Site visit inspection report on compliance with HTA licensing standards

Dorset County Hospital

HTA licensing number 12449

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**

22 & 23 May 2019

Summary of inspection findings

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

Ten major shortfalls and nine minor shortfalls were found against the Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards.

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

Dorset County Hospital (the establishment) has been licensed by the HTA since July 2007. The establishment is licensed for removal of relevant material from the deceased, storage of bodies of the deceased and relevant material for use for scheduled purposes, and the making of a post mortem (PM) examination. The establishment have not undertaken PM examinations since June 2017; however, the establishment remain licensed for this activity and plans to undertake PM examinations in the near future.

The Designated Individual (DI) has changed since the last HTA inspection; the DI is the Head Biomedical Scientist in Microbiology and Pathology Services Manager. The Corporate Licence Holder (CLH) is Dorset County Hospital NHS Foundation Trust, and the CLH contact is the Executive Medical Director for the Trust.

At the time of the inspection, the Mortuary was staffed by a locum Mortuary Manager who is a trained Anatomical Pathology Technologist (APT), one trainee APT and three Bereavement Officers. The establishment has recently revised a number of mortuary procedures and the mortuary has undergone a recent refurbishment.

The mortuary receives approximately 840 bodies from the hospital, each year. Bodies are transferred to another HTA-licensed establishment for PM examination. For adult PM examination cases, once the PM examinations are complete, all tissue blocks, slides and wet tissue samples are sent to the histopathology laboratory at Dorset County Hospital to be stored.

PM samples are traced using a unique PM reference number. The establishment uses an electronic database to record the details of the samples and the family's wishes for the fate of the samples. The inspection identified several shortfalls relating to the establishment's processes for the management and disposal of PM samples (see shortfalls against standards GQ2(c), T1(g), T1(h) and T2(a)).

Adult hospital consented PM examinations are not offered by the establishment; there are plans to offer this service when PM examination activity resumes at the establishment.

Consent for paediatric/perinatal hospital PM examinations is sought by consultant obstetricians and bereavement midwives, using the consent form and information leaflet provided by the Stillbirth and Neonatal Death (Sands) charity. Staff receive face-to-face consent training every other year, which is provided by the HTA-licensed establishment to which these cases are sent for PM examination. There is a register of trained staff, and only staff who have completed this consent training are permitted to seek consent.

There is a fridge in the maternity department for storage of perinatal/paediatric cases prior to transfer to the mortuary (see shortfalls against standards PFE2(e) and (f)).

Removal of relevant material in Sudden Unexpected Death in Infants (SUDI) cases is undertaken in the Accident and Emergency (A&E) department.

Description of inspection activities undertaken

The inspection team carried out a visual inspection of the premises where licensed activities take place at the establishment, including the mortuary body store areas, viewing suite, histopathology laboratory, maternity and A&E departments. Interviews with key members of staff, a review of governance and quality system documentation and traceability audits were also undertaken. The processes for removal of relevant material in the A&E department in SUDI cases were reviewed and discussed with staff (see shortfall against standard GQ1(g)).

Audits were conducted for four adult bodies and one paediatric case in refrigerated storage. Body location and identification details on identification bands were crosschecked against the information recorded in the electronic and paper mortuary registers and relevant documentation. A discrepancy was found for one case where release of a body had not been recorded in the mortuary register (see shortfall against standard GQ1(a)).

Audits of traceability were conducted for samples from three PM examinations performed under coronial authority and one hospital consented case. This audit included cases where the PM examination was undertaken at the establishment, as well as cases where the PM examination was undertaken at another HTA-licensed establishment and the samples transferred to Dorset County Hospital for storage. Consent documentation for the retention of samples and disposal records were reviewed. A number of discrepancies were identified (see shortfalls against standards GQ2(c), T1(g), T1(h) and T2(a)).

