Site visit inspection report on compliance with HTA licensing standards

Harrogate Distrct General Hospital

HTA licensing number 12118

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**

4 & 5 September 2018

Summary of inspection findings

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

Although the HTA found that Harrogate District General Hospital had met the majority of the HTA's standards, three major and nine minor shortfalls were found against the Consent, Governance and Quality systems, Traceability and the Premises, Facilities & Equipment standards. These related to the policy for seeking of consent for post-mortem (PM) examination; training for seeking of consent for PM examination; SOPs; audits; risk assessments; the use of three identifiers; traceability of tissues; premises and equipment.

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

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

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

The establishment receives approximately 1000 bodies each year from deaths in the hospital and the community, and performs around 285 PM examinations annually for HM Coroner for North Yorkshire. The total figure for PM examinations includes high-risk (up to category three), around seven forensic and three hospital (consented) PM examinations. Paediatric/perinatal PM examinations are transferred to another HTA-licensed establishment. Consent for paediatric/perinatal PM examination is sought at the establishment by clinicians who have received training in the seeking of consent for PM examination. Consent for adult hospital (consented) PM examinations is sought by hospital consultants, usually supported by a consent trained Consultant Histopathologist who also carries out PM examinations (see shortfall against C2(b)).

The establishment has a total of 30 refrigerated body spaces within the main body store, 25 of which are doubled-ended for direct access in to the PM room and five freezer spaces for long-term storage of bodies, if required. In addition, there are 20 permanent refrigerated spaces located in the secure reception area, external to the main body store. All body store doors are locked at all times. The establishment do not have any refrigerated storage spaces for bariatric bodies, or formal documented agreements with other establishments for the storage of these bodies (see shortfall against PFE2(c)).

Swipe card access is required for all doors in to the mortuary. The external door used by funeral directors, is covered by departmental CCTV that is readily available for the mortuary staff to visually verify who is requesting access. However, the internal door only has an intercom system, meaning staff cannot visually verify who is requesting access at this door before it is remotely unlocked (see shortfall against PFE1(d)).

Portering staff transfer and admit all hospital bodies using a concealment trolley. They are also responsible for admitting all community bodies' out-of-hours. Hospital bodies are transferred to the mortuary with a 'Mortuary Transfer Sheet' which is kept with the body, in addition to the identification bands. Upon admission, a fridge is selected and the mortuary register, fridge door whiteboard and body store whiteboard details are completed by the

porters. Community bodies are transferred to the mortuary by funeral directors (see *Advice*, item 4) and may only be admitted to the mortuary using two identifiers (see shortfall against T1(c)). The mortuary staff complete body identification checks as soon as possible on the day, or the next working day if the body was admitted out of hours (see shortfall against GQ1(a)) and place a red identification band on each body stating the 'body count number' and body store location number. Bodies may be released from the mortuary using one or two identifiers (see shortfall against T1(c)).

Training in mortuary practice and procedures has been provided to the charge-hand and deputy charge-hand porters, who are responsible for the transfer and admission of bodies in to the mortuary.

The PM suite contains three PM tables, each with an associated dissection unit. When removing bodies from refrigerated storage, APTs carry out initial identification checks against coronial or consent documentation and again with the pathologist prior to the external examination and evisceration commencing. Pathologists complete each PM examination before commencing the next case to help mitigate against any risk of a mix-up of organs and tissue samples between cases. All PM cases and any tissue retained during PM examinations are recorded in a dedicated database and spreadsheet. In addition, the pathologist completes a tissue form, which is sent with all histological samples to the on-site histopathology laboratory detailing the type and quantity of tissue pieces retained (see *Advice*, item 15).

There are currently three Consultant Histopathologists who fulfil the PM Service at the establishment. The mortuary is staffed by a Mortuary Manager and Senior APT, who are both fully qualified.

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

Description of inspection activities undertaken

The establishment has been licensed by the HTA since August 2007. Previous routine site visit inspections took place in March 2011 and March 2015. This report describes the third routine site visit inspection in September 2018. Formal interviews were conducted with the DI, mortuary staff, hospital porters, Consultant Histopathologist and PM consent seekers (adult and perinatal). The inspectors also carried out a visual inspection of the mortuary, including the body store area, post mortem room and viewing suite.

