Site visit inspection report on compliance with HTA licensing standards

Royal Gwent Hospital

HTA licensing number 12036

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**

6 & 7 February 2019

Summary of inspection findings

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

Although the HTA found that Royal Gwent Hospital had met the majority of the HTA's standards, eight minor shortfalls were found against standards relating to standard operating procedures (SOPs), audits, the use of three points of identification for bodies, traceability of tissue taken during post-mortem (PM) examination, the use of temperature monitoring, and bodystore 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

The establishment comprises Royal Gwent Hospital (RGH, 'the hub') and Nevill Hall Hospital (NHH, 'the satellite'). The hospitals are part of the Aneurin Bevan University Health Board and are based in Newport and Abergavenny, respectively. The DI is a Consultant Histopathologist and the Corporate Licence Holder contact is the Chief Executive Officer. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes) 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 3,800 bodies per year from both the hospital and community and carries out approximately 850 PM examinations a year. The majority of these are on behalf of HM Coroner for Gwent, with only four hospital ('consented') PM examinations carried out last year. Another HTA licensed establishment performs paediatric/perinatal PM examinations although consent is sought for these PM examinations by on site clinicians and midwives. Consent for hospital PM examinations is sought by trained pathologists and is recorded using the NHS Wales consent forms and patient information booklets. The form used to record consent for paediatric/perinatal cases is the NHS Wales consent form supported by the associated information booklet, based on the SANDs consent form. Both adult and paediatric/perinatal forms used to record consent are compliant with statutory and regulatory requirements.

The establishment have ceased PM activity at NHH and have handed over management of the bodystore to the Health Board's Facilities Department, who are using the mortuary as a bodystore only. However, the establishment have maintained the satellite licence as they are currently storing tissue blocks and slides from PM examination cases that had previously been undertaken at NHH. In addition, pregnancy loss remains (PLR) may be stored on the gynaecology wards for up to two days before being transported to the mortuary.

Since the last inspection the body storage area has been expanded to provide a total of 176 refrigerated spaces, 24 of which can be converted to freezers. There are 60 spaces suitable for bariatric bodies, including a walk in cold room that is capable of housing a hospital bed from a ward and can be converted to hold shelving for bodystore trays. There is dedicated spaces for paediatric/perinatal cases and pregnancy remains. The body storage area is separated into two distinct areas allowing the establishment to limit access. Community bodies are generally stored in one area, with banks of pass through refrigerated spaces for direct access to the PM suite. Hospital bodies, which are less likely to require PM examination are generally stored in a separate bodystore area, unless they require PM examination. Paediatric, forensic and suspected high-risk cases are transferred to other HTA-licensed establishments for PM examination. At the time of inspection there were three adult bodies and one set of pregnancy remains in long-term, frozen storage. The freezer bank had been set to run at -5°C (see shortfall against PFE2 (a)).

Bodies from within the hospital are brought to the mortuary by porters, accompanied by ward staff. Bodies are transferred from the ward through the main hospital using concealment trolleys. On entry to the mortuary portering staff will locate an available fridge space and transfer the body, while the ward staff member notes the name on the white board and completes the mortuary register. Community bodies are brought into the mortuary through the rear entrance, accessed through a covered carport area with a roller shutter door, allowing vehicles to reverse up to the mortuary rear entrance. A 'Mortuary Notification Sheet' is completed for all bodies detailing the deceased's name, DOB, address and place of death, with a second copy of the form placed on the shroud of the body (see *Advice,* item 1). If, on a rare occasion a body does not have a wristband attached, a toe tag with their name and unique mortuary number is attached to a lower limb by the mortuary staff. Hospital bodies are admitted out-of-hours by portering staff. However, mortuary staff always attend out-of-hours to admit bodies from the community.

Release of bodies is controlled; funeral directors must present a Registrar's Certificate (the green form) or the relevant certificate of release from HM Coroner. Details from the certificates are checked against the Mortuary Notification Sheet, wristband/toe tag and the mortuary register. In addition, funeral directors bring documentation that contains the name, DOB and address, however, only the name and DOB may be cross-checked prior to release (see shortfall against T1(c)). The establishment produce a daily list of the names of all the bodies and their fridge location. This makes it easier to locate bodies for release and highlights any incidences of same or similar name. Mortuary staff list the names of all bodies on a whiteboard, although this is primarily used to identify empty spaces and the daily print out is used to locate individuals (see *Advice,* item 3).

Swipe card or key lock access is required for both external doors to the mortuary. There is hospital CCTV coverage of the access doors to the mortuary and visitors gain access to the mortuary via a verbal intercom system.

