Site visit inspection report on compliance with HTA licensing standards

Holly Tree Lodge

HTA licensing number 12405

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**

13 & 27 July 2017

Summary of inspection findings

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

Although the HTA found that Holly Tree Lodge (the establishment) had met the majority of the HTA's standards, 18 shortfalls were found against the governance and quality, traceability and premises, facilities and equipment standards.

Particular examples of 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

Holly Tree Lodge public mortuary is located in a purpose-built building in the grounds of the East Cemetery in Bournemouth. The establishment has been licensed by the HTA since February 2007, based at the current premises since December 2010. The mortuary is managed by Bournemouth Borough Council. The governance of the mortuary recently changed departments within the Council and now comes under the Council's Bereavement Services Department. The DI is the Mortuary and Coroner's Support Manager and the CLHC is the Head of Bereavement Services.

The establishment undertakes approximately 1,800 PM examinations a year under the jurisdiction of HM Coroner for Dorset. These include forensic and up to Category 3 high risk post-mortem (PM) examinations. The establishment also undertakes a small number of adult hospital consented PM examinations for other establishments, for which it has been providing a consent form for completion *(see shortfall against C1).*

The establishment is secured by an electronic swipe card security system, which is managed by the Council, and closed-circuit television (CCTV) at the front and rear of the premises. Funeral Directors, contracted by the Coroner, bring bodies in from the community. Out-of-hours they can use their swipe cards to gain access to the body store area, whilst access to other areas of the mortuary is restricted.

The body store has capacity for 99 bodies, including 14 spaces that can be converted to freezers. One bank of five fridges is dedicated for paediatric cases. The fridges and freezers are remotely temperature monitored and alarmed, and are subject to regular maintenance. Staff also record the temperatures daily but there isn't a formal process in place to review them for any trends.

The main PM suite has three regular sized and one bariatric table, all of which are height adjustable. There are four dissection benches. There is a separate high risk/forensic PM room, which has one downdraft table, suitable for bariatric bodies. During the site visit, the HTA inspection team identified a number of issues with the cleanliness of both rooms *(see shortfalls against PFE1 (a) & (c)).*

The establishment uses a paper form (the C11 tracking form) as a mortuary register and an electronic database to record the details of the bodies in the mortuary. This database can also be accessed by the Coroner's Office and allows the establishment and the Coroner's Office to maintain oversight of all cases.

The first part of the C11 tracking form is completed by the funeral director when they bring bodies in from the community. The details are then confirmed by the APTs when they check the body. The C11 form, however, only allows space for specific identifiers from the funeral director and if they do not have those specific details, there is nowhere for them to add

additional information which would help the establishment ensure they have three identifiers for the deceased *(see shortfall against T1(c)).*

The C11 form records all activity relating to the deceased within the mortuary, such as PM examination, and is used as part of the release procedure when the funeral director signs to confirm receipt of the deceased.

A new system for transporting tissue taken as part of the PM examination has recently been introduced. Samples are now sent to a specific HTA-licensed establishment, where the pathology laboratory manages the processing, distribution to the relevant Pathologist, and carrying out of the wishes of the family in relation to the tissue once Coronial authority has ended. In the case of forensic PM examinations, the police take any tissue samples away with them.

The mortuary premises include a viewing room for family and identification purposes. Access from the building entrance area and viewing room to the rest of the establishment is restricted and a member of staff is always on the premises whilst viewings are conducted. Viewings are arranged via the Coroner's Office or with mortuary staff themselves. Out-of-hours lone viewings at the establishment are rare and, when they are undertaken, staff have a lone working security device that will contact security services when triggered.

Description of inspection activities undertaken

This report describes a non-routine inspection of the establishment following an incident that resulted in the mortuary being closed for almost five months at the beginning of 2017. This incident was not reported to the HTA at the time, but was brought to our attention by a member of the public. The DI and Corporate Licence Holder contact changed after the incident, and the HTA wanted assurance that the premises were in order and that suitable practices were being followed in the conduct of licensing activities after such a lengthy closure. Additionally, on a recent inspection of a local hospital, the HTA identified an issue with the consent forms provided by Holly Tree Lodge.

The DI was unable to attend the initial inspection visit so a further follow-up site visit was undertaken on 27 July 2017.

The HTA conducted a visual inspection of the premises, reviewed documentation and carried out interviews with the Designated Individual, the Corporate Licence Holder contact and establishment staff.

As part of the inspection, audits of the body store were undertaken. Four bodies were selected at random from the fridges and one from the freezer. The identity tag on the body in the freezer was inaccessible and the paperwork for the individual had been filed to indicate that the body had been released from the mortuary. Additionally, there was an inconsistency

between the number of forms in the folder dedicated to bodies in freezer storage and the actual number in storage; as a result, the remaining four bodies in the freezer were audited on day one of the inspection. There were issues with the number of identifiers on each body selected from both the fridges and the freezers.

