of a deceased child may take place in the Accident and Emergency Department. The process and documentation for these cases was reviewed as part of the inspection and found to be compliant with current guidelines.

**Description of inspection activities undertaken**

The establishment has been licensed by the HTA since August 2007. Previous routine site visit inspections took place in October 2012 and June 2014. This report describes the third routine site visit inspection in August 2018. Formal interviews were conducted with the DI, Cellular Pathology/Mortuary Manager, mortuary staff, hospital porters, the Coroner, Consultant Histopathologist and PM consent seekers (adult and perinatal). The inspectors also carried out a visual inspection of the mortuary, including the body store area, post mortem room and viewing suite.

Traceability audits of body identifiers, storage locations, mortuary register details and associated documentation was carried out for four adult bodies (two hospital and two community bodies). Four anomalies were found:

- One body that had undergone PM examination had a difference in the spelling of the surname between the identification bands, the mortuary register and release documentation. There was no documented evidence to confirm that the discrepancy had been checked prior to PM examination (see Advice item 3);
- The details on the identification band of one community body (which was handwritten) were smudged, making the details unclear and difficult to read;
- The fridge number of one body was recorded incorrectly in the mortuary register and the electronic record;
- There was a difference in the year of the DOB of one body between the NOD form and the other records.

In addition, an audit of four cases where tissue had been removed for histological analysis during PM examination was conducted for four Coroner's cases. The inspection team visited the histopathology laboratory to review retained tissue (tissue slides only) and the associated traceability records. In addition, records of the relatives' wishes regarding the fate of the tissue following its analysis were reviewed to determine if they had been acted upon appropriately. Two anomalies were found:

- Tissue slides for one case from 2017, carried out by a 'visiting' pathologist, could not be located in the tissue slide archive. The establishment do not maintain traceability records of slides sent off-site, including when or if they are returned (see shortfall against T1(g));

- The number of tissue slides located for one case did not match the electronic record. In addition, the relatives wishes recorded on the electronic system did match the hard copy tissue instructions form from the Coroner's Office;

**Inspection findings**

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

**Compliance with HTA standards**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice** | | |
| b) There is a documented standard operating procedure (SOP) detailing the consent process | The SOP 'Checking Consent Paperwork' (LP-MOR-CONSENT) does not state the full hierarchy of qualifying relationships as outlined in the HT Act 2004 or the HTA's codes of practice. The person concerned (in life) or a nominated representative have not been included. | **Minor** |
| g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided | Although the form used to record consent for PM examination is based on the HTA's model consent form, the additional 'notes' section refers to the 'next of kin' (NOK). This implies that someone other than the person ranked highest in the hierarchy of qualifying relationships could give consent to a PM examination and retention of tissues for use for scheduled purposes. | **Minor** |
| **C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent** | | |
| a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice | i) The documentation used for training mortuary staff in seeking consent for adult consented PM examination has not been updated since January 2013 and refers to the HTA's superseded codes of practice (see *Advice,* item 1).<br>ii) Senior clinicians who seek consent for paediatric/perinatal PM examination may have had some PM consent training but there is no documented evidence, or that this training is refreshed (see *Advice*, item 2) | **Minor** |

**GQ1 All aspects of the establishment's work are governed by documented policies and procedures**

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| a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. | Although the establishment has SOPs covering the majority of activities carried out under the licence, some key ones are missing, others do not reflect current practice, or require updating, further detail or clarification. Examples include, but are not limited to:<br>• The process for the management and storage of long-term bodies is not documented (see *Advice*, item 4);<br>• The process for the transfer and recording of tissue slides sent off-site is not documented;<br>• The Quality Manual (QM-GEN-QUALMANHFT) refers to the HTA's previous codes of practice;<br>• SOP 'PM Procedure' (LP-CMOR-POSTM) does not state that the identification of bodies is initially checked when removed from the body store, prior to being transferred to the PM room, or that the pathologist always checks the identification of the body prior to external examination and evisceration, however, this is standard practice. In addition, the SOP states that two or three identifiers may be checked, when three are routinely checked;<br>• SOP 'The Storage, Release and Transfer of Babies/Foetuses' (LP-MOR-HHFTBABY) does not state that PM consent forms are faxed to the referring establishment to be checked prior to the transfer taking place. In addition, the paperwork required to release a fetus/baby for funeral is not stated;<br>• SOP 'Viewing of Deceased Patients' (LP-MOR-VIEW) states that a minimum of two identifiers are checked. In practice, only the name is checked when preparing the body for viewing and when the relatives attend (see *Advice*, item 9);<br>• SOP 'Respectful Disposal of PM Tissue' (LP-HIS-RESPECT) is not being followed and does not include how the instructions for tissue are managed with tissue blocks being stored at another licensed establishment.<br>Relevant SOPs do not specify which identifiers can be used, how many identifiers should be | **Minor** |

