Site visit inspection report on compliance with HTA licensing standards

Royal Glamorgan Hospital

HTA licensing number 12338

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**

28 and 29 March 2018

Summary of inspection findings

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

The HTA found that Royal Glamorgan Hospital had a total of 19 major and 13 minor shortfalls against the Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards. These related to policies and training for paediatric/perinatal post-mortem examinations; training and documentation relating to HTA reportable incidents, portering staff, governance meetings, standard operating procedures, risk assessments and audits; traceability of bodies and tissue retained during post-mortem examinations; fridge and freezer maintenance and alarms; post-mortem room ventilation; and security.

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

Royal Glamorgan Hospital (the establishment) is part of the Cwm Taf University Health Board. This report refers to the activities carried out at the Royal Glamorgan Hospital (RGH; the hub site) and the Prince Charles Hospital (PCH; the satellite site). The Histopathology Manager manages the mortuary, the DI is a Consultant Histopathologist and the Corporate Licence Holder contact is the Chief Executive Officer. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes) and; storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes.

The establishment runs a PM examination service across the two centres, performing PM examinations three days a week at RGH and two days a week at PCH. There are four full time Anatomical Pathology Technologists (APTs) who work across the two sites, under the direction of a lead APT. The establishment receives approximately 2300 bodies each year from both the hospital and community, performing around 620 PM examinations a year, including high-risk (up to hazard group 3 biological agents); the majority of the PM examinations are conducted for HM Coroner for South Central Wales. Another HTA-licensed establishment performs paediatric/perinatal PM examinations although consent is sought for these PM examinations by on site clinicians and midwives. Consent for hospital ('consented') PM examinations is sought by trained pathologists and is recorded using the NHS Wales consent forms and patient information booklets. The form used to record consent for paediatric/perinatal cases is the NHS Wales consent form supported by the associated information booklet, based on the SANDs consent form. Both adult and paediatric/perinatal forms used to record consent are compliant with statutory and regulatory requirements.

The establishment has a total of 42 refrigerated body spaces (at the hub), including five spaces that are suitable for bariatric bodies. The establishment however does not use the bottom row of the refrigerated units, as it is difficult to access using the mortuary trolleys, resulting in only 35 spaces in general use. There are two spaces reserved for paediatric/perinatal cases and pregnancy remains (see *Advice*, item 21). The establishment had a PM suite viewing room that had problems with rising damp. Rather than renovating and retaining the viewing room, the establishment converted it into a 4°C 'cold room' with spaces for eight bariatric bodies and three additional storage 'bays' capable of accommodating bariatric bodies. The establishment stores larger bariatric bodies on an embalming trolley that is also used during PM examinations. At the time of inspection, there was a body on the embalming trolley within the cold room (see shortfall against PFE3(b)).

Swipe card or key lock access is required for both external doors to the mortuary. There is no hospital CCTV coverage of the access doors to the mortuary or intercom system, and visitors request access to the mortuary by ringing a door bell (see shortfall PFE1(d)).

Portering staff transfer and admit all hospital bodies to the mortuary. Bodies are transferred from the ward through the main hospital and across a hospital service area used by Health Board vehicles (see *Advice*, item 23). Community and hospital bodies are brought into the mortuary through the rear entrance, accessed through a covered area allowing vehicles to reverse up to the mortuary rear entrance (see shortfall against PFE1(d) and *Advice*, item 15).

It was stated that the mortuary staff had provided training in mortuary practices to the portering supervisors and this training is cascaded to the wider portering team (see shortfall against GQ3(a)).

On arrival in the mortuary, portering staff place bodies in an available refrigerated body space, together with the 'Notification Of Death' (NOD) form (see *Advice*, item 9). During working hours, mortuary staff log the body into the electronic system and generate a unique mortuary ID that is printed on labels and attached to the body ID bracelets. If a PM examination is requested, these unique identifying labels are also attached to relevant paperwork. The unique number is also added to the mortuary register; however due to restricted space in the current register, a label is not placed in the register at RGH (see *Advice*, item 3). If a body is admitted out of hours, mortuary staff will determine that a body has been placed in the refrigerated body spaces during their morning checks of the body store (see *Advice*, item 9). Once body checks are completed, the staff log the bodies into the electronic system. Mortuary staff complete the mortuary register and place the names of bodies on the relevant fridge door whiteboards, but do not currently log the location into the electronic system or the mortuary register (see *Advice*, item 10).

