Site visit inspection report on compliance with HTA licensing standards

Bradford Royal Infirmary

HTA licensing number 12244

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 August 2017

Summary of inspection findings

This is the first inspection of this establishment against the revised HTA licensing standards, which came into force on 3 April 2017.

Although the HTA found that the establishment had met many of the HTA standards in most areas, a number of shortfalls were found. This includes a critical shortfall in relation to a number of wet tissue samples, blocks and slides held beyond the time necessary for the Coroner's purposes. This shortfall had been identified on the previous inspection and the HTA had been assured it had been addressed. Four major shortfalls were identified in relation to audits, training for those seeking consent takers risk assessments. In addition, nine minor shortfalls were found in relation to consent training, risk assessments and standard operating procedures (SOPs). Several of these minor shortfalls were also identified during the previous inspection, but the actions agreed at the time had not been undertaken or had ceased during the period intervening the inspections.

Examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

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

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

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

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

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

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

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

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

Background to the establishment

Bradford Royal Infirmary is part of the Bradford Teaching Hospitals NHS Foundation Trust and the mortuary comes under the management of the Diagnostics Directorate. The DI is a Consultant Histopathologist and the Corporate Licence Holder Contact is the Chief Executive. At the time of inspection there was only one member of staff working in the mortuary; this had been the case for a number of months but a new Mortuary Assistant was due to start a few weeks after the site visit.

The mortuary is located in a separate building close to the main hospital; it is secured by a key lock, to which a limited number of people have access, and closed-circuit television (CCTV). Deceased patients from the hospital are transferred to the mortuary by the hospital porters, through a swipe card controlled 'staff only' access door, which is close to the mortuary building. One contracted funeral director has a set of keys for use when bringing bodies from other hospitals out of hours, but during the day they use an intercom buzzer to gain access to collect the deceased.

The establishment does not receive bodies from the community; however, they occasionally receive bodies from other hospitals in the Trust when there is a requirement for hospital consented post mortem (PM) examination or when cremation papers need to be signed. Consent for adult hospital PM examinations is sought by clinicians, recently with the additional support of the bereavement staff. The clinicians may not have been trained in the requirements of the Human Tissue Act (HT Act). Furthermore, bereavement staff have not had any recent training on the requirements of the HT Act in relation to consent *(See shortfall against standard C2(a)).*

Occasionally brain and spinal cord removal is carried out within the mortuary, and NHSBT tissue teams attend to remove donated tissue. Perinatal and paediatric cases are sent to another HTA-licensed establishment for PM examination. Consent for these is sought by bereavement midwives, using forms and information leaflets provided by the establishment who undertake the PM examinations. These forms are based on the model consent form provided by the Stillbirth and Neonatal Death charity, SANDS.

The mortuary body store comprises 50 fridge spaces, including four that that can accommodate bariatric cases, and two freezer spaces. There is a separate fridge for pre-term babies and products of conception. The freezers are quite small in size and cannot accommodate bariatric bodies; in order to mitigate the risk of decomposition of any bariatric bodies that require long term storage, the establishment has an agreement with another HTA-licensed establishment for additional freezer storage. However, when the establishment recently asked to invoke this agreement, the request was refused.

The fridges have a remote temperature monitoring system that contacts the hospital estates department when triggered. The upper trigger point is set at 9°Celcius; however, the alarm

system has not been tested. In addition, staff were unsure whether there is a lower temperature trigger and, if there is, it has never been tested *(See shortfall against standard PFE2(e)).* The temperatures are recorded manually during the week.

The PM suite contains one fixed, height adjustable, PM table and a trolley table; the rollers on the trolley table show signs of rust. Whilst there are very few PM examinations, there is a colour-coded system in place to avoid the mix up of organs if two examinations were to take place at the same time. The airflow system in the PM suite was working to such a poor standard that it has now been switched off. A business case for a new system has recently been approved *(See shortfall against standard PFE3(c)).*

Receipt and release procedures for adult bodies have a strong focus on ensuring that there are a minimum of three identifiers. This system is followed when the deceased arrives from the hospital and when a body is released to funeral directors. There is a same or similar name system to highlight to staff that additional care may be required on release. These systems are not in place for pre-term babies or products of conception that are stored in the mortuary prior to release for burial *(See shortfall against T1(c) and (d)).*

Viewings of the deceased are arranged via the hospital bereavement service or directly with the mortuary. Out of hours viewings are infrequent and are managed by the site team, who are trained to confirm with the family who they have come to see.

Description of inspection activities undertaken

This report describes the HTA's third, routine site visit inspection of the establishment. The last inspection was carried out in 2012 and was a themed inspection, which covered a subset of the Consent, Governance and Quality systems standards. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the body store, PM suite and viewing area.

A traceability audit was conducted for three adult bodies, including one in freezer storage, and one paediatric case. The audit included checks of storage locations and identifiers recorded in the paper records and the corresponding mortuary register entries. No anomalies were identified.