The PM suite at RGH contains four downdraft PM tables, with two dissection sink areas. Only one pathologist works within the suite per session, to ensure that there is no mix-up of tissue and organs. However, trainee pathologists may use the fourth PM table, which is separated from the other three and they are always accompanied by a dedicated Anatomical Pathology Technologist (APT).

Where possible, PM cases are scheduled, and mortuary staff notified, the day before the examination. A minimum of three points of identification are used to confirm the identity of all bodies prior to PM examination and pathologists perform an external examination prior to evisceration. Material taken for subsequent histological examination is dissected, placed into tissue cassettes with hand written labels, and placed in pots containing tissue fixative in the PM suite, together with a histology request form. Pots and forms are stored in the PM suite for up to a week, and transferred in a batch to histopathology laboratory (see shortfall against T1 (g)). On receipt of PM tissue in the laboratory, the tissue pieces are transferred to

printed cassettes, embedded and processed. Blocks are logged into the electronic laboratory information management system (LIMS), together with a scan of the request form. The Lead APT and Quality Officer at RGH and the Pathology Quality Manager at NHH, carry out a quarterly reverse traceability audit on all PM tissue blocks and slides and check that tissue has been retained or disposed of as appropriate, depending on the consent provided by the family.

Nursing staff on the maternity units at RGH and NHH transfer all fetuses and pregnancy remains to the mortuary, and do not undertake any storage at the unit. The gynaecology wards at RGH and NHH store PLR in a dedicated fridge. The fridge, at both sites, is contained within a restricted access room on the ward, and a daily log book is used to record contents and temperatures. There is an audible alarm which may be heard on the ward (see shortfall against PFE2(e)). PLR will be kept in the dedicated fridge while the parent is on the ward, and if the PLR is being sent to another HTA licensed establishment for a PM examination, they may be retained for up to two days. All PLR for PM examination are sent directly to the other HTA licensed establishment, but will be returned to the mortuary. After processing, laboratory staff dispose of residual material sensitively, or arrange for the transfer of the remains to the mortuary, depending on the wishes of the family (see *Advice,* item 6).

Description of inspection activities undertaken

This report describes the third routine site visit inspection in February 2019. Formal interviews were conducted with the DI, the Quality and Mortuary Manager, the Lead APT, portering staff, maternity and gynaecology staff at both RGH and NHH, and other key members of staff working under the licence. A visual inspection of the mortuary including the body store, viewing room, PM suite, maternity and gynaecology wards at both RGH and NHH, and the histopathology laboratory was conducted.

In the RGH body store, traceability audits of body identifiers, storage locations and register details were carried out for five adult bodies (three from the hospital and two from the community), including one body and one case of PLR in long-term storage. The case of PLR had not been transferred to long-term storage until after it had been in refrigerated storage for three months (see shortfall against GQ1(a)) and the change in location had not been noted in the mortuary register. It was also noted that one of bodystore freezers was set at -5C (see shortfall against PFE2 (a)). One of the adult bodies in refrigerated storage was found to be leaking fluid (see shortfall against GQ1(a)).

While the management of the body store at NHH has been handed over to NHH facilities, it is still a satellite on the licence. Therefore, the inspection team did undertake a visual inspection of the bodystore and viewing room. This also included a traceability audit of two adult bodies in refrigerated storage. No anomalies were found.

As part of the inspection, tissue retained during the PM examinations of four bodies between 2016-2018 (RGH) was audited for traceability. The tissue blocks, slides, records and compliance with the associated consent were audited. In addition, PM tissue blocks, slides and records for four cases stored in the archive at NHH, dating back to 2004, were audited. There were minor anomalies found where tissue had been taken and processed but was not included in the list of samples contained within the mortuary spreadsheet or consent form (see shortfall against T1(g)). In addition, the establishment scan and save copies of the sample request forms that accompany the tissue and are used as a record of traceability. The scanned copies were not available for two of the four sets of tissue blocks and slides that had been uploaded to the new LIMS system, however, full traceability was maintained.