Where possible, PM cases are scheduled, and mortuary staff notified, the day before the examination. A minimum of three points of identification are used to confirm the identity of all individuals prior to PM examination and pathologists perform an external examination prior to evisceration. Material taken for subsequent histological examination is labelled in the mortuary and transferred to histopathology together with a histology request form (see shortfall against T1(g)). On receipt of tissue retained following PM examination in the histology laboratory, the tissue pieces are trimmed, embedded and processed. If necessary, pathologists will dissect organs in the laboratory to remove tissue pieces for embedding and subsequent processing. Blocks are logged into the electronic laboratory database, which in some cases will either record the number of organs received, or the blocks generated from individual organs in the laboratory, or a combination of both (see shortfall against T1(g)). The departmental secretaries transcribe the number of blocks and organs taken during PM examination into the PM specimen spreadsheet, which also records links to scanned copies of the Hospital or Coronial (when received from the Coroner) consent form, PM examination notes, and Histology request form. There is a single column in the spreadsheet for recording the amount of tissue taken during PM examination and it was apparent that the number of blocks recorded was actually the total number of tissue blocks, pieces of tissue, and whole organs taken during the PM examination. This did not account for individual items or blocks

subsequently generated in the laboratory (e.g. from organs) (see *Advice*, item 13). Historically the laboratory did not retain the paper histology request form, although the current procedure is to retain the paper form and scanned copy.

The maternity unit at RGH has a fridge for the storage of fetuses and pregnancy remains prior to the transfer to the mortuary (see shortfall against PFE2(e)). Laboratory staff collect perinatal/pregnancy remains of less than 24 weeks gestation from the wards while theatre staff transfer pregnancy remains directly to the histology laboratory. After processing, laboratory staff dispose of residual material sensitively, or arrange for the transfer of the remains to the mortuary, depending on the wishes of the family (see shortfall against T1(b)).

The PM suite at RGH contains three non-downdraft PM tables. The establishment utilises a system of coloured containers to minimise the risk of organ and tissue mix-up. The establishment reported that maintenance and servicing of the PM suites ventilation system is overseen by the Estates department; however, they were unable to provide any documentation relating to maintenance or servicing during the inspection. Following the inspection, the Estates department informed the HTA that there is no formal reporting for the ventilation assessment but they have measured the airflow at 9.8 changes per hour and would expect it to exceed 10 airchanges per hour with equipment in the room (see shortfall against PFE3 (c)).

Prince Charles Hospital (the satellite site)

The mortuary at PCH has 40 refrigerated body spaces, four fridge spaces that could be converted to freezer body spaces and eight bariatric spaces. A bank of refrigerated spaces are reserved for paediatric/perinatal bodies, products of conception and pregnancy remains.

Community bodies are delivered to the mortuary at PCH through a dedicated rear entrance. Funeral Directors (FD) approach a roller shutter door system and contact mortuary staff using a voice-only intercom system. The door is raised using a button located next to the door itself, requiring staff to go to outside to allow FDs to reverse in to the covered ‘car port’ area (see shortfall against PFE1(d)).

Porters transfer all bodies to the mortuary from the wards at PCH. On admission to the mortuary, portering staff transfer the bodies, together with the NOD form provided by the ward, into an available refrigerated body space and log the deceased’s details into the mortuary register (see *Advice*, items 2 and 9). Mortuary staff log the details into the electronic database and assign a unique ID to the body using the same system as RGH. They place a sticker with the unique ID into the mortuary register with the location of the body.

PCH have an obstetrics and gynaecology ward containing a fridge for the storage of products of conception (POCs) or fetuses prior to their transfer to the PCH specimen

reception, for transfer to the mortuary and subsequently to the histology laboratory at RGH (see shortfalls against PFE1(e), PFE2(e) and PFE2(f)).

The PM suite at PCH contains three downdraft PM tables in a large room and an additional PM table in a separate room for high risk cases. Each table has an associated dissection bench. Pathologists complete each PM examination before commencing the next case to help mitigate against any risk of a mix-up of organs and tissue samples between cases. As at RGH, estates oversee the servicing and maintenance of the satellite's ventilation system. During and after the inspection, the establishment were unable to obtain service or maintenance records from the Estates department (see shortfall against PFE3 (c)).

Description of inspection activities undertaken

The establishment has been licensed by the HTA since November 2007 and this report describes the third routine inspection, with the last occurring in February 2014. This was the first inspection of the establishment against the HTA's revised licensing standards, which came into force in April 2017. The current DI has been in post since the licence was granted and was present during previous inspections. Formal interviews were conducted with the DI, Mortuary staff at the RGH and PCH, the lead APT, maternity staff, PM consent seekers (adult and perinatal), a Coroner's officer and hospital portering staff. A visual inspection of the premises was conducted at both the hub and satellite sites including the body stores, viewing rooms, PM suites and of areas within the maternity and gynaecological wards where fetuses, POC and pregnancy remains may be stored. The emergency departments at both RGH and PCH confirmed that they follow the 'NHS Wales' guidelines for 'Procedural Response to Unexpected Deaths in Childhood (PRUDiC) 2014' and do not collect relevant material from the deceased.

Traceability audits of body identifiers, storage locations and mortuary register details were carried out for three adult bodies at RGH and three adult bodies and one fetal body at PCH. In addition, tissue taken during PM examination was audited for traceability for three individuals at RGH and four individuals from PCH.