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| | used and what they should be checked against. | |

| **GQ2 There is a documented system of audit** | | |
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| a) There is a documented schedule of audits | The current schedule of audits does not include vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability (see Advice, item 6). | **Minor** |
| c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention | The establishment do not carry out any tissue traceability audits (see shortfall against T1(g)). | **Minor** |

| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
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| a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis | Although the establishment has a range of risk assessments in place, some do not consider all the risks relating to the activity being assessed. For example, the risk assessment for viewing of bodies does not consider the risk of viewing a wrong body. In addition, some risk assessments included risks that are not relevant to the activity being assessed.<br><br>In addition, some risk assessments are past their review date. | **Minor** |

| **T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail** | | |
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| c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier | i) Bodies are released from the mortuary using predominantly two identifiers and in certain circumstances, may be released using only one identifier (see *Advice*, item 8).<br><br>ii) When appointments for viewings are booked with relatives, only the name of the deceased is obtained from the relatives and used to identify the body to be prepared for viewing. In addition, only the name is checked with relatives when they attend for viewings (see *Advice*, item 9). | **Major** |

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| g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). | The establishment do not record the transfer, receipt or return of tissue slides sent to consultant histopathologists not based at the establishment, therefore the DI cannot be assured of their continued traceability or location.<br><br>Tissue slides for filing that are no longer required for review by consultant histopathologists, have not been regularly archived, meaning it is not always possible to easily locate slides and provide assurance they are there.<br><br>The tissue traceability audits could not be fully completed during the inspection as the location of one set of tissue slides could not be confirmed. The establishment is required to confirm the location and quantity of these tissue slides.<br><br>In addition, the establishment do not have a formal procedure for the repatriation of tissues or organs with bodies, when this is requested and how this information is provided to the mortuary staff to prevent the release of a body before tissue and/or organs are repatriated. | **Major** |

| **T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.** | | |
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| a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete | The establishment have not been disposing of tissues retained following PM examination once the Coroner's authority has ended (see *Advice*, item 11). | **Major** |
| b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary | The establishment have not been following their own procedure for monthly follow-up of relatives' wishes for retained tissues with the Coroner's Office. This has meant some tissues have been stored for longer than necessary. | |

| **PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.** |
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| a) The premises are clean and well maintained | The mortuary premises are showing signs of wear:<br>• The body store and PM room floor is heavily marked and stained, despite regular cleaning by staff;<br>• There are some areas of minor damage to walls within the body store, exposing porous bare plaster, meaning walls cannot be sufficiently cleaned or disinfected;<br>• Numerous fixtures are constructed of wood and some have become damaged, meaning the protective covering has been penetrated, especially in areas that are frequently used. For example, the doors into the body store and PM room. The damage makes the wood porous, therefore cannot be adequately cleaned or disinfected. | **Major** |

| **PFE2 There are appropriate facilities for the storage of bodies and human tissue.** | | |
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| a) Storage arrangements ensure the dignity of the deceased | It was noted by the inspection team that the double doors leading to mortuary corridor are left open. Staff stated this was because of the activities of the department the corridor is shared with. The corridor doors are directly opposite the main doors into the mortuary body store. Leaving these doors open could allow non-mortuary staff and hospital visitors to see into the mortuary and see body store activities. | **Minor** |
| c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs | The establishment do not have any functioning freezer spaces for the long-term storage of bodies and there is currently no other contingency freezer storage available at the second licensed establishment within the Trust. There is a risk that bodies cannot be satisfactorily stored to prevent unnecessary deterioration in their condition.<br>The DI informed the inspection team that this issue has been included on the Trust's risk register, however, we were not made aware of the proposed actions to address this. | **Major** |