On the return visit, audits were undertaken of traceability of two bodies moved to freezer storage since the first visit. One discrepancy in the date of birth recorded on the wrist tags and mortuary paperwork was identified for one body. The inspection team also identified two bodies in the mortuary with similar names that had not been flagged in accordance with the establishment' procedures. During the second visit the inspection team also undertook a process audit of release of a body to a funeral director; in this case the funeral director only provided the name of the deceased. Mortuary staff proceeded to check for three identifiers against the information in their own internal systems as the SOP does not specify exactly what identifiers should be checked, or that the funeral director should be supplying all three identifiers upon arrival.

Inspection findings

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

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
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.	The consent form supplied to other establishments by Holly Tree Lodge is out of date and on occasion has not been fully completed. The HTA has checked that no offences under the Act have taken place, however, the DI is advised to cease using this form and put an agreement in place with any establishments requesting adult hospital PM examinations that ensures consent is sought line with the HT Act by properly trained individuals. The agreement should also consider training, for staff at Holly Tree Lodge, on how to assess whether the forms have been completed correctly.	**Minor**

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.	As discussed with the DI, some of the mortuary SOPs do not accurately reflect current practice and do not contain sufficient detail of identification procedures. Examples include but are not limited to: - SOP2 'PM carried out by the public Mortuary' lacks sufficient detail on identification procedures; - SOP2 also states that incidents should be reported to the Mortuary Manager, there is no longer a mortuary Manager in place; - SOP3 'Release of the deceased' says that 'the ID wristband must be checked by the Technician and the funeral director' but gives no further details of what identifiers to check or what they are checked against; - SOP4 'Viewing and identification of deceased persons' tells staff to inform family if there is an infection present but gives no details of how to maintain the confidentiality of the deceased. There is also no mention of checking who the visitors have come to see or of checking the identity details they supply. There is no storage contingency plan that addresses what steps to take if the establishment were to reach full capacity or in the event of a major equipment failure.	**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	There is no formal document management system in place. Currently, SOPs do not identify the author and all were still marked as being version 1, even though it was clear that there had been previous versions.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	The establishment does have a system for recording that mortuary staff have access to and have read and understood the SOPs and policies relevant to the activities they undertake. However, these records are not complete for all mortuary staff and so it is unclear whether all staff are aware of updates to procedures and carrying out their duties in accordance with them.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment does not have a documented schedule of audits for activities taking place under the licence. In 2014 the establishment undertook a major review of mortuary practice, but there has been nothing since then and regular audits of compliance with mortuary procedures, traceability of bodies or mortuary records are not undertaken.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
d) Staff have annual appraisals and personal development plans	There have been no formal appraisals for establishment staff since 2014.	**Minor**
f) There is a documented induction and training programme for new mortuary staff	There is a Council general induction document, but nothing that is specific to the mortuary or activities taking place there.	**Major**

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	There is no formal document management system in place.	**Minor**
b) There are documented SOPs for record management which include how errors in written records should be corrected	There is no SOP for record management.	**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	The SOP on reporting incidents to the HTA does not include all reportable incidents (e.g. 'viewing of the wrong body'. This means that staff may fail to report some incidents	**Minor**

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The incident reporting SOP contains insufficient detail on the deadlines for reporting and how to report incidents to the HTA. The previous inspection highlighted that there was no Person Designated tasked with reporting incidents during the DI's absence. This is still the case. As the DI is not based at the establishment full-time, if there is no Person Designated for the mortuary, it is unlikely an incident would be reported to the HTA within the required timeframe.	**Minor**
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed	Investigation reports for adverse events do not always include sufficient details of the investigation and follow up actions. The establishment cannot therefore evidence that all adverse events have been properly investigated and appropriate corrective and preventative actions completed.	**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	Mortuary risk assessments consider health and safety risks for staff and some risks to the deceased; however, there is insufficient consideration of some risks, particularly accidental damage, serious security breach and major equipment failure.	**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 always use three identifiers. The HTA's audit of body traceability identified inconsistencies in the number of identifiers available on identification tags and the mortuary register for all but one body. The C11 tracking form used as the mortuary register only allows for three identifiers to be entered, some of which may not be available to the funeral directors when they bring a body from the community. The procedures for identification of bodies for viewings and release of bodies from the mortuary to funeral directors rely on only one or two identifiers. This poses a significant risk of misidentification of the deceased.	**Major**

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register	The current process when a body is frozen is to move the C11 tracking form to a separate plastic wallet at the front of the register folder. However, at the time of inspection, there were more forms in the folder than bodies in the freezer. Additionally, for the body selected as part of the body store audit, the form had been filed elsewhere, indicating that the body had been released. There is no system to record what year the mortuary reference number relates to, which means it cannot readily be used to identify the correct record.	**Major**