Audit findings from RGH (the hub)

Three adult bodies (one from the community and two from the hospital) were randomly selected from the body store. The names of the individuals were written on the fridge doors, but the body location was not noted in any of the mortuary documentation. All three bodies had the accompanying NOD forms, but it was noted that the age section of the NOD form was completed inconsistently, sometimes with age in years and sometimes with the patient hospital label including the date of birth, and that this information (age or date of birth) was recorded in the mortuary register (see *Advice*, item 2).

As part of the inspection, tissue collected during the PM examinations of three individuals in 2016 and 2017 was audited for compliance with the associated consent records. Anomalies were found in all three cases (see shortfalls against T1(g), T2(a) and T2(c)).

Audit findings from PCH (the satellite)

Three adult bodies were randomly selected from the body store and while no anomalies were found, one individual was observed to be leaking fluids, but had not been placed in a body bag (see *Advice*, item 18). When prompted, mortuary staff advised the inspection team that fetal tissue had been discovered earlier that morning, that had been in refrigerated storage since early 2018 (see shortfall against T1(b)).

As part of the inspection, tissue collected during the PM examinations of four individuals in 2016 and 2017 was audited for compliance with the associated consent. Anomalies were found in three of the four cases (see shortfalls against T1(g), T2(a) and T2(c)).

Inspection findings

The HTA found the establishment to have 19 major and 13 minor shortfalls against the HTA's licensing standards for the PM sector.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.	The establishment does not have a single documented policy that governs consent for post-mortem examination of tissue. While much of the required information is contained in a range of documents, this needs to be collated in a single concise document and updated to refer to the hierarchy of qualifying relationships rather than 'Next of Kin' (NOK). Under the Human Tissue Act 2004 (the Act) consent for non-coronial PM examinations must be provided by the person highest in the hierarchy of qualifying relationships, as defined in the Act.	**Minor**

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 some staff may have received training in seeking consent for PM examinations on fetuses, babies or children, following the All Wales procedures, Maternity department staff at RGH could not remember when they had received training and stated there was no system in place to ensure that training was delivered and refreshed regularly. The paediatric consultant interviewed at PCH informed the inspection team that they had not received any specific training in the seeking of consent for PM examination and were unaware of options for disposing of tissue after the PM process. As individuals who have not undergone specific consent training do seek consent, the standards C2(c) and (d) cannot be met.	**Major**

b) Records demonstrate up-to-date staff training	While there is a record of the individuals from both RGH and PCH who have received training in seeking consent for perinatal/paediatric PM examination, it was apparent that individuals who had not received training had sought and obtained consent. It was unclear if establishment staff understood who is authorised to seek consent, and if they have received refresher training.	**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.	While the establishment has several SOPs in place, the SOPs do not cover all of the procedures which the establishment is carrying out under its HTA licence. This issue was identified in the establishment's internal audit (Dec 2017) where it was noted that >90% of mortuary documents required revision and/or rewriting. The establishment is in the process of migrating its documents to a new document control system and has taken the decision to update all documents prior to their transfer into the new system rather than to migrate non-compliant documents. Procedures being undertaken at the establishment but where there was no suitable SOP include, but are not limited to: • contingency plans and a procedure for moving bodies to contingency storage before all of the establishment's capacity is used; • the management of bodies in long term storage. • lone working.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Portering staff at the satellite establishment reported that when the refrigerated body store reaches capacity, they place bodies on PM tables in the PM suite; this has happened on a number of occasions. This practice does not provide dignified storage of the deceased.	**Major**

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	There were examples of documents that had been written, reviewed and authorised by a single individual. These included, but were not limited to: - SOP for 'Transfer of bodies to other institutions MTBOI' version 1 - SOP for 'The storage and disposal of clinical materials received and generated by cellular pathology' version 2.2 - Quality Manual version 6.11	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The DI reported that he thought there was no storage of relevant material (e.g. fetal remains and products of conception) at the Maternity and Gynaecology wards. During the inspection, it was found that material was stored in both of these areas prior to transfer to the mortuary. Storage times of the material prior to transfer to the mortuary usually ranged from 24 to 72 hours, but could be for extended periods of time if there were issues with obtaining information or instructions from the family. The DI had no oversight of these activities.	**Major**

GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	The inspection team were told that tissue audits have been regularly carried out but they were difficult to complete as the establishment had not received the instructions from the deceased's family with regards to tissue retained during PM examination for some of the Coronial cases. The establishment did not record the individual cases as audit findings and did not follow them up as a response to the audit, to establish the deceased family's instructions for tissue (see also shortfall against T2(b)).	**Major**

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Although there is an audit schedule in place covering 2017 onwards, there is no evidence that the audits are being completed and that audit findings are being followed up. A recent audit of stored tissue conducted in quarter one of 2018 has identified that tissue dating back to 2016 that should have been disposed of has been retained. Tissue prior to 2016 has not been audited, but it is likely that this issue will include all stored tissue. This has been raised as a HTA reportable incident but indicates that any audits carried out prior to this were not adequate. Subsequent to the inspection the establishment have extended the audit to cover stored tissue from 2014 and plan to perform a complete audit of all stored tissue.	**Major**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	While mortuary staff do undergo both induction and competency-based training in mortuary procedures, they were unaware of the HTA Reportable Incident (HTARI) categories. In addition, there was no evidence that staff had received training specifically related to the requirements of the Human Tissue Act 2004 and the codes of practice. (see *Advice*, item 6) Portering staff transfer bodies to the mortuary from the wards at both sites. Mortuary documents indicated that mortuary staff provide training to the senior porters and this is cascaded to all porters. However, there was no evidence that this training had been cascaded and porters indicated that they had received no specific mortuary training.	**Major**