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| e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range | The dedicated refrigerated unit for the storage of fetuses and neonatal bodies in the body store, the temporary refrigerated unit (when in use) and the fridge in the maternity unit are not connected to a remote alarm system. There is a risk that staff will not be alerted when temperatures deviate from within set ranges.<br><br>In addition, the fridge alarms are not regularly tested to provide assurance they will trigger in the event of deviations in temperatures from their expected ranges. | **Minor** |

| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** | | |
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| a) Items of equipment in the mortuary are in good condition and appropriate for use | The following items are showing areas rust, the legs of the metal trolleys within the PM room and bases of the metal clinical waste bins. | **Minor** |

### Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | C2(a) | The DI may wish to consider liaising with the DI and mortuary staff at the second licensed establishment within the Trust, who are trained in seeking consent for PM examination, to update the training material used by staff at the establishment. In addition, as the training material covers the consent requirements for the living and deceased under the HT Act 2004, the DI may wish to clarify which sections of the training are relevant for the seeking of consent for PM examination and the use of tissues for scheduled purposes.<br><br>This will help provide assurance that mortuary staff are trained using the correct information and understand the requirements of the HT Act 2004 and the HTA's codes of practice. |
| 2. | C2(a) | The maternity unit staff have already considered how they can fulfil the training requirements for seeking consent for PM examination. The DI is advised to continue with the 'in-house' training plan, using the Sands documentation for assistance. |
| 3. | GQ1(a) | The DI is advised to ensure that when discrepancies are found with the identification details of bodies, they are followed-up and documented to provide assurance any issues have been resolved prior to any procedures taking place, for example, a PM examination. |
| 4. | GQ1(a) | When developing the procedure for the long-term storage of bodies the DI is advised to monitor and escalate these cases before the recommended 30-day period elapses for bodies to be moved into frozen storage. |
| 5. | GQ1(e) | The DI is advised to ensure that all mortuary staff are included in the distribution lists for the SOPs and risk assessments on the electronic |

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| | | document system. This will help provide assurance that staff have read and understood the procedures that govern their work. |
| 6. | GQ2(a) | This DI is advised to select sufficient numbers when undertaking audits to help provide assurance that processes and procedures are robust and fit-for-purpose. |
| 7. | GQ4(b) | The DI is advised to ensure that mortuary records are appropriately amended/corrected, for example, using a single line to cross through errors or changes in the mortuary register. |
| 8. | T1(c) | The DI is advised to consider requesting funeral directors that do not bring the Trust's release form to release a body, to bring sufficient documentation stating three identifiers (one being unique) that can be checked with the identification on the body. For example, full name, DOB and DOD. |
| 9. | T1(c) | In addressing the shortfall identified against standard T1(c), the DI may wish to strengthen the procedure for viewings by introducing a form to be completed by relatives when they attend. This can include relevant information to check the identification on the deceased, before the viewing takes place. This may help to mitigate the risk of misidentification and relatives viewing a wrong body. |
| 10. | T1(g) | The DI is advised to consider electronically scanning the histology tissue forms which contain the details of the tissues retained at PM examination and the relatives wishes for tissue, into a shared folder that can be accessed by the relevant staff. Currently, these forms are not kept by the establishment and cannot be easily accessed. |
| 11. | T2(a) | Tissue blocks are currently stored at the laboratory where they are processed. The DI is advised to implement a system where she will be assured that the relatives' instructions for all tissues will be carried out and documented, especially with tissue blocks and slides being stored at different locations. |
| 12. | PFE3(c) | Although the ventilation system is working at the required standard, the service report states that compliance with the minimum standard is poor. In addition, a minimum of two tables should be running at all times to ensure negative pressure is maintained in the PM room. The DI is advised to ensure that this happens and the system is closely monitored to provide assurance that it continues to work at the required standard. |

**Concluding comments**

The mortuary team appear to work well together, demonstrate enthusiasm, and care for the work they undertake. They appear to have good communication and relationships with service users, both internal and external to the Trust and received praise from different people interviewed throughout the inspection. There are several areas of strength and good practice:

- Training for mortuary staff is thorough and a particular area of strength;
- Coloured magnets are used as a visual cue to highlight pertinent information regarding bodies in storage. For example, 'danger of infection' and 'same and similar name'
- The establishment have developed a HTARI training session for staff to raise awareness of incidents and discuss scenarios that give rise to incidents that require

reporting to the HTA;
- There is a dedicated fetus/baby ‘shared’ spreadsheet that can be accessed and updated by the mortuary and maternity unit staff;
- The maternity unit use pre-prepared document packs to ensure that staff can readily use the correct paperwork depending on the gestational age of the fetus or baby;
- The mortuary use a dedicated form to record the receipt, transfer, return and release of fetuses and babies from the mortuary.