Traceability audits of body identifiers, storage locations, mortuary register details and associated documentation were carried out for three adult bodies (one hospital and two community bodies) and one perinatal body. One anomaly was found:

- one community body that had undergone a PM examination had a difference in the spelling of the first name between the identification band, fridge and body store whiteboards and the mortuary register. There was no documented evidence to confirm that the discrepancy had been checked prior to PM examination.

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

- the body count number for one body had been transposed when entered in to the electronic laboratory record;
- the number of pieces of tissue retained at PM examination in one case did not match the number of blocks entered in to the electronic laboratory record. At the time of 'blocking' the tissue, two pieces had been placed in to one tissue cassette, however, this had not been recorded and was only found by physically checking the tissue blocks in storage;
- the number of pieces of tissue in one case had not been recorded on the tissue form by the pathologist and therefore could not be reconciled with the laboratory electronic record. In addition, the number of blocks in storage for this case did not match the laboratory electronic record; one specific block was missing. The reason for the missing block was identified during the inspection and was recorded on the tissue form, however, this had not been recorded on the electronic laboratory record;
- For one case, two tissue forms had been received with the relatives' instructions for tissue. It was unclear if the second form received at a later date superseded the original form, or the instructions on the second form were in addition to the original instructions given;
- It is not practice to record the total number of slides generated from tissue blocks in the electronic laboratory record.

See Shortfall against T1(g).

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
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 Trust policy 'Death Certification, Cremation Forms and PM examination' does not include the hierarchy of qualifying relationships as outlined in the HT Act 2004 or the HTA's codes of practice. In addition, the policy refers to the 'next of kin' (NOK) which could imply that someone other than the person ranked highest in the hierarchy of qualifying relationships, could consent to a PM examination and retention of tissues for use for scheduled purposes. The policy also refers to the HTA's previous codes of practice (Codes 1, 3 and 5).	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	The system in place to record which clinicians have completed and reviewed the PM consent training for adult hospital (consented) PM examinations does not provide sufficient assurance that they have done this (see *Advice*, item 3). In addition, the Consultant Histopathologists who are involved in the seeking of consent for PM examination may not always acknowledge their annual refresher training via the laboratory document system.	**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.	Although the establishment has SOPs covering the majority of activities carried out under the licence, some key ones are missing, others do not reflect current practice, or require updating, further detail or clarification. Examples include, but are not limited to: • NOK and the HTA's previous (and now superseded) codes of practice are referred to in various SOPs ; • SOP 'PM Examination' (MO-LP-002), Section 2 does not refer to the full hierarchy of qualifying relationships of who can give consent for a PM examination. Section 4 refers to the NOK giving consent to retain tissue for scheduled purposes. In addition, Section 4 states that block and slides maybe kept indefinitely. This is contrary to the RcPath Guidance 'The Retention and Storage of Pathological Records and Specimens (5th edition); • SOP 'Reception of Bodies (MO-LP-001), Section 2 states that only the full name of the body is checked against the details on the mortuary transfer sheet. However, all identifiers are checked. In addition, this SOP covers the storage of long-term bodies, however, it does not include the procedure or time scales for the follow-up of these cases that the mortuary staff follow; • SOP 'Incident and Non-conformance Management Procedure – Histopathology and Mortuary' (HP-QP-CAPA), Appendix 3, requires updating to include all the HTARI categories; • The establishment does not have a departmental SOP for lone working in the mortuary. When SOPs state that identification details should be checked, the number of identifiers (three, one being unique), what the identifiers could be and what they are checked against, should be consistently stated in all relevant SOPs. All SOPs require review to ensure they contain correct and sufficient detail, reflect the HTA's current codes of practice and correct references to external documents and guidance (see *Advice*, item 8).	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The current schedule of audits does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability (see *Advice*, item 9).	**Minor**
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The current audit for PM tissues only covers reviewing those tissues with instruction for disposal. Full audits of tissue retained at PM examination through to the laboratory are not undertaken.	**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	There is no specific risk assessment for lone working within the mortuary. The generic risk assessment in place does not sufficiently cover mortuary activities to adequately assess the risks to staff. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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	i) Bodies may be released from the mortuary using only one or two identifiers, depending on the documentation presented at the time of release (see *Advice*, item 12). ii) Community bodies are not consistently identified using three identifiers (one being unique) (see *Advice*, item 13). iii) The Trust policy for the viewing of bodies specifies that only two identifiers are used to book a viewing and subsequently checked with relatives when they arrive (see *Advice*, item 14).	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	i) Although the tissue slides generated from tissue blocks are recorded in the electronic laboratory system, the total number of slides have to be manually counted from the record which could lead to errors. This does not ensure adequate traceability or audit of tissue slides in storage. ii) Pertinent information is not recorded in the electronic laboratory system, for example, if two pieces of tissue have been placed into one cassette, and may only be recorded in paper format, for example, on the histology request form.	**Minor**