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	Incidents are reported through the Health Board DATIX system and recorded on the mortuary non-compliance spreadsheet. However, during the visual inspection and interviews with mortuary staff, who reported that they were not aware of the HTARI reporting requirements, it became evident that there were a number of incidents that had not been reported, either internally (including to the DI) or to the HTA. As mortuary and portering staff indicated they were unaware of the HTARI reporting requirements and there was evidence that they had not reported a number of incidents it was not possible to assess the standards GQ5(b) to (d).	**Major**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The establishment does have a number of risk assessments (RA) in place; however, the majority of these related to Health and Safety rather than HTA relevant activities. An internal audit undertaken by the establishment identified that, as the majority of SOPs do not reflect current practices and require updating, the RAs based on SOPs are also incomplete/inadequate. As this standard was not met standard GQ6(b) could not be assessed	**Major**

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)	During the body audit at the PCH body store issues were identified with fetal remains. There were discrepancies with documentation and staff were unclear when some remains had been brought to the mortuary. Record keeping was inconsistent for the remains reviewed These issues resulted in delays for follow up in the cases that were reviewed as part of the inspection. Further traceability issues were identified by the establishment during the inspection. These incidents have been raised as a HTA reportable incidents. The establishment's procedure is that products of conception with a gestation of less than 24 weeks are transferred directly to the laboratory. During the inspection however, it was noted that portering staff often transfer this material directly to the mortuary and place it in refrigerated storage. As no paperwork is left for mortuary staff and they do not routinely check the allocated fridge spaces for pregnancy remains, there were several instances where mortuary staff were unaware that this material had been brought to the mortuary. In addition, there were no records available at PCH recording storage or transfer of tissue from the early pregnancy unit. The only documentation used was the 'Certificate of midwife/nurse/medical practitioner in respect of Fetal remains' form that accompanies the tissue to either the laboratory or the mortuary. The maternity ward at RGH maintains a record of material in storage and its subsequent transfer. At the time of inspection it was noted that the record book was new, containing a single entry. Staff were unable to provide the previous record book.	**Major**

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	Three identifiers are used when admitting bodies to the mortuary. In addition, when entering the deceased's details onto the establishment's electronic tracking system, a unique mortuary identification number is generated. The establishment's system prints labels that are attached to paperwork relating to the deceased and the deceased's identity bracelets. However, families are not asked to provide three identifiers when attending the establishment to undertake a viewing of the deceased and often, only the name of the deceased is used. In addition, bodies are released from the mortuary to funeral directors using the 'Disposal order' form. While Funeral Directors may add additional identifying information to the back of the form, the inspection team witnessed mortuary staff releasing a body using the name of the deceased only. The use of less than three separate identifiers when identifying bodies presents a risk of misidentification and potentially the viewing or release of an incorrect body.	**Major**
d) There is system for flagging up same or similar names of the deceased	At PCH, names are not currently placed on individual fridge spaces. Mortuary staff obtain body location information from the mortuary register. Staff indicated that individuals with the same or similar name were highlighted in the mortuary register. While this was observed to be the case for two individuals with the same surname, it was noted that two other individuals recorded on the same page, who had the same surname and had been in the mortuary at the same time, were not highlighted. (see *Advice*, item 12)	**Minor**
f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register	There are currently no documented SOPs describing when bodies should be placed into long term storage, or for the release of bodies that have been in long term storage.	**Minor**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	A record of the quantity of tissue blocks retained at PM examination is recorded on the histology request form that is sent with the tissue to the laboratory. The details of the tissues taken are recorded once they are booked in at the laboratory. During the tissue traceability audit it was noted that the number of blocks recorded in the laboratory database and PM specimen spreadsheet did not match those listed on the histopathology request form and was often a combination of the blocks taken during PM examination and whole organs, or included the blocks created from organs during dissection in the Histopathology laboratory (see *Advice*, item 13). Based on these findings the inspection team was not assured that specimens received in to the histopathology laboratory at RGH were accurately recorded. Staff reported that organs received into the histology laboratory are often dissected into smaller pieces of tissue for embedding. Rather than recording receipt of the whole organ, the establishment records the number of blocks created from the organ in the laboratory's electronic system. Residual tissue following the creation of the tissue blocks is disposed of when the pathologist confirms it is no longer needed. In addition, there are no records of when PM specimens are transferred from the mortuary. This includes transfer to the pathology reception at PCH, for transport to the histopathology laboratory at RGH, or when samples leave either mortuary and arrive at the histopathology laboratory. This gap in records means that the traceability of tissues taken at both mortuaries cannot be sufficiently audited. A number of blocks and slides were audited during the inspection. Of four sets of tissue taken during PM examination at PCH anomalies were found with two: • One set of tissue had been recorded as having two additional 'recut' slides for H&E staining but were recorded under an incorrect PM number • One set of tissue should have had 14 blocks and 15 slides on file, but the blocks could not be located, even though they had been 'counted' during a recent internal audit.	**Major**