A conversation with the DI prior to the inspection, identified that there was tissue in storage, under the licence which may have been retained after Coronial authority had ended. The DI had subsequently received from the Coroner a list of all outstanding inquests, which the DI is currently trying to reconcile against laboratory records. However, there is no up to date list of exactly what tissue and organs are being stored in the mortuary building which means that the DI cannot accurately identify what the establishment holds in order to compare it with the list from the Coroner. This had been identified on previous inspections and the HTA had been assured that the issue had been addressed *(see shortfall against T1(a)).*

Inspection findings

The number and severity of shortfalls identified is of significant concern to the HTA, particularly as the HTA had previously been assured that action was taken to remedy some of these shortfalls. Taken together, we believe these shortfalls demonstrate that the DI has not ensured that there are suitable practices in place for the conduct of licensed activity

This calls into question the suitability of the DI and the HTA will be maintaining oversight of the actions taken to address these shortfalls, to ensure that they are rectified promptly and appropriately. A follow-up site visit inspection will be undertaken to provide the necessary assurance.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
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	Only one member of the Bereavement staff involved in seeking consent for adult hospital PM examinations has received training about the requirements under the Human Tissue Act and this training was approximately 10 years ago; there has been no refresher training since. Additionally, consent is not always sought in the presence of trained staff. Until recently, clinicians were unsupported by bereavement staff and it was possible that the people who were involved in taking consent had never received any training in relation to the consent requirements of the Human Tissue Act. There has been at least one occasion, mentioned to the inspection team, where a family, having given consent, contacted the bereavement service to ask questions at which point it became clear that the information given to them at the time they gave consent was insufficient to enable them to give informed consent. *(See advice item 1)*	**Major**

b) Records demonstrate up-to-date staff training	As there is no regular training for staff, records cannot demonstrate up-to-date training. Training has been arranged for staff who seek consent for paediatric and perinatal PM examinations; however, this will be specific to the forms used for these activities and will not cover the hospital's adult PM examination consent forms.	**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.	Some of the mortuary SOPs do not accurately reflect current practice and in some cases do not contain sufficient detail of identification procedures. Examples include, but are not limited to: - SOP BRIM003.04 for Coroner's PM examination doesn't state what identifiers should be checked before transfer of a body to the public mortuary; - SOP BRIM004.04 on Hospital PM examinations states that an Executor can give consent; this should be a Nominated Representative. The document also refers to Next of Kin but makes no mention of the hierarchy of qualifying relationships as set out in the Human Tissue Act. Additionally, the document refers to brain removal as if it's standard practice, rather than checking that consent is in place; - SOP BRIM015.03 Storage of Babies refers to a fridge on the maternity ward; however, current practice is to transfer deceased babies to the mortuary immediately and there is no longer a fridge in maternity; - SOP BRIM020.02 Infant PM examinations is still a live document but infants are now transferred to another HTA-licensed establishment for PM examination.	**Minor**
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	Some SOPs are version controlled and ratified by someone other than the author but not all. There is a new records management system in the pipeline but there is no confirmation when it will be implemented.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There are no process audits undertaken of activity in the mortuary or of tissue samples being stored under the licence. This was identified as a shortfall on the previous inspection, after which the DI assured the HTA that six monthly audits would be undertaken.	**Major**

GQ4 There is a systematic and planned approach to the management of records		
a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	There are plans to introduce a new records management system for the mortuary however there is currently nothing in place and it is unclear exactly when the new system will be implemented and what areas it will cover.	**Minor**
b) There are documented SOPs for record management which include how errors in written records should be corrected	There is no SOP for records management in place.	**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	Health and Safety risks have been identified but no risks to the deceased have been assessed. This issue was identified during the previous inspection and assurance was supplied by the DI that appropriate risk assessments would be carried out.	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is system for flagging up same or similar names of the deceased	There is a same or similar name system in place for adults but this is not applied to pre-term babies or products of conception in the mortuary register; this is especially problematic when the mothers full name is not recorded.	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	There are a number of organs, wet tissue samples, blocks and slides in storage at the establishment, some dating back to 2006. The establishment does not have an accurate record of exactly what specimens they have in storage. Additionally the establishment has not cross-checked the tissue against the wishes of the family in relation to retention or disposal, nor have they clarified with the Coroner whether the investigations are complete. Even though the tissue is not being stored for a scheduled purpose, the long-term storage of tissue samples is not considered appropriate. The inspection team identified tissue in storage from one case that should have been returned to the family, as per their wishes. This issue was identified as a major shortfall during the previous inspection and despite assurances to the HTA the issue has not been fully dealt with.	**Critical**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	The mortuary viewing room door that leads to the body store area cannot be secured when families attend for viewings. The lack of access control means that visitors to the mortuary could enter the body storage area unrestricted. This presents a risk to the dignity of the deceased, and the safety of 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 freezer spaces at the establishment are relatively small and cannot accommodate bariatric bodies. The establishment has a mutual aid agreement with another licensed establishment to help with storage issues when they arise. However, at the time of inspection there was a body that should have been in storage at -20^{o}Celcius but was too large for the establishment's own freezers. In this case the mutual aid establishment had refused to assist the mortuary. This has left the body at risk of increased decomposition and is a risk to the dignity of the deceased.	**Minor**