There are a number of areas of practice that require improvement, including five major shortfalls and ten minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

**Report sent to DI for factual accuracy: 06/09/18**

**Report returned from DI: 11/09/18**

**Final report issued: 04/10/18**

**Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

**Date: 23/04/19**

## Appendix 1: HTA licensing standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Standards that are not applicable have been excluded.

**Consent**

**C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice**

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

*Guidance*

*This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.*

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

*Guidance*

*Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.*

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

*Guidance*

*This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the*

*Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.*

**C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent**

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

*Guidance*

*Refresher training should be available (for example annually).*

b) Records demonstrate up-to-date staff training.

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

d) Competency is assessed and maintained.

**Governance and quality systems**

**GQ1 All aspects of the establishment's work are governed by documented policies and procedures**

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

*Guidance*

*SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.*

*Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.*

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

*Guidance*

*For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.*

*The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.*

*If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required.*

*However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.*

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

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

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

*Guidance*

*These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.*

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

*Guidance*

*Meeting minutes should be recorded and made available to staff.*

**GQ2 There is a documented system of audit**

a) There is a documented schedule of audits.

*Guidance*

*As a minimum, the schedule should include a range of vertical and horizontal audits*

*checking compliance with documented procedures, the completion of records and traceability.*

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

*Guidance*

*Staff should be made aware of the outcomes of audits and where improvements have been identified.*

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

*Guidance*

*Audits of stored tissue should include samples held under the authority of the police, where applicable.*

**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks**

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

*Guidance*

*This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.*

*APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.*

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

*Guidance*

*Assessment of competence should include the standard of APTs' reconstruction work.*

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

*Guidance: attendance by staff at training events should be recorded.*

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

*Guidance*

*The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.*

*Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.*

**GQ4 There is a systematic and planned approach to the management of records**

a) There is a system for managing 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.

*Guidance*

*Records include mortuary registers, PM examination records, tissue retention forms and*

*records of transfer and return of organs/tissue sent elsewhere for examination.*

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

**GQ5 There are systems to ensure that all untoward incidents are investigated promptly**

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

*Guidance*

*HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.*

*Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.*

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

**GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored**

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

*Guidance*

*Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.*

b) 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.

*Guidance*

*Relevant staff should have knowledge of risks and the control measures that have been taken*

*to mitigate them.*

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

**Traceability**

**T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail**

a) Bodies are tagged/labelled upon arrival at the mortuary.

*Guidance*

*The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.*

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

*Guidance*

*Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.*

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

*Guidance*

*Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.*

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

*Guidance*

*Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.*

*Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place*

*present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.*

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

   i. material sent for analysis on or off-site, including confirmation of arrival

   ii. receipt upon return to the laboratory or mortuary

   iii. the number of blocks and slides made

   iv. repatriation with the body

   v. return for burial or cremation

   vi. disposal or retention for future use.

*Guidance*

*Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.*

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

*Guidance*

*Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment forthese cases.*

**T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.**

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

*Guidance*

*Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution. Clinical waste bags or household bin bags should not be used for*

*this purpose.*

*Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.*

d) The method and date of disposal are recorded.

**Premises, facilities and equipment**

**PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue**

a) The premises are clean and well maintained.

*Guidance*

*Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.*

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

*Guidance*

*Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.*

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

**PFE2 There are appropriate facilities for the storage of bodies and human tissue**

a) Storage arrangements ensure the dignity of the deceased.

*Guidance*

*Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.*

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

*Guidance*

*Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.*

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

*Guidance*

*There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.*

*Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.*

*Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.*

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

*Guidance*

*Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.*

g) Bodies are shrouded or in body bags whilst in storage.

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

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

*Guidance*

*Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.*

*Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk*

*assessments and same/similar name systems.*

*The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities*

*forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.*

*Establishments should consider entering in to Mutual Aid Agreements*

*with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.*

**PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored**

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

*Guidance*

*Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.*

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

*Guidance*

*COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.*

d) Staff have access to necessary PPE.

*Guidance*

*Where face masks should be worn, they should be face fitted.*

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

*Guidance*

*This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.*

## Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

**1. Critical shortfall:**

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

*or*

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

**2. Major shortfall:**

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

*or*

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

**3. Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a

departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

## Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

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