	Anomalies were found with two sets of tissue taken from PM examination at RGH, of three sets that were audited; • One set of tissue recorded in the electronic database indicated two blocks and four slides (recently amended from two to four after the recent tissue audit). Two slides were found during the audit; • Samples from another PM examination recorded that 12 blocks were stored, and had been counted during the recent tissue audit. On inspection, one block was missing. The establishment are required to account for this missing tissue as part of their audit and CAPA follow-up process (see shortfall against GQ2(c)).	

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	As part of a recent tissue traceability audit undertaken by the establishment in preparation of this site visit inspection, the establishment have identified that blocks and slides from some PM examinations in 2015, 2016 and 2017 have been retained when they should have been disposed of.(see shortfall against GQ2(b)). (see *Advice*, item 14)	**Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The establishment has a good relationship with the Coroner's office and the Coroner's officers regularly check to confirm that there are no bodies in long-term storage that they are unaware of. However, the establishment has no formal procedures to establish the family's wishes with regards to tissue retained following coronial PM examinations where these wishes have not been received from the Coroner's office. Not receiving the family's wishes for tissues once the Coroner's authority had ended has been a finding on previous internal tissue traceability audits, which the establishment has failed to follow-up.	**Major**

c) Disposal is in line with the wishes of the deceased's family	In preparation for the inspection, the establishment performed a tissue audit of stored tissue. It was identified from documentation during the inspection that in one case, the establishment had made a decision regarding the disposal of retained tissue that was not in accordance with the consent given by the relatives and did not consult with the family regarding the decision. By chance, the establishment's instructions were not carried out and the tissue was retained, in accordance with the relative's wishes. Retrospectively, the establishment notified the family who were pleased that the tissue had been retained, as this was their wish. However, following the tissue audit prior to the inspection, the establishment have now disposed of this tissue (see *Advice*, item 14). This incident has further highlighted issues with the establishment's procedures for the management of tissue retained following PM examination. Current procedures for the repatriation of tissues to a body are considered 'completed' when mortuary staff have been notified there is tissue to be returned, not when the tissue has been physically repatriated and recorded. A robust and documented procedure is required to help mitigate the risk of tissues not being dealt with in accordance of the relative's wishes.	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	There were issues with the cleanliness and maintenance at both the PCH satellite site and the RGH hub site, including but not limited to. <u>PCH</u> - visible cracking and damage to the sealant between the PM suite floor and the base of the PM tables in the High Risk PM room and main PM suite; - residual blood on the floor of the main PM suite; - hair in the drains (High Risk and main PM suites); - blood and small pieces of tissue in the drain of main PM suite. <u>RGH</u> - there were signs of damp; the wall covering is peeling away from the wall in multiple areas; areas of flaking paint in the body store and PM suite; - there was evidence of mould in and around the body store area; - body store flooring dirty and in poor condition with cracks and noticeable damage; - the floor seals around the base of the stainless steel stanchions at the end of the PM tables and around the boot baths, are lifting; - visible rusting at the base of the refrigerated body store doors; - damage to the door into the viewing room. The issues identified above, in addition to poor cleaning and disinfection routines, pose a potential health and safety risk to mortuary staff and others who work in the mortuary.	**Major**

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 current access arrangements at PCH for funeral directors present a potential risk to the security of the establishment, the staff and the dignity of the deceased: • As there is no camera or mortuary CCTV, staff cannot visually verify who is requesting access at the roller shutter door and can only grant access by leaving the security of the mortuary office. There is no Health Board CCTV covering this area; • The roller shutter door is routinely left raised which poses a potential security risk; • The access doors (directly behind the roller shutter doors) in to the mortuary are clear glass meaning that mortuary activities, for example, the transfer of bodies in to the bodystore, could be observed by unauthorised persons; The roller shutter doors must be routinely closed, including when a funeral director is in attendance to ensure the dignity of the deceased when bodies are being admitted or released, and to protect against unauthorised access. (see *Advice*, items 15 and 16) The rear entrance through which bodies are admitted into the mortuary at RGH is 'protected' by a covered area, which prevents direct line of sight from some of the surrounding buildings, and allows cars to reverse up to the entrance. However, the entrance is overseen by an adjacent building containing the Histopathology laboratory and offices on the second floor. There appeared to be a direct line of site from the offices on the second floor, which may allow people working in the building to view bodies being admitted or released from the mortuary. This may impact on the dignity of the deceased. On arrival of the inspection team at the RGH premises, mortuary staff were releasing bodies, the rear door was left open and unattended, and the inspection team were able to enter the mortuary without being challenged.	**Major**