Inspection findings

The HTA found the LH and the DI 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 do not contain sufficient details of procedures. For example: • MORT-SOP-0006 'Viewing of the deceased' does not state that three identifiers of the deceased are required from the family, and are checked against the wristband of the deceased before viewing takes place. • MORT-SOP-0005 'Admit and release' is not clear and does not state what release documentation funeral directors should bring with them to the mortuary for release of bodies. This presents a risk that staff do not undertake mortuary activities in a consistent manner. This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient details of procedures. *Refer to shortfall against standard T1(c).*	**Major**
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	SOPs have not been reviewed regularly. Several SOPs have been authorised by the author.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	Licensed activities in the A&E department are not included in the establishment's governance framework for the licence. There is no Person Designate nominated to help oversee licensed activities in this department. The DI does not have regular contact with staff undertaking licensed activities in this department.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	The establishment's governance meetings do not cover matters relating to HTA-licensed activities. Although the HTA licence is a standing agenda item for these meetings, the meeting minutes do not provide evidence that matters relating to this are discussed. *See Advice, item 1.*	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment has not followed their audit schedule, and has not conducted regular audits of licensed activities. The schedule of audits does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and tissue and body traceability. The frequency of scheduled audits is not sufficient. *See Advice, item 2.*	**Major**
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 has not followed their procedure for auditing and following-up when the coroner's authority for storage of PM samples has ended and whether samples should be disposed of. The inspection identified several cases for which the establishment cannot provide evidence that they have coronial authority/consent for storage of the samples: • The establishment could not provide evidence of coronial authority/consent for the storage of two samples of wet tissue from two PM cases. There is a risk that the establishment is storing these samples without appropriate consent. • The inspection identified 24 cases, dating back to 2017, for which the establishment has not processed the forms documenting the family's wishes for the fate of tissues. • For one of 24 these cases, the coroner's authority for storage of the samples ended in February 2018 and the family's wishes were for disposal of the samples. The establishment is storing PM tissue blocks and slides from this case without appropriate consent. *Refer to shortfall against standard T2(a).*	**Major**

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	The system for refresher training for APTs and bereavement staff working in the mortuary is poor. A number of mortuary procedures have changed recently and there are no records to evidence that staff have been trained in the revised procedures. This presents a risk of staff not following the establishment's procedures for key mortuary activities, for example identification of the deceased. The inspection identified a number of discrepancies in traceability that resulted from staff not following the documented procedures (see shortfalls against Traceability standards). *See Advice, item 3.*	**Major**
c) Staff are assessed as competent for the tasks they perform	There is no formal system for ongoing competency assessments for all staff involved in mortuary activities. A number of mortuary procedures have changed recently and the mortuary has undergone a recent refurbishment, including changes to some mortuary equipment. Staff have not been assessed as competent to undertake the revised procedures or work with the new equipment.	**Major**
f) There is a documented induction and training programme for new mortuary staff	There is no formalised induction programme for staff working in the mortuary.	**Minor**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Visiting or external staff do not receive an induction or training in the mortuary's local policies and procedures.	**Minor**

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	Staff have not been following the establishment's incident reporting procedure. The inspection identified two HTA Reportable Incidents (HTARIs) that the establishment had not notified to the HTA.	**Minor**

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	The establishment's documented risk assessments do not cover all licensable activities and the risks of incidents associated with these activities. For example, the following risks have not been assessed: • serious security breach; • risks to integrity of tissue; • storage of foetuses in the maternity Department; • removal of relevant material from the deceased in the A&E Department; • contingency storage arrangements; • disposal of tissue; and • tissue traceability.	**Major**
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	The establishments risk assessments do not always include the possible risks to the deceased in order to help identify mitigating actions. The risk assessments also do not contain sufficient detail of what control measures are in place to mitigate the risks.	**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 procedures for identification of bodies do not use a minimum of three identifiers. i) Identification of bodies for release from the mortuary relies on crosschecking only two identifiers of the deceased provided by the funeral director against the body. The release form sent from the coroner's office contains only two identifiers that can be checked against the identification bands on the body. ii) For viewings of bodies, families are not asked to provide three identifiers of the deceased. Often only the name of the deceased is requested and crosschecked against the identification bands on the body. *See Advice, items 5 & 6.*	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The inspection identified the following discrepancies in traceability of PM samples: • The number of tissue blocks and slides recorded on the electronic database for one case was inaccurate as the result of a transcription error. • For another PM case, one tissue block and 23 slides recorded on the database could not be located in storage. Following the inspection, the establishment located the tissue block; however, the slides could not be located. As the establishment has not been recording when slides are returned from Pathologists to the laboratory, this means that when slides are not stored in the laboratory, the establishment does not know whether the slides are being stored by the pathologist or have been lost. *See Advice, item 7.*	**Major**
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	The establishment are not following their procedure to actively follow up with pathologists for the return slides which have been sent to them for analysis	**Minor**