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 mortuary premises are showing some signs of wear: • There are small areas of minor damage to fixtures constructed of wood, for example door frames, in areas that are frequently used, resulting in the loss of effectiveness of the protective covering in those areas. The damage makes the wood porous, so that it cannot be adequately cleaned or disinfected; • The seal between the edges of the PM room floor and wall covering is starting to detach in some places and requires attention to ensure the area can be sufficiently cleaned and disinfected; • There is a large area of patchy flaking paint and exposed plaster in the corridor leading to the body store. This is apparently a continuing issue caused by moisture from the equipment in the department next door. However, this means that the wall cannot be sufficiently cleaned or disinfected.	**Minor**
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)	Mortuary staff cannot visually verify who is requesting access at the internal mortuary door, before they remotely unlock it and permit access to the mortuary. There is only an intercom. The hospital CCTV covering this area is not available for mortuary staff to readily view. This increases the risk of the door being opened to unauthorised people, potentially causing a security and/or safety issue for staff.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have any refrigerated storage for bariatric bodies and only has a verbal agreement with another licensed establishment for the storage of these bodies, when required. The procedure for using ice packs from the freezer to help cool bariatric bodies is not sufficient to ensure the condition and the dignity of these bodies are maintained. The DI informed the inspection team that this issue has been included on the Trust's risk register for some time. However, a request for capital funding to address this issue has not been approved.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The establishment has been informed by the company who service the mortuary equipment that the PM tables cannot be serviced; the age and design of the tables prevents this and replacement parts are no longer available. Two out of the three tables no longer move up and down and cannot be repaired. In addition, the PM tables cannot sufficiently accommodate bariatric bodies. The DI informed the inspection team that again, this issue is included on the Trust's risk register. However, a request for capital funding to address this issue has not been approved.	**Major**

Advice

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

No.	Standard	Advice
1.	C1 (c)	The DI is advised to consider if tissue with consent for retention actually is, or should be kept indefinitely, especially if it is not being used for the purposes for which it has been retained, for example, education or research. Indefinite retention is referred to in the written information for PM consent for relatives. It is important that this information is accurate and reflects practice, ensuring relatives are fully informed.
2.	C2(a)	The DI is advised to update the PM consent training presentation with the correct reference to the HTA's licensing standard regarding PM consent training (C2).