	There is no hospital CCTV coverage, or intercom system, to allow mortuary staff at RGH to verify who is requesting access. This compromises the security of staff and premises, especially out-of-hours. In addition, staff reported that external lighting was inadequate, posing a potential risk to staff work alone out-of-hours.	
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The fridges in which fetuses, products of conception and pregnancy remains are stored at the Maternity wards of both RGH and PCH, were not locked or in a secure room, although they were on secure wards. The viewing gallery for the PM room at PCH is accessed via the public reception of the bereavement office. During the inspection, it was noted that the door to the viewing gallery was left unlocked. This means that visitors to the bereavement office may inadvertently enter the viewing galley and see into the PM suite.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	The fridge and freezer units are under appropriate service contracts, but this is overseen by estates and mortuary staff were unaware of the outcome of service visits or any issues with the equipment. During the inspection, mortuary staff were unable to locate any service documentation. Following the inspection, service documentation for the fridges at the PCH site has been provided; however, it has not been possible to locate service records from the RGH site that are appropriately dated. (see *Advice*, item 22)	**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	Prior to the inspection, the DI stated that the maternity units at both the hub and satellite did not have fridges for the storage of perinatal bodies. However, during the inspection it became apparent that there were fridges on the maternity wards of RGH and PCH where paediatric/perinatal bodies, products of conception and pregnancy remains are stored. The fridges where the material was being stored in these areas were not temperature monitored or fitted with an alarm to alert staff to an equipment failure. While the refrigerated body storage and freezer units in the establishment's body stores were alarmed, this was overseen by Estates and mortuary staff were not aware of the acceptable temperature or trigger ranges. The establishment had no procedures in place to test the temperature monitoring alarm system to assure itself that the alarms were operating as expected should temperatures deviate from their expected ranges. At RGH, the fridge temperature range was reported as 0-5°C, with an alarm triggering at 5.2°C. The visual monitors on the wall indicated that some of the refrigerators were running at 9-13°C, but staff reported these had no relationship any longer to the refrigerated storage, and there was no way for staff to check the current running temperature. At PCH, the refrigerated body store normal range was reported as 4-8°C but staff were unaware of the trigger points. Both RGH and PCH had a separate laboratory fridge/freezer unit in the mortuary where tissue samples for DNA analysis could be stored. Neither unit was on the temperature monitoring alarm system. (see *Advice*, item 17)	**Major**

f) Temperatures of fridges and freezers are monitored on a regular basis	Paediatric/perinatal bodies, products of conception and pregnancy remains are stored in unmonitored fridges on the maternity wards at both RGH and PCH. Staff at both establishments visually confirm the fridges are working but this is not recorded or the method validated. While the main body refrigerated and frozen storage units are monitored at both RGH and PCH, the current system does not allow for a regular review of the temperatures. Although a new system that is being installed and currently running in parallel with the older system will facilitate the staff reviewing the temperatures of the storage fridges and freezers; however, it was not in routine use at the time of the inspection. In addition, there was a fridge/freezer unit in the RGH body store and in the PCH main PM room where tissue for future DNA analysis may be stored which was not connected to the monitoring system. There is a wireless transmitter device in the bodystore at PCH for the new fridge/freezer monitoring system. The mortuary staff stated this would intermittently alarm, possibly due to the loss of connection to the temperature monitors inside the fridges. The DI should investigate this further to ensure that the new system is adequately monitoring the fridge temperatures and will trigger the alarm when required. (see *Advice*, item 19)	**Minor**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	While there are contingency plans in place, these are not formalised as part of a documented procedure. The establishment has a service level agreement (SLA) with a funeral director concerning contingency body storage. However, during recent adverse weather conditions the establishment were unable to arrange for the FD to transfer bodies to the contingency storage and undertook an alternative method of transportation that led to loss of dignity to the deceased and has resulted in a HTA HTARI notification. Therefore, this SLA requires review to ensure that bodies can be transferred when required.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	At PCH, a the saw in the PM suite was rusty and damaged, and rust was evident at the base of the fridge doors in the body store.	**Minor**
b) Equipment is appropriate for the management of bariatric bodies	Larger bariatric bodies at RGH are stored on an embalming trolley, which will be used as a PM table should the body require a PM examination. After a PM examination, mortuary staff will clean the trolley. During the visual inspection, there was a body on the trolley in the cold room and it was noted that there was residual blood on the undercarriage and on one of the wheels, after it had been cleaned and returned to the cold room.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Servicing and maintenance of the ventilation system at both RGH and PCH is overseen by the hospital Estates services. During the inspection, and following the inspection, the establishment has been unable to provide any servicing records or assurance that the servicing was undertaken. Estates services at RGH confirmed that while not formally documented they had established that the air ventilation system worked at 9.8 changes per hour and they were confident that with equipment in the room this would meet the required 10 air changes per hour. The establishment undertakes high risk PM examinations and the lack of assurance that the ventilation is working to the minimum 10 air changes per hour, poses a potential health and safety risk to staff. (see *Advice*, item 22)	**Major**
d) Staff have access to necessary PPE	The establishment performs high risk PM examinations. While FFP3 facemasks are available for mortuary staff and pathologists to use, staff have not been face-fitted for these. In addition, staff with facial hair cannot be face-fitted and require fully ventilated hoods, which were not available.	**Minor**

