

Site visit inspection report on compliance with HTA licensing standards

Bedford Hospital

HTA licensing number 12324

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**

17 May 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 Bedford Hospital had met the majority of the HTA's standards, a number of shortfalls were found against standards on Consent, Governance and Quality Systems and Traceability. These relate to lack of consent training for paediatric and perinatal post mortem examination, poor governance documentation, lack of audits, lack of training for staff, poor risk assessments and body traceability. Three of these shortfalls have been classified as major (see Appendix 2) and require urgent action.

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

This report refers to the activities carried out by Bedford Hospital (the establishment), licensed under the HT Act 2004 for post mortem (PM) examination, removal from the body of a deceased person of relevant material 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 Corporate Licence Holder (CLH) is the Bedford Hospital NHS Trust; the Designated Individual (DI) is the Medical Director of the Trust; and the Corporate Director of the Trust is the CLH named contact.

Two pathologists employed by the Trust conduct around 270 adult PM examinations each year on behalf of HM Coroner for Bedfordshire; the establishment is hoping to increase its coronial workload in the coming year. In addition to routine coroners cases, a number of Home Office cases, two or three consented adult PM cases and a small number of high-risk cases up to category 3 are undertaken each year. The establishment routinely sends bodies to other facilities for PM examination: high-risk category 4 cases are sent to St George's Hospital in London; paediatric and perinatal cases are sent to Addenbrookes Hospital in Cambridge after consent has been taken by the treating clinician at Bedford Hospital and forensic paediatric and perinatal cases are sent to Great Ormond Street Hospital.

The Trust's pathology services are operating under Viapath, an independent provider which also provides pathology services to Guy's and St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust.

The mortuary is staffed by four Anatomical Pathology Technologists (APT), including one member of locum staff and the mortuary manager. There is a member of staff on call at all times.

The PM suite consists of three downdraft tables and a single cut-up bench, although organ cut-up is usually carried out on a tray placed over the body on the PM table. Where there is more than one PM in progress, the tray is moved from table to table. There is currently no system in place to prevent mix-up of organs when more than one PM is taking place, which may become an area of risk if coronial workload increases (see advice item 4).

Prior to PM evisceration of the body by the APT, the pathologist carries out an external examination of the body and checks three points of identification with a member of mortuary staff.

The body store has 80 refrigerated spaces in total and was not at capacity at the time of inspection. These fridges provide 50 spaces allocated for hospital deaths, 20 spaces for

community deaths, five for bariatric bodies and five for paediatric bodies. There are also five freezer spaces, a separate bariatric bed fridge for super bariatric patients and a separate fridge unit for non-viable fetuses (NVF). The body store, bariatric bed fridge and NVF fridge are all temperature monitored, with a dual alarm system linked both to the hospital switchboard and the on-call staff member's phone, which will alarm when the temperature deviates from its expected range. It is a web-based interface system that allows the on-call staff member to log on remotely and review the reason for the alarm before attending the mortuary out of hours.

Porters transfer and admit all hospital bodies to the mortuary. Mortuary staff oversee this process within normal working hours and undertake patient identification checks of all bodies. Out of hours, bodies are brought by porters and are formally checked in by mortuary staff in the morning. The mortuary manager is responsible for training the porters.

The entrance to the mortuary used by funeral directors is screened from public viewing, has a one way camera and two way intercom at the entry and exit points. Despite the mortuary being suitably staffed, lone and out of hours working does occur and there are procedures and security arrangements in place to provide protection for staff. However, the documentation regarding lone working does not always reflect actual practice.

In March this year, at the request of the Trust's Director of Support Services, mortuary staff at West Suffolk NHS Foundation Trust undertook a peer review of the mortuary and bereavement services at the establishment in preparation for the HTA site visit.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since 2008. This was the third routine site visit inspection, with the previous inspection taking place in September 2012. However, this was the first inspection of the establishment against the new HTA standards that came into force on the 3rd of April 2017. The timetable was developed after consideration of the establishment's previous inspection reports, compliance update information and discussions with the DI. It included a visual inspection of all areas where licensable activity is undertaken: the mortuary and body store, PM suite, viewing gallery (storage of blocks and slides) and the Emergency Department. Interviews were held with the DI; Persons Designated (Consultant Paediatrician, Consultant Emergency Department); Corporate Licence Holder contact, Deputy Mortuary Manager, Consultant Histopathologist and a Coroner's Officer. A thorough review of governance and quality documentation was also undertaken.