3.	C2(b)	The DI is advised to continue with the plan to include the PM consent training presentation in the Trust e-learning mandatory training for the relevant clinicians to help provide better assurance that training has been undertaken.
4.	GQ1(a)	The DI may wish to consider implementing a form to be completed for bodies admitted out-of-hours to ensure that information regarding these bodies is communicated efficiently to the porters and mortuary staff; for example, when there is a risk of infection. This is especially important as bodies from the community may not always be received in body bags and the mortuary staff may not receive information for a few days.
5.	GQ1(a)	The storage of long-term bodies is referred to in the SOP 'Reception of Bodies' (MO-LP-001). The DI is advised to include more detail of how these cases are identified and the escalation process to deal with them.
6.	GQ1(a)	The DI is advised to ensure that when discrepancies are found with the identification details of bodies, they are followed-up and documented to provide assurance any issues have been resolved prior to any procedures taking place, for example, a PM examination.
7.	GQ1(a)	To help identify any identification issues when bodies for Coroner's PM examination are admitted to the mortuary, the DI is advised to ensure that mortuary staff confirm the identification details on the body with the Coroner's authority for PM examination. By performing these checks with the documentation on admission, issues can be addressed as soon as possible and help prevent delays at PM examination.
8.	GQ1(a)	The DI is advised to update all relevant SOPs to refer to the updated Health and Safety Executive guidance 'Managing infection risks when handling the deceased' (July 2018) document. This guidance supersedes the 'Safe working and prevention of infection in the mortuary and PM room' document that is currently referred to.
9.	GQ2(a)	The DI is advised to select representative numbers when undertaking audits to help provide assurance that processes and procedures are robust and fit-for-purpose.
10.	GQ3(c)	Staff are currently competency assessed for the activities they undertake every three years. The DI is advised to consider competency assessing staff every two years to effectively identify and address any areas that staff require refresher training in.
11.	GQ6(a)	The DI is advised to risk assess only having the mortuary register in paper format, as the information contained within the register is not stored elsewhere. In addition, the DI is advised to consider options to store this information electronically, for example, in a spreadsheet.
12.	T1(c)	To help address the shortfall identified against T1(c), the DI is advised to request that funeral directors bring the hospital release form already issued by the General Office to relatives, to release all hospital bodies from the mortuary. The addition of the hospital or NHS number on this form will provide mortuary staff with the required three identifiers (one being unique) to release a body.
13.	T1(c)	The DI is advised to liaise with the Coroner's Office and/or funeral directors that bring bodies to the mortuary to reiterate the importance of bodies being identified with three identifiers, one being unique. Although issues with insufficient identifiers are addressed when they are identified, this may help reduce the frequency of occurrence and prevent delays.

14.	T1(c)	In addressing the shortfall identified against standard T1(c), the DI may wish to strengthen the procedure for viewings by introducing a form to be completed by relatives when they attend. This can include relevant information to check the identification on the deceased, before the viewing takes place. This may help to mitigate the risk of misidentification and relatives viewing a wrong body.
15.	T1(g)	The histology tissue forms are stored in paper format only. The DI is advised to consider electronically scanning these forms which contain the details of the tissues retained at PM examination, the number of cassettes generated when the tissue is blocked and other pertinent information that is not currently recorded in the electronic laboratory system
16.	PFE1(d)	The DI is advised to consider the use of panic alarms for the mortuary staff, when working out-of-hours or alone that will alert people externally to the mortuary if an issue arises.
17.	PFE2(e)	The DI is advised to liaise with the fridge/freezer maintenance company to adjust the freezer defrost setting to allow the upper freezer trigger point to be set to an appropriate temperature.
18.	N/A	The mortuary staff currently highlight bodies with same and similar names with signs on the body store doors. The DI may wish to consider the use of coloured signs or magnets on body store doors to highlight other pertinent information, for example, potential infectious disease risks from bodies or for implant devices.

Concluding comments

The mortuary staff appear to work well together and with service users, demonstrating enthusiasm, care for the work they undertake and dedication to providing a good service. In addition, staff demonstrated a willingness for continuous improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA. There were several areas of strength and good practice:

- The use of different coloured white board pens on a rotational weekly basis to help identify bodies that have been in storage for longer than usual;
- All bodies are given a red identification band stating the body count and fridge number, once they have been checked to act as an additional traceability measure while in the care of the mortuary;
- The Mortuary Manager has a robust system for following up relatives wishes for retained tissues to help ensure they are not retained for longer than necessary;
- All bodies that have undergone a PM examination have a ‘Tissue removal form’ attached to indicate whether tissue has been retained or not. This is a visual prompt for mortuary staff to check records to help prevent bodies being released before the relatives wishes for tissues have been received from the Coroner’s Office;
- A flow chart for the procedure for viewings is attached to the viewing room door, meaning staff who conduct viewings out-of-hours can easily reference the procedure;
- Mortuary staff have sensitively decorated the plastic containers used for fetuses and babies while they await release for their funeral;

There are a number of areas of practice that require improvement, including three major shortfalls and nine 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: 03/10/18

Report returned from DI: 25/10/18

Final report issued: 06/11/18

Completion of corrective and preventative actions (CAPA) plan

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

Date: 01/04/19

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the

injures and let them know that reconstruction may be required.

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

change. Staff should be involved in the risk assessment process.

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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