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	While the majority of equipment does undergo regular maintenance, this is overseen by estates and mortuary staff were unable to locate maintenance reports during the inspection. The mortuary should have copies to provide assurances the equipment is functioning to the required standard. This would allow mortuary staff to identify when servicing, maintenance and equipment issues need to be escalated to senior staff. (see Shortfall against PFE2d, and *Advice*, item 22)	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(e)	There are a number of different consent forms in use by the Coroner's office, but all do refer to the retention, repatriation, or sensitive disposal of tissues (blocks and slides) and organs. The establishment routinely seek consent for the retention of organs for the future use of research or education and training. However, in the case of organs small sections of tissue are embedded and retained while the majority of tissue is disposed of through incineration. To ensure that relatives are fully informed, the DI should ensure that PM information makes it clear that in cases of retention it is likely that the majority of the tissue may be disposed of, as this information may affect the relative's decision to retain a whole organ, for example.
2.	GQ1(a)	The establishment uses a Notification of Death (NOD) form, which is completed on the wards at RGH and PCH and contains the patient details. Portering staff use the details on the NOD form to complete the mortuary register at PCH; however, the mortuary register is completed by mortuary staff at RGH. The NOD form refers to the age of the individual, rather than date of birth (DOB). It was noted that completion of this section varied, sometimes containing the age of the deceased and sometimes the DOB. Mortuary staff confirmed they checked the identification bands of bodies against the NOD and would clarify any inconsistencies. The DI is advised to review the NOD form and include the DOB as a more purposeful identifier for bodies, and consider adding other pertinent information, e.g. infection risk.
3.	GQ1(a)	The DI is advised to consider further standardisation of practices across RGH and PCH. For example: • At PCH, the sticker generated on admission, containing the unique identification number, is added to the mortuary register. There is not enough space in the RGH register to add the sticker, and future versions of the register should have enough space to do so. • The fridges should be numbered the same way, for example, top to bottom. This may help to reduce the risk of errors when staff

		work across sites as there would be a standardised numbering system.
4.	GQ1(h)	The DI is advised to instigate regular meetings including staff from all the areas of the hospital where licensable activity takes place so that they are aware of the licensing frameworks and can be updated regarding any changes to practices.
5.	GQ2(c)	Due to the issues identified during the recent audit of stored tissue, the DI is advised to perform a complete audit of all stored tissue at the establishment. This will be managed through the HTA Reportable Incident management system
6.	GQ3(a)	The DI has a training presentation about the HT Act, the seeking of consent, HTARI categories and incident reporting, and the role of the HTA that he gives to trainee pathologists at the establishment. In addressing the shortfall identified against standard GQ3(a), the DI is advised to give the same presentation to all establishment staff that undertake activity under the licence and also to deliver this training at regular intervals so that it provides refresher training.
7.	GQ4(a)	Notification of Death (NOD) forms accompany bodies to the mortuary and are placed on the chests of the bodies in the refrigerated storage. The DI is advised to consider a process through which the NOD forms and unique mortuary number labels are stored separately from the bodies (i.e. filed in sequential number order) or in plastic wallets to prevent their potential contamination with body fluids. Mortuary staff indicated that contaminated NOD forms would be discarded, the DI is advised to assess how long these forms need to be retained by the mortuary.
8.	GQ6(b)	PM examination services are spread across the hub and satellite. When there are limited APT available this results in a single member of staff being present at the establishment where PM examinations are not taking place. The DI is advised to risk assess the security arrangements for lone working, both in and out of working hours, and provide appropriate safety equipment.
9.	T1(b)	The DI is advised to consider a process where porters use a ‘marker’, for example, on fridge doors when bodies have been admitted out-of-hours. This may help staff to identify which bodies require checking and will help to mitigate the risk of any bodies being omitted.
10.	T1(b)	The DI is advised to consider whether a system where staff at RGH record the location of bodies in the mortuary may help to facilitate and strengthen the traceability of bodies.
11.	T1(c)	The DI may wish to consider using the unique mortuary number as an additional identifier for bodies while in the care of the mortuary. This number can be added to the bodystore door white boards (when in place) and will help identify unknown bodies or bodies with same and/or similar names.
12.	T1(d)	Individuals with the same or similar names are located in sequential fridge spaces in RGH. The DI is advised to consider a system where bodies with similar names are placed in different fridge racks as the physical separation may help to mitigate the risk of misidentification. At RGH, surnames are written of the fridge body space doors to help identify the individual in storage. In cases of similar names, the full first name, or initials, are also written on the door. The DI is advised to consider