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	The establishment cannot provide assurance that tissue is disposed of as soon as reasonably possible. Although the coroner's office send the establishment the family wishes for the fate of tissue, the establishment do not always follow this up in a timely manner. This presents a risk of PM samples being stored without coronial authority/consent and not returned to the family when this has been requested. The inspection identified several cases where the establishment could not evidence that they have disposed of tissue in a timely manner (refer to shortfall against standard GQ2(c) for details of these discrepancies).	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	i) There is no system of testing the mortuary body store temperature alarm system. Staff do not manually challenge the alarms on a regular basis; they are also not recording each time the alarm is tested. This means that the establishment cannot provide assurance that the alarms will trigger when temperatures deviate from the expected ranges. ii) The fridge in the maternity department for storage of perinatal/paediatric cases is alarmed but this alarm only sounds locally and may not be heard by staff. This alarm is also not manually challenged by staff.	**Major**
f) Temperatures of fridges and freezers are monitored on a regular basis	Fridge and freezer temperatures in the mortuary body store and the fridge in the maternity department are not formally monitored or reviewed for trends to identify potential equipment failures before they occur.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(h)	The DI is advised to include incidents as a standing item on the agenda for HTA governance meetings. This will help to ensure that staff are aware of the types of incidents that must be reported to the HTA and encourage learning from incidents.
2.	GQ2(a)	In addressing the shortfall identified under this standard, the DI is advised to review the schedule of audits to include: • a selection of process audits of staff undertaking procedures; • vertical and horizontal audits checking compliance with documented SOPs, completion of records and traceability; • audits of traceability of bodies and retained tissue. Audits should be undertaken on a regular basis as this can help to ensure that procedures are performed correctly.
3.	GQ3(a)	The DI is advised to include training in the requirements of the HT Act and details of the HTA licence in the induction training package for mortuary staff. This will help to raise awareness of the requirements of the HT Act and the establishment's arrangements for governance of the licence.
4.	GQ3(e)	The DI is advised to review the training available for mortuary staff to ensure that they are all provided with opportunities for training and development. Additionally, the DI is advised to review staff annual appraisals to determine if training needs have been identified.

5.	T1(c)	In addressing the shortfall identified under this standard, the DI is advised to consider ways to strengthen the procedure for undertaking viewings. The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include space to record relevant identification information of the deceased so that three identifiers can be crosschecked against the body before the viewing takes place.
6.	T1(c)	In addressing the shortfall under this standard, the DI is advised to liaise with the coroners' office to request that the relevant three identifiers are included on the release forms sent by them to the mortuary. The DI may wish to consider introducing a standardised release form for funeral directors to, complete and bring to the mortuary when collecting a body, which contains the a minimum of three identifiers of the deceased.
7.	T1(g)	In addressing the shortfall identified under this standard, the DI is advised to ensure that the electronic database for PM samples ensures that the following information is being recorded: • number of blocks and slides made including any special staining; • disposal or retention for future use including date of disposal; • repatriation of tissue with the body of the deceased; • return to family for own arrangements; and • destination of tissue sent off for analysis including date of arrival and date of return.
8.	PFE3(f)	As the mortuary has undergone a recent refurbishment, all equipment is still within guarantee. The DI is advised to continue with plans to formalise a regular maintenance schedule for mortuary fridges and freezers The DI is advised to ensure that the mortuary is notified of all servicing of mortuary equipment and is provided with copies of service records. This will help the mortuary staff to ensure timely servicing of all mortuary equipment.

Concluding comments

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

The HTA requires the Designated Individual to submit a completed 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: 19 June 2019

Report returned from DI: 27 June 2019

Final report issued: 15 July 2019

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 September 2020

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.