During the inspection, the release of two bodies to contracted funeral directors was observed and the process checked against the SOP. The admission of a NVF to the mortuary by a porter was also observed (see advice item 5).

The HTA conducted audit trails on three bodies stored in the refrigerators. Body location and identification details on body tags were cross-referenced against the information on the fridge doors, whiteboard and in the mortuary book. There were a number of discrepancies in relation to traceability of the bodies, suboptimal same/similar name procedures and a lack of awareness of the current status of bodies held in the mortuary at the time of the visit (see shortfalls against T1 (b), T1 (c) and T1 (d)).

Vertical traceability audits were carried out on tissue that had been removed during three PM examinations, including one adult hospital consented case and two adult coronial cases. Paper records (adult hospital consent form, Coroner's form for wishes of the deceased and PM histology request forms), were compared with the number of blocks and H&E stained slides ,which are being stored in the viewing gallery of the PM suite. A traceability audit was also conducted on a whole organ that was sent to Papworth for specialist examination and was later repatriated with the body. No discrepancies were found.

The Emergency Department at Bedford Hospital has procedures for dealing with cases of sudden unexpected death in infants (SUDI) under coronial authority. There are robust procedures in place including a checklist of all necessary actions (e.g. removal of blood, CSF and biopsies). The resuscitation areas are spacious, secure and ensure the dignity of the deceased.

Material held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored at the establishment were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

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.

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	Although no paediatric or perinatal post mortem examinations take place on site, consent is sought for these by the establishment's staff. These staff have not been provided with training on consent for PM examination. However, they use consent forms that meet HTA requirements and provide information parents about the PM examination and the options available to them.	Minor
b) Records demonstrate up-to-date staff training	There are no records to demonstrate that staff are suitably trained to seek consent for paediatric or perinatal post mortem examination.	Minor
d) Competency is assessed and maintained	The competency of staff seeking consent has not been assessed and maintained.	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.	<p>Several key SOPs and policies governing mortuary activities do not accurately reflect current practice, for example:</p> <ul style="list-style-type: none"> the SOP on PM examination does not reference the requirement to check three identifiers; the lone-working policy suggests forensic work is carried out alone, when there is actually a 'buddy' system in place; Reference to viewing of the deceased is in several different documents and versions and there is no reference to the check made with the family about who they have come to view. <p>Some SOPs could be rationalised, particularly viewing of the deceased for which there are several versions, echoing the findings of an external peer review carried out in March 2017 in preparation for the HTA site inspection.</p> <p>The contingency plan for mortuary capacity is awaiting review and sign-off.</p>	Minor
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	<p>The establishment does not have a procedure to manage the long-term storage of bodies.</p> <p>From the body audit that was conducted by the HTA, a body was found to have been in the fridge since March 2017, having not had a PM examination; mortuary staff were unaware of the status of this body, the condition of which was deteriorating with visible blistering and marbling.</p> <p>Bodies are not being moved into long-term storage after 30 days, in line with HTA guidance, which is a risk to the dignity of the deceased.</p>	Major
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	SOPs and policies are often written and reviewed by the same individual, which means they are not subject to any form of quality assurance.	Minor

e) There is a system for recording that staff have read and understood the latest versions of these documents	The HTA saw no evidence of a system for recording that new or existing staff have read and understood the latest versions of the documents, many of which are new. For example, staff appear unaware of the escalation process for mortuary over-capacity, despite it being documented in the SOP.	Minor
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	The majority of governance documents are new so there are few documented deviations. There is no scheduled audit activity for documented SOPs (see GQ2 below).	Minor

GQ2 There is a documented system of audit

a) There is a documented schedule of audits	Mortuary activities are not subject to audit. A premises audit was carried out in April 2017, which covered security arrangements and the condition of premises. However, there is no evidence of follow-up actions or of the findings being shared with establishment staff for future learning.	Major
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	See GQ2 (a)	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	See GQ2 (a)	Minor

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

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	The HTA was not provided with evidence of the training that is provided to porters who undertake mortuary duties.	Minor
d) Staff have annual appraisals and personal development plans	Staff do not have annual appraisals or personal development plans.	Minor

e) Staff are given opportunities to attend training courses, either internally or externally	Staff are not provided with the opportunity to develop skills in the form of internal or external training courses.	Minor
f) There is a documented induction and training programme for new mortuary staff	There is no documented induction and training programme for new mortuary staff.	Minor
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	There is no documented induction for visiting/external staff which includes local policies and procedures.	Minor