		implementing a system to mandate the recording of forenames as this may help to strengthen identification procedures. The DI is also advised to implement a similar system at PCH.
13.	T1(g)	The establishment uses an electronic spreadsheet to record the number of blocks, organs and other issue taken during PM examinations. In addressing the shortfall identified against standard T1(g), the DI is advised to consider a system where the individual tissue and sample types are recorded, to help strengthen the establishment's traceability processes.
14.	T2(a)	In addressing the shortfall identified against standard T2(a), the DI is advised to perform a complete audit of all retained tissue in order to establish the full extent of the cases where tissue has been retained when it should have been disposed of. This audit should be performed before disposing of any further tissue so that only tissue requiring disposal is disposed of.
15.	PFE1(d)	The DI is advised to explore options with the Health Board to provide adequate CCTV coverage of the access areas of each mortuary to help strengthen the security of the premises.
16.	PFE1(d)	The DI may wish to consider installing the controls for the roller shutter door within the mortuary office so they can operated remotely and help ensure the security of the premises and staff.
17.	PFE2(a)	The DI is advised to ensure there is a procedure in place so that fridge and freezer temperatures are maintained at an appropriate range (e.g. around +4°C +/- 2°C for fridges and around -20°C +/- 4°C for freezers).All staff should be aware of the appropriate fridge and freezer temperatures and be able to recognise any potential equipment failures before they occur.
18.	PFE2(a)	The DI is advised to develop a procedure where bodies are assessed at admittance, checked during their stay in the mortuary, and are placed into body bags when it is appropriate to do so. This will help maintain the dignity of the deceased and protect staff and other bodies in storage from potential contamination.
19.	PFE2(f)	The DI is advised to ensure staff in all areas consistently monitor and record fridge and freezer temperatures, reviewing them for trends. Where possible, electronic system records should be regularly reviewed, to identify any potential equipment failure before it occurs.
20.	PFE2(g)	During the visual inspection, it was noted that several bodies, while shrouded, were not completely covered with the head, face or limbs exposed in some individuals. The DI is advised to consider processes to ensure that bodies are adequately covered whilst in the body store, to ensure the dignity of the deceased.
21.	PFE2(h)	While there were several spaces dedicated for paediatric/perinatal storage, it was noted that the spaces immediately above them were occupied by adult bodies, while there was space available elsewhere in the body stores. The DI should consider a system where alternative spaces are used before those above the spaces dedicated to paediatric storage.
22.	PFE3(c)	Estates oversee the maintenance of critical equipment within the mortuary. Subsequent to the inspection, PCH have been unable to confirm that the PM suite ventilation system is serviced and meets the required 10 air changes per hour. The RGH estates department have confirmed that they measured the air changes at 9.8 per hour and this would be expected to

		meet 10 airchanges per hour when is use. The DI is advised to ensure that the two PM suites have suitable ventilation meeting the minimum requirement of 10 air changes per hour and that this is formally documented with agreements in place to ensure that the ventilation system is maintained and serviced. The DI is also advised to liaise with the Health Board's Estates department to develop a system through which the mortuary staff are aware of the equipment maintenance schedule and are able to review and keep copies of the maintenance records to be able to provide an assurance that equipment is working within the ranges expected by mortuary staff.
23.	N/A	The DI is advised to consider alternative options for the transfer of bodies from the main hospital building at RGH to the mortuary. The transfer occurs through the main hospital and outside of the hospital building. Concerns have been raised about people seeing the trolley in transit and is a potential loss of dignity to the deceased.
24.	N/A	The establishment were observed to use 'inverted' clinical waste bags for organs and tissues returned to the body during PM examination. To help maintain the dignity of the deceased, the DI is advised to consider the use of clear viscera bags for this purpose.

Concluding comments

There are a number of areas of practice that require improvement, including 19 major shortfalls and 13 minor shortfalls.

The inspection team identified considerable issues with the traceability of tissue retained at PM examination, their subsequent management and disposal. This issue extended to pregnancy remains, fetuses and stillbirths.

Subsequent to the inspection the DI and establishment staff have been proactive in responding to the identified issues and have initiated a number of audits to identify the full extent of the issues identified, and have provided additional oversight at both the hub and satellite facilities.

At the time of inspection the establishment were in the process of implementing a new temperature monitoring system, Laboratory Information Management System (LIMS) and electronic document control system. As part of the process, they had performed an internal audit and gap analysis against the HTA licensing standards and identified a number of areas that required improvement. Rather than make changes in a piecemeal fashion, the establishment decided to make significant changes (i.e. review and rewrite all SOPs) as part of a larger project to improve the establishment's procedures. While this will ensure that all documents are brought into compliance, it results in a gap where there is currently inadequate documentation and governance of licensable activities.

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: 7 June 2018

Report returned from DI: 22 June 2018

Final report issued: 10 July 2018

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: 15 July 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 theyare placed back into normal storage.

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

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

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

   Guidance

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

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

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

   Guidance

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

d) Staff have access to necessary PPE.

   Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

departure from expected standards.

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

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

Follow up actions

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

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

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

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