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	The inspectors noticed a number of areas where cleaning was not up to the expected standard. Blood stains were visible on equipment in both the normal and the high risk PM rooms. Other indicators, such as material swept into a corner, demonstrate that thorough cleaning is not undertaken by staff.	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There are documented cleaning schedules for operational and non-operational areas; however the standards of cleanliness indicate that the document is not detailed enough.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) 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)	Items of equipment in the mortuary showed signs of rusting: • scales in the main PM suite; • frame of the oscillating saw; • hydraulic trolleys in both PM suites; and • frame of the clinical waste bin in the high-risk PM suite.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	The DI is advised to remove the statement from SOP2 PM examinations that blood samples should be taken from the deceased and sent off for testing in

		the event of a needle stick injury. This is not permitted without the consent of the family of the deceased.
2.	GQ1(c)	There is an SOP 'Religious differences on handling bodies' which list traditions around body preparation for a range of religions. The use of this document as an SOP may prove restrictive. The content may be better provided as an information guide for staff. Any specific religious requirements should always be checked with the family of the deceased.
3.	GQ1(h)	After a two year gap, team meetings have been re-introduced. The DI is advised to ensure the meetings are minuted and that an agenda item is added to ensure that any HTA matters are discussed.
4.	GQ2(a)	When developing an audit schedule, the DI is advised to ensure a check of any bodies in long term storage is included.
5.	GQ2(b)	When implementing an audit schedule the DI should ensure that a suitable process is in place to follow up on any anomalies found ensuring that any corrective and preventative action plans include information on who is responsible foe the actions and a timeframe in which they will be completed.
6.	GQ3 (a)	The DI is advised to update the training for funeral directors when the new C11 form comes in to force, which should include any further changes in process and highlight why three identifiers are necessary.
7.	GQ3(b)	A number of SOPs refer to a Mortuary Manager, but there is no such role in the current staffing structure at the establishment. If a decision is made not to introduce the role of Mortuary Manager, the SOPs should be amended.
8.	GQ6	On the last inspection, a shortfall was found under GQ6 of the previous HTA standards whereby bodies were not being checked until removal from storage for a PM examination. This was rectified at the time with a new process implemented whereby bodies were checked for identity details and condition the morning after they arrived. This practice seems to be slipping and occasionally bodies are not checked until later in the process. The DI is advised to ensure that bodies are always checked as soon as possible after arrival to ensure any issues can be identified and dealt with promptly.
9.	T1(b)	The DI should consider adding a date field on the C11 form to record when a body is moved into freezer storage.
10.	T1(c)	The DI is advised to ensure that anyone who requests a viewing provides three identifiers of the deceased and that staff always ask them who they have come to see rather than supply a name to visitors.
11.	T1(d)	The same and similar name system indicates in a number of areas if two or more bodies of deceased people with a similar name are in the mortuary. However, it is not standard practice to remove the fridge magnet when one body is released, meaning that as a visual cue these magnets become obsolete. The DI is advised to remind all mortuary staff of the procedure for checking and flagging bodies with same or similar names.
12.	PFE1(d)	Access to the mortuary is managed using an access control system which is managed by the Council. The DI is advised to regularly review who has access to the mortuary to ensure there is no unexpected or unnecessary access by contractors.

13.	PFE2(a)	The fridges that can convert to freezers are those closest to the door funeral directors use when they bring bodies to the mortuary. The DI should make arrangements for these to be clearly marked as not to be used by funeral directors when switched to freezer mode. Similarly, the fridge that is dedicated for paediatric cases should also be clearly labelled as such.

Concluding comments

The new DI and Corporate Licence Holder are dedicated to improving practices and are keen to ensure all standards are met. There were some areas of good practice identified on inspection:

- The mortuary contacts the Coroner once a body has been with them for over two weeks to get an indication of why there is a delay in collection and can take appropriate steps to follow up with funeral directors or to move the deceased to freezer storage;
- The more recent bodies that were put in the freezer have the location of their identity band marked up on the outside of the body bag so it can be easily accessed when needed;
- Once the name of the family selected funeral director has been confirmed by the Coroner, staff write the funeral director's company name in a different colour pen on the fridge door sign for the deceased, to act as an additional guide for staff on release of bodies.

There are a number of areas of practice that require improvement, including six major and 12 minor shortfalls.

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

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

Report sent to DI for factual accuracy: 23 August 2017

Report returned from DI: 11 September 2017

Final report issued: 15 September 2017

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: 20 March 2018

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.

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 they are 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 for these 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

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

vi. fridges / freezers

vii. hydraulic trolleys

viii. post mortem tables

ix. hoists

x. 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.

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

d) 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.

e) Staff have access to necessary PPE.

Guidance

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

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

g) 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.