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Staff interviewed during the inspection were not able to demonstrate sufficient knowledge and understanding of the HTARI procedure (see GQ5 (b) below).	Minor
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	HTARI reporting is only briefly described in the Trust's Incident Reporting and Investigation Policy. The lack of a mortuary-specific procedure on the reporting of incidents means that staff are not fully aware of the requirement to report them to the HTA, the types of incident to report, the process that should be followed, who should report them in the absence of the DI and within what timeframe they should be reported (five working days) (see advice item 2).	Minor
d) information about incidents is shared with all staff to avoid repeat errors	The HTA has not seen any evidence of the sharing of information regarding incidents for future learning. This is largely due to the lack of governance meetings which have only recently been re-introduced. These provide a good opportunity for discussing incidents and making sure that staff benefit from the findings of root cause analyses.	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	Risk assessments of mortuary activities appear to have only been conducted in 2017. They are set out in an uncontrolled document which is very brief and does not contain adequate detail of the risks and who is responsible for any mitigating actions that need to be taken to address identified risks.	Minor
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	See GQ6 (a)	Minor

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

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)	On two bodies with same/similar names stored at the time of the inspection, the names on their wristbands were spelled differently from their names on the mortuary board, which could lead to errors in identification. In addition, the format of names written on the mortuary board is inconsistent.	Minor
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	There is evidence of poor practice in relation to traceability procedures. During the HTA body audit, the body of a person with a similar name to another deceased in the mortuary was found to have only one identifier on a single wristband. This contained a first and last name that was spelled differently from the name recorded in the mortuary register and on the mortuary whiteboard.	Major
d) There is system for flagging up same or similar names of the deceased	The system for flagging up same/similar names is not sufficient to mitigate the risk of error in identification (see T1 (a) above). Same/similar names are not highlighted in the mortuary register.	Minor

Advice

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

No.	Standard	Advice
1.	GQ1 (h)	Governance meetings have recently been re-introduced however are not attended by all mortuary staff. The DI is advised to implement regular mortuary meetings that can be attended by all staff and these should also be minuted.
2.	T1 (g)	Often, PM tissue is sent to referral centres for specialist examination. The tissue (blocks and slides) are returned referencing a new identifying number, assigned by the referral centre. The DI is advised to implement some form of indicator, for example, a card placed in the block and slide store, to indicate that the samples have been sent off site and to prevent loss of traceability to the tissue.
3.	T1 (o)	There is no system in the PM suite to prevent mix up of organs and tissues during PM examination. This has not resulted in a problem thus far as only one or two PM examinations have taken place simultaneously. However, as coronial workload is due to increase, the DI is advised to establish a system to prevent organ and tissue mix-up when three post mortem examinations are taking place simultaneously.
4.	T2 (a)	The DI, in conjunction with the maternity department, is advised to implement a documented system for the receipt and release of NVFs to and from the mortuary, highlighting when specimens are ready for disposal. The current informal arrangement is that the porters bring the NVFs to the mortuary with accompanying paperwork, however this is not always consistent.
5.	T2 (f)	The DI is advised to take steps to ensure that tissue is not kept for longer than necessary. This may mean working with the Coroner to agree a process or a means of regular communication (refer to HTA's communication flow chart for coroners' examinations Annex B in the Code of Practice on PM examination: https://www.hta.gov.uk/sites/default/files/Code%20B%20-%20PM%20Final_0.pdf).

Concluding comments

Despite the number of shortfalls, the HTA considers the DI to be a suitable person to oversee the conduct of licensed activities. He and the Director of Support Services are dedicated to making improvements and have the commitment of the mortuary team. Although the DI is the Medical Director, he has time protected time to fulfil the role and his duties with regards to the mortuary.

There were example of good practice observed throughout the inspection:

- The premises are extremely clean and in good condition and there are robust security measures outside the mortuary;
- The shuttle form that has been developed for the processing of PM tissue is very detailed and acknowledges each stage of tissue movement from receipt to dispatch, preventing loss of traceability within the Trust.

There are a number of areas of practice that require improvement, including 3 major shortfalls and 21 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: 14/06/2017

Report returned from DI: 16/06/2017

Final report issued: 21/06/2017

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: 16 August 2017

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
<p>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.</p> <p>b) There is a documented standard operating procedure (SOP) detailing the consent process.</p> <p><i>Guidance</i></p> <p><i>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.</i></p> <p>c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.</p> <p><i>Guidance</i></p> <p><i>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.</i></p> <p>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.</p> <p>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.</p> <p>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.</p> <p>g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.</p>

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 or 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

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.