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
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.	Mortuary SOPs and policies do not reflect current practices or cover all licensable activities. For example: - The SOP on cleaning after a PM examination indicates that formalin should be used. This is not the practice and it was evident during the inspection that cleaning with other, more appropriate, agents is undertaken; - During the body audit a case of pregnancy loss remains that had only been transferred to longterm storage after three months was identified. This was due to issues with follow-up with the parent, and the process for dealing with these types of issues was not adequately documented; - While bodies are checked on admission there is no process in place to periodically check bodies to ensure they are maintained in appropriate conditions and do not require, for example, shrouds replacing due to leakage of body fluids, or transfer to long-term storage prior to 30 days; - Several SOPs and policies, such as 'Post Mortem Authorisation & Retention and Disposal of Human Tissue' note that '….consent for an autopsy from a NEAR relative or nominated representative of the deceased.' However, this is clarified in other sections such as page 7 of the same document where it discusses the need for consent to be provided by an individual in a 'qualifying relationship'. ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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	Several of the mortuary SOPs had been authored and reviewed by the same individual. ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment does undertake regular audits. However, the audits do not cover all licensable activities, for example, bodies in storage, admission and release of bodies, PM procedures, and PM tissue records in the electronic LIMS system.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	The establishment's SOPs and procedures require three points of identification to be used to identify bodies and tissue. During the visit the inspection team witnessed the release of three bodies. While the correct paperwork was in place, with the required three points of identification, the mortuary staff only checked two points of identification against the wristband on the body. ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Tissues taken during PM examinations are stored in the PM suite; the associated request form, which is the only record of the retained tissue, is stored in a separate cabinet prior to transfer to the histopathology laboratory. The mortuary do not keep a record of the tissues retained at PM examination that can be checked prior to the physical transfer of the tissue to the histopathology laboratory for assurance the specimens are still there and that they can be accounted for. (see *Advice,* item 5) In addition, during the audit of material taken during PM examination it was noted that, for one of the four cases audited, two pieces of tissue had been taken that were not recorded or noted on the subsequent mortuary spreadsheet or consent documentation.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The freezer bank used to store three adult bodies and one case of pregnancy loss remains was maintained at -5°C. In addition, the PLR in long term-storage had been transferred to the freezer after three months in refrigerated storage. ***Prior to the final report being issued the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.***	**Minor**
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 body store fridge and freezer units have a local audible alarm that will be triggered when the temperatures deviate from the set range, and the alarms are tested regularly. However, there is no alarm system to notify staff of temperature deviations when no-one is in the mortuary (e.g. out of hours). Although staff access the mortuary regularly overnight and on weekends, this does not provide sufficient assurance to the DI that a temperature deviation will discovered within an appropriate time scale. In addition, the Gynaecology Departments at both RGH and NHH have fridges where PLR may be stored awaiting transfer for examination or disposal. While the temperature is monitored daily and there is a local audible alarm, there is no assurance that staff will access the area where the fridge is located to hear the alarm.	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis	The temperature of the body store fridges and freezers are manually checked and recorded by mortuary staff during normal working hours, however, this is not routinely or regularly done out-of-hours.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	'Mortuary notification sheets' are placed on the chests of the bodies in the refrigerated storage. The DI is advised to consider a process through which these forms are placed in plastic wallets to prevent their potential contamination with body fluids.
2.	GQ1(g)	The DI is advised to consider the requirements for continued licensing of the NHH satellite site to ensure that appropriate oversight of any licensed

		activities continues. The HTA should be formally notified of any changes to the licensed activities. The DI is also advised to consider options for relocating and/or assessing the requirement of continuing to store PM tissue blocks and slides at NHH.
3.	T1(b)	The establishment print a daily list of all the bodies in storage. This list highlights the same and similar names, and also provides a reference point for the location of all bodies in storage. The DI is advised to consider implementing a process where the white board, currently used to identify available spaces, is used for identifying bodies in real time accounting for new admissions and release throughout the day.
4.	T1(b)	During the inspection it was noted that there was inconsistent use of the white board. On some occasions the bodies in storage were listed as first name then last name, while other individuals were listed as last name then first name. The DI is advised to standardise this process to prevent any possible confusion.
5.	T1(g)	The DI is advised to consider implementing a system where a copy of the histology request form, or other record is retained by the mortuary to assist with traceability of tissues, and that the specimen containers and corresponding request forms are checked prior to transfer to the laboratory.
6.	N/A	The DI is advised to liaise with the maternity and gynaecaology departments to consider the option of providing sensitive incineration for the disposal of pregnancy loss remains, as outlined in the HTA document ‘Guidance on the disposal of pregnancy remains following pregnancy loss or termination’.

Concluding comments

This report outlines the third routine site visit inspection of Royal Gwent Hospital (RGH). Since the last inspection the establishment have expanded the RGH bodystore and consolidated PM examination service from the NHH satellite site, including the transfer of mortuary staff.

There are a number of areas of practice that require improvement, including eight minor shortfalls. The HTA have provided advice to the DI related to Governance and quality systems, and to traceability of bodies and tissue from PM examinations.

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 March 2019

Report returned from DI: 22 March 2019

Final report issued: 10 April 2019

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.