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The fridge and freezer units are alarmed; however, these are not tested, including the follow up process. Staff were unaware as to whether there is a lower temperature alarm trigger or whether the fridge for pre-term babies and products of conception was alarmed.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Due to poor functioning and the subsequent risks to the health and safety of staff and tissue retrieval teams, the ventilation system in the post mortem room has been turned off. However, the establishment is still undertaking tissue retrievals and post mortem activities to ensure the dignity of the deceased, such as cleaning, within the post mortem room.	**Major**

Advice

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

No.	Standard	Advice
1.	C2(a)	The Association of Anatomical Pathology Technologists, in association with the HTA, run consent training courses; the DI is advised to ensure staff attend, this, or similar, training.
2.	GQ1(e)	There is a form that records that staff have read SOPs and this form is signed and dated by staff. However, the form itself references the first version of the SOP when the list was started and does not record the actual version number that staff have read. The DI is advised to amend this document to record the exact version of the SOP.
3.	GQ1(g)	The DI is advised to consider adding Persons Designate to the licence for maternity and A&E, to ensure there is full oversight of all activities under the licence.
4.	GQ5(a)	The HTA Reportable Incident SOP is out of date. The DI is advised to ensure they are working with the most recent guidance documentation from the HTA when reviewing the SOP.
5.	GQ5(b)	The Trust Incident Reporting and Investigation Policy V3 includes a list of external agencies who should be informed in the case of an incident; the HTA has not been included in the list. The DI is advised to ensure that the HTA is added to this list.
6.	GQ6(a)	The HTA has developed an advice document for establishments that demonstrates how the HTA reportable incident categories can be used to develop risk assessments. The DI is advised to consider this document when reviewing risk: https://www.hta.gov.uk/policies/regulation-post-mortem-sector-2014-16-what-we-have-learned

7.	T1(c)	For adult bodies, the systems for identification are robust. However, for pre-term babies and products of conception only the mother's surname along with the prefix of 'Baby of' is entered into the mortuary register. This could easily lead to misidentification. The DI is advised to ensure that the mother's details are recorded in the register and that release only happens on the presentation of these details by the funeral director.
8.	T1(g)	The mortuary numbering system restarts at the beginning of each year to make it easier to identify the number of bodies received into the mortuary. However, if any bodies remain in freezer storage for a length of time, this runs the risk of two people having the same mortuary number at the same time. The DI is advised to add a year pre-fix to the start of the mortuary number.
9.	T2(d)	The system in place to record that tissue has been disposed of records when and how tissue is disposed, but has no detail of who arranged the disposal. The DI is advised to considered recording this information.
10.	PFE2(c)	When the establishment asked to invoke the mutual aid agreement with the neighbouring HTA-licensed establishment for freezer storage, the refusal was not escalated to the DI. The DI should ensure that there is an escalation process in place so further steps could be taken if the scenario were to arise again in the future.
11.	PFE2(f)	The temperature of the storage fridges averaged around 6 to 7°Celcius in the period leading up to the inspection; this is above the sector norm. The DI is advised to investigate why the fridge temperatures are running higher than recommended and, to ensure they are adjusted to average at 4°Celcius.
12.	PFE2(g)	The bodies in the freezer were only wrapped in sheets. The DI is advised to ensure the deceased are also placed in body bags before being placed in freezer storage.
13.	PFE3(a)	The rust on the rollers on the PM trolley table means they cannot be properly decontaminated; the DI is advised to replace them.
14.	PFE3(c)	A business case for a new ventilation system in the PM suite has recently been approved; however, the specification was only for four air changes per hour rather than the required 10 changes. The DI is advised to review the specification to ensure the new system meets the required standards.
15.	N/A	Due to the small number of PM examinations, clear viscera bags have not been ordered; the DI is advised to ensure they are available prior to any PM examinations taking place.

Concluding comments

The HTA viewed some areas of strength and it is clear that the mortuary manager, despite having to work without an assistant for a number of months, is implementing a number of changes to further strengthen practices.

- Rotating the use of a different colour pen helps to easily identify the bodies that have been in the mortuary for more than two weeks and facilitates the management of storage capacity;
- Signage is used to good effect throughout the mortuary;
- The mortuary Manager is committed to increasing awareness and understanding of the activities undertaken so hospital staff are better equipped to answer questions from families.

There are a number of areas of practice that require improvement, including one critical, four major, and 11 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: 25 September 2017

Report returned from DI: 6 October 2017

Final report issued: 19 October 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: 13 February 2019

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the

Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required.

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and

records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place

present a risk to traceability. Full identification checks